Appendix E: Evidence tables

E.1 Dementia diagnosis

E.1.1 Dementia diagnosis

- What are the most effective methods of primary assessment to decide whether a person with suspected dementia should be referred to a dementia service?
- What are the most effective methods of diagnosing dementia and dementia subtypes in specialist dementia diagnostic services?

Please see appendix P

E.1.2 Distinguishing dementia from delirium or delirium with dementia

- What are the most effective methods of differentiating dementia or dementia with delirium from delirium alone?

Full citation		**Cole MG, McCusker J, Dendukuri N, Han L: Symptoms of delirium among elderly medical inpatients with or without dementia. The Journal of neuropsychiatry and clinical neurosciences 14(2): 167-75.2002**
Study details	Country/ies	Montreal, Canada
	Study type	Secondary analyses of two concurrent studies on delirium: a non-experimental prospective study of delirium prognosis and a RCT for delirium management
	Aim of the study	To examine the prevalence and patterns of symptoms of delirium among elderly delirious medical inpatients with or without dementia using the Confusion Assessment Method (CAM) and the Delirium Index(DI) to rate the severity of delirium.
	Study dates	Not stated
	Sources of funding	Not stated
Participants	Number of patients	262 patients (excluding non-cognitively impaired patients)
	Inclusion criteria	Patients were 65 years and over, and admitted to a medical ward from the emergency department
	Exclusion criteria	• Stroke patients • Patients admitted to oncology, intensive care or coronary care units and not transferred to a medical ward within 48hrs • Patients transferred to long-term care, transferred or discharged • Patients that refused screening, were previously enrolled in study, missed or lived outside the area • Patients who did not speak English of French
	Eligible participants characteristics	128 patients with delirium (DSM-III-R criteria positive for delirium) 40 patients with delirium superimposed on dementia 94 patients with dementia (non-cognitively impaired patients were excluded as they did not match the population of interest) Mean age (SD): 83.8 years (7.1) No. of men: 96 (37%) (Delirium Dementia, Delirium, Dementia 43.8%, 47.5%, 22.3% respectively)
Tests	Type of test	Confusion Assessment Method (CAM) or Delirium Index (DI)

<table>
<tr><th>Full citation</th><th></th><th>Cole MG, McCusker J, Dendukuri N, Han L: Symptoms of delirium among elderly medical inpatients with or without dementia. The Journal of neuropsychiatry and clinical neurosciences 14(2): 167-75.2002</th></tr>
<tr><td></td><td>Reference standard</td><td>DSM III-R for delirium and IQCODE for dementia</td></tr>
<tr><td>Results</td><td>Prevalence</td><td>Detection of Delirium
Proportion (%) of patients with >5 or >6 symptoms using the CAM
<table>
<tr><td></td><td></td><td colspan="3">DSM III-R</td></tr>
<tr><td>CAM symptoms</td><td></td><td>Delirium superimposed on Dementia (n= 128)</td><td>Delirium (n= 40)</td><td>Dementia (n=94)</td></tr>
<tr><td>>5</td><td></td><td>100</td><td>100</td><td>39.4</td></tr>
<tr><td>>6</td><td></td><td>98.4</td><td>95</td><td>24.5</td></tr>
<tr><td></td><td>Total</td><td>100</td><td>100</td><td>100</td></tr>
</table>
Proportion (%) of patients with >2, >3 or >4 symptoms using the DI
<table>
<tr><td></td><td></td><td colspan="3">DSM III-R</td></tr>
<tr><td>DI symptoms</td><td></td><td>Delirium superimposed on Dementia (n= 128)</td><td>Delirium (n= 40)</td><td>Dementia (n=94)</td></tr>
<tr><td>>2</td><td></td><td>91.5</td><td>82.5</td><td>70.4</td></tr>
<tr><td>>3</td><td></td><td>77.4</td><td>60</td><td>42.7</td></tr>
<tr><td>>4</td><td></td><td>61.0</td><td>42.5</td><td>15</td></tr>
<tr><td></td><td>Total</td><td>100</td><td>100</td><td>100</td></tr>
</table></td></tr>
<tr><td>Comments</td><td></td><td>The non-cognitively impaired patient group was excluded from our analyses as they do not fit the RQ17 research protocol.

Quality assessment
Patient selection: consecutive patients admitted from the emergency room to a medical ward. Of the 1,552 eligible patients screened, 187 were DSM-IIIR positive for delirium, but it is unclear how the non-delirious group was selected from the remaining patients other than by taking account of age (>70 years) and Short Portable Mental Status Questionnaire (SPMSQ) scores to match to the delirious group.</td></tr>
</table>

Full citation		Cole MG, McCusker J, Dendukuri N, Han L: Symptoms of delirium among elderly medical inpatients with or without dementia. The Journal of neuropsychiatry and clinical neurosciences 14(2): 167-75.2002
		Dementia patients were diagnosed using the IQCODE with a cut off of 3.51 prior to admission. Index test: The CAM was administered by the study nurse to patients with scores of 3 or more on the SPMSQ or whose notes indicated delirium. The following week the SPMSQ was repeated daily for patients scoring <3 on SPMSQ, or >3 but CAM negative. The CAM was repeated if the SPMSQ scores increased or the nurses' notes indicated delirium. It is unclear if the nurse knew the results of the DSM III-R or IQCODE tests. The DI test was carried out within 24hrs of diagnosis test by a trained research assistant who was blind to the patient's DSM- III-R diagnosis. Reference standard: The DSM III-R test was used to diagnose the delirious patient groups. It is unclear who administered this test or when this was done in relation to the other tests. Flow and timing: The DI test was carried out within 24hrs of diagnosis. The CAM test was repeated in some patients (see above) and it is unclear how much time elapsed between first diagnosis and administration of the CAM test. Of the initial selection of 187 delirious and 174 non-delirious patients 19 delirious and 20 non-delirious patients were excluded from the study due to missing dementia status details. All patients taking part in the study were included for analyses.

Full citation		Erkinjuntti T, Sulkava R, Wikström J, Autio L: A SCREENING TEST FOR dEMENTIA AND DELIRIUM AMONG THE ELDERLY. The Journal of the American Geriatrics Society 35(5): 412-416.1987
Study details	Country/ies	Kerava, Finland
	Study type	Prospective cross-sectional study
	Aim of the study	To evaluate SPMSQ as a tool to identify patients with delirium and dementia in elderly medical inpatients and within the community.
	Study dates	May- August 1982
	Sources of funding	Not stated
Participants	Number of patients	70 (excluding non-cognitively impaired patients)
	Inclusion criteria	Medical inpatients 65 years or over

<table>
<tr><th>Full citation</th><th></th><th>Erkinjuntti T, Sulkava R, Wikström J, Autio L: A SCREENING TEST FOR dEMENTIA AND DELIRIUM AMONG THE ELDERLY. The Journal of the American Geriatrics Society 35(5): 412-416.1987</th></tr>
<tr><td></td><td>Exclusion criteria</td><td>Not stated</td></tr>
<tr><td></td><td>Eligible participants characteristics</td><td>Of 282 hospital patients 2 refused to take part, 18 had intractable illness or were mentally unfit.
192 patients without mental impairment were excluded from our analyses as they do not match the population of interest.
23 patients with dementia
41 patients with delirium
6 patients with delirium superimposed on dementia

Mean age (SD): 75.5 years (7.2) (for whole hospital sample)
No. of men: 109 (39%) (for whole hospital sample)</td></tr>
<tr><td>Tests</td><td>Type of test</td><td>Short Portable Mental Status Questionnaire (SPMSQ)</td></tr>
<tr><td></td><td>Reference standard</td><td>Multiple factors: diagnostic criteria listed in table 1 in paper plus all medical files and information, and results of the Dementia Scale.</td></tr>
<tr><td>Results</td><td>Prevalence</td><td>Numbers of people within each category based on SMPSQ error scores
<table>
<tr><td></td><td colspan="3">Reference criteria</td></tr>
<tr><td>SPMSQ</td><td>Delirium superimposed on Dementia</td><td>Delirium</td><td>Dementia</td></tr>
<tr><td><3</td><td>0</td><td>11</td><td>0</td></tr>
<tr><td><4</td><td>2</td><td>25</td><td>2</td></tr>
<tr><td><5</td><td>2</td><td>34</td><td>5</td></tr>
<tr><td>Total</td><td>6</td><td>41</td><td>23</td></tr>
</table></td></tr>
<tr><td>Comments</td><td></td><td>Community and Hospital dementia patients were recruited, but we only analysed the hospital group as the community group lacked corresponding delirious and dementia with delirium patient groups for comparison.

Quality assessment</td></tr>
</table>

Full citation		Erkinjuntti T, Sulkava R, Wikström J, Autio L: A SCREENING TEST FOR dEMENTIA AND DELIRIUM AMONG THE ELDERLY. The Journal of the American Geriatrics Society 35(5): 412-416.1987
		Patient selection: consecutively admitted medical inpatients; unclear what constitutes an intractable illness here as an exclusion criterion. Index test: Carried out by a research assistant. It is unclear whether they knew the reference diagnosis. Reference standard: Diagnostic criteria use to obtain reference diagnosis listed in paper and included the Dementia Scale. No details of the skills of the person conducting the test. Unclear how accurate these criteria are. The Dementia patients were further subdivided using clinical data and interviews, with only moderate to severe groups being classed as demented for the study purposes. Flow and timing: The SPMSQ was administered by a research assistant on the weekday following admission. The gap between reference and index test is not stated. All patients taking part in the study were included for analyses.

Full citation		Leonard M, McInerny S, McFarland J, Condon C, Awan F, O'Connor M, Reynolds J, Meaney AM, Adamis D, Dunne C, Cullen W, Trzepacz P, Meagher DJ: COMPARISON OF COGNTIVE AND NEUROPSYCHIATRIC PROFILES IN ELDERLY MEDICAL PATIENTS WITH DELIRIUM, DEMENTIA AND COMORBID DELIRIUM-DEMENTIA. BMJ Open 6(3): e009212. 2016
Study details	Country/ies	Limerick, Ireland
	Study type	Prospective cross-sectional study
	Aim of the study	To examine the neuropsychiatric and cognitive profiles of patients with dementia, delirium or dementia with delirium and to determine which of these features best differentiate between these patients.
	Study dates	October 2011- July 2012
	Sources of funding	Health Research Board grant: HRA 2011/48
Participants	Number of patients	144 (excluding non-cognitively impaired patients)
	Inclusion criteria	Patients ≥ 60 years with altered mental state suggestive of a neurocognitive disorder that had been referred to a psychiatry for later life consultation-liaison service at University Hospital Limerick.
	Exclusion criteria	None mentioned
	Eligible participants characteristics	144 patients: 50 patients with delirium

<table>
<tr><th>Full citation</th><th></th><th>Leonard M, McInerny S, McFarland J, Condon C, Awan F, O'Connor M, Reynolds J, Meaney AM, Adamis D, Dunne C, Cullen W, Trzepacz P, Meagher DJ: COMPARISON OF COGNTIVE AND NEUROPSYCHIATRIC PROFILES IN ELDERLY MEDICAL PATIENTS WITH DELIRIUM, DEMENTIA AND COMORBID DELIRIUM-DEMENTIA. BMJ Open 6(3): e009212. 2016</th></tr>
<tr><td></td><td></td><td>32 patients with dementia
62 patients with delirium superimposed on dementia
(32 cognitively intact- excluded from our analyses as they do not match the population of interest)

Mean age (SD): 80.3 years (7.7)
No. of men: 71 (49.4%)</td></tr>
<tr><td>Tests</td><td>Type of test</td><td>Delirium Rating Scale Revised 98 (DRS-R98), Cognitive Test for Delirium (CTD), Neuropsychiatric Inventory (NPI-Q) for dementia</td></tr>
<tr><td></td><td>Reference standard</td><td>Diagnostic and Statistical Manual of Mental Disorders (DSM) IV for delirium or dementia; Informant Questionnaire on Cognitive Decline in the Elderly- short form (IQCODE-SF) ≥ 3.5 for dementia and cognitive difficulties</td></tr>
<tr><td>Results</td><td>Prevalence</td><td>DRS-R98 item severities (% scoring ≥2)
<table>
<tr><td>DRS-R98</td><td></td><td colspan="3">DSM IV</td></tr>
<tr><td></td><td></td><td>Delirium superimposed on Dementia (n=62)</td><td>Delirium (n=50)</td><td>Dementia (n=32)</td></tr>
<tr><td></td><td>Sleep- wake disturbance</td><td>53</td><td>73</td><td>22</td></tr>
<tr><td></td><td>Perceptual disturbances and hallucinations</td><td>23</td><td>32</td><td>6</td></tr>
<tr><td></td><td>Delusions</td><td>10</td><td>21</td><td>9</td></tr>
<tr><td></td><td>Lability of affect</td><td>33</td><td>47</td><td>9</td></tr>
<tr><td></td><td>Language</td><td>23</td><td>39</td><td>10</td></tr>
<tr><td></td><td>Thought process abnormalities</td><td>38</td><td>63</td><td>22</td></tr>
<tr><td></td><td>Motor agitation</td><td>25</td><td>55</td><td>16</td></tr>
<tr><td></td><td>Motor retardation</td><td>13</td><td>20</td><td>3</td></tr>
</table></td></tr>
</table>

Full citation		Leonard M, McInerny S, McFarland J, Condon C, Awan F, O'Connor M, Reynolds J, Meaney AM, Adamis D, Dunne C, Cullen W, Trzepacz P, Meagher DJ: COMPARISON OF COGNTIVE AND NEUROPSYCHIATRIC PROFILES IN ELDERLY MEDICAL PATIENTS WITH DELIRIUM, DEMENTIA AND COMORBID DELIRIUM-DEMENTIA. BMJ Open 6(3): e009212. 2016

	Orientation	52	37	22
	Attention	72	80	31
	Short-term memory	69	60	60
	Long-term memory	42	42	31
	Visuospatial ability	60	70	60
	Temporal onset of symptoms	54	78	13
	Fluctuation in symptom severity	11	26	27
	Physical disorder	84	92	33

Frequencies of the NPI severity items

NPI		DSM IV		
		Delirium superimposed on Dementia (n=62)	Delirium (n=50)	Dementia (n=32)
	Delusions	17	12	5
	Hallucinations	21	14	5
	Agitation/aggression	35	23	12
	Depression/dysphoria	30	14	14
	Anxiety	31	21	16
	Elation/euphoria	7	1	2
	Apathy/indifference	30	15	9
	Disinhibition	18	8	1
	Irritability/lability	36	23	11

Full citation		Leonard M, McInerny S, McFarland J, Condon C, Awan F, O'Connor M, Reynolds J, Meaney AM, Adamis D, Dunne C, Cullen W, Trzepacz P, Meagher DJ: COMPARISON OF COGNTIVE AND NEUROPSYCHIATRIC PROFILES IN ELDERLY MEDICAL PATIENTS WITH DELIRIUM, DEMENTIA AND COMORBID DELIRIUM-DEMENTIA. BMJ Open 6(3): e009212. 2016

	Aberrant motor behaviour	25	19	9
	Sleep and night time disturbances	32	13	12
	Appetite/eating disturbances	29	16	10

Frequencies (%) of the NPI distress items

NPI		DSM IV		
		Delirium superimposed on Dementia (n=62)	Delirium (n=50)	Dementia (n=32)
	Delusions	17	12	5
	Hallucinations	19	15	4
	Agitation/aggression	33	23	12
	Depression/dysphoria	28	15	14
	Anxiety	28	20	15
	Elation/euphoria	6	1	2
	Apathy/indifference	27	12	9
	Disinhibition	15	8	1
	Irritability/lability	33	21	11
	Aberrant motor behaviour	20	19	9
	Sleep and night time disturbances	31	13	12
	Appetite/eating	23	16	9

Full citation		**Leonard M, McInerny S, McFarland J, Condon C, Awan F, O'Connor M, Reynolds J, Meaney AM, Adamis D, Dunne C, Cullen W, Trzepacz P, Meagher DJ: COMPARISON OF COGNTIVE AND NEUROPSYCHIATRIC PROFILES IN ELDERLY MEDICAL PATIENTS WITH DELIRIUM, DEMENTIA AND COMORBID DELIRIUM-DEMENTIA. BMJ Open 6(3): e009212. 2016**
		disturbances
Comments		The control group was excluded from analyses as they were cognitively intact. The CTD data was not in a format that we could use and was therefore excluded from subsequent analyses. NPI severity and distress items were not presented in the GRADE analyses as the sensitivity was < 60% for every item. For delirium to be confirmed, the DRS-98 score was considered to be > 15 (on the severity scale) or 18 points (total scale), but the paper did not present the data for the number of patients that met these criteria for each group, just the mean score per group. As a result we used the available data to analyse the individual elements of the test (see GRADE table). **Quality assessment** Patient selection: Consecutive referrals enrolled. Exclusion criteria not stated so unclear if all eligible patients were enrolled or whether selection occurred. Index test: Assessments were carried out by trained staff, any uncertainties were discussed and a consensus reached. DRS-98 rated the previous 24hrs, CTD measured cognition at that point in time. NPI-Q focuses on disturbances over previous month. It is unclear whether the assessors were aware of the results from the reference tests. Reference standard: Assessments were carried out by trained staff, any uncertainties were discussed and a consensus reached. DSM IV diagnosis of delirium was assessed at consultation, independently of the index tests. Dementia was determined using DSM IV or IQCODE test. Positive diagnosis of both disorders was observed in patients with comorbid dementia and delirium. Flow and timing: Cases were diagnosed at consultation using the reference tests then the DSR-R98 and CTD were administered. NPI-Q and IQCODE were completed on the same day, after consulting family/ carers.

Full citation		**Meagher J, Leonard M, Donnelly S, Conroy M, Saunders J, Trzepacz PT: A COMPARISON OF NEUROPSYCHIATRIC AND COGNITIVE PROFILES IN DELIRIUM, DEMENTIA, COMORBID DELIRIUM-DEMENTIA AND COGNITIVELY INTACT CONTROLS. J. Neurol Neurosurg Psychiatry 81: 876-881. 2010**

<table>
<tr><th>Full citation</th><th></th><th>Meagher J, Leonard M, Donnelly S, Conroy M, Saunders J, Trzepacz PT: A COMPARISON OF NEUROPSYCHIATRIC AND COGNITIVE PROFILES IN DELIRIUM, DEMENTIA, COMORBID DELIRIUM-DEMENTIA AND COGNITIVELY INTACT CONTROLS. J. Neurol Neurosurg Psychiatry 81: 876-881. 2010</th></tr>
<tr><td>Study details</td><td>Country/ies</td><td>Limerick, Ireland</td></tr>
<tr><td></td><td>Study type</td><td>Prospective cross-sectional study</td></tr>
<tr><td></td><td>Aim of the study</td><td>To examine the neuropsychiatric and cognitive profiles of patients with dementia, delirium or dementia with delirium and to determine which of these features best differentiate between these patients.</td></tr>
<tr><td></td><td>Study dates</td><td>Not stated</td></tr>
<tr><td></td><td>Sources of funding</td><td>Departmental funds from Limerick Mental Health Services</td></tr>
<tr><td>Participants</td><td>Number of patients</td><td>100 (excluding non-cognitively impaired patients)</td></tr>
<tr><td></td><td>Inclusion criteria</td><td>Patients with altered mental state identified on daily rounds</td></tr>
<tr><td></td><td>Exclusion criteria</td><td>Not stated</td></tr>
<tr><td></td><td>Eligible participants characteristics</td><td>100 patients:
40 patients with delirium
40 patients with dementia
20 with delirium superimposed on dementia
(40 cognitively intact- excluded from our analyses as not cognitively impaired)

Mean age (SD): 73.2 years (10.0)
No. of men: 52 (51.8%)</td></tr>
<tr><td>Tests</td><td>Type of test</td><td>Delirium Rating Scale Revised 98 (DRS-R98) and Cognitive Test for Delirium (CTD)</td></tr>
<tr><td></td><td>Reference standard</td><td>Diagnostic and Statistical Manual of Mental Disorders (DSM) IV</td></tr>
<tr><td>Results</td><td>Prevalence</td><td>CTD component analyses- attention item
Spatial Span forwards (SSF) results using a cut off of <4 points to indicate delirium

<table>
<tr><td></td><td></td><td colspan="3">DSM IV</td></tr>
<tr><td></td><td></td><td>Delirium superimposed on Dementia (n=40)</td><td>Delirium (n=40)</td><td>Dementia (n=20)</td></tr>
</table>
</td></tr>
</table>

Full citation		**Meagher J, Leonard M, Donnelly S, Conroy M, Saunders J, Trzepacz PT: A COMPARISON OF NEUROPSYCHIATRIC AND COGNITIVE PROFILES IN DELIRIUM, DEMENTIA, COMORBID DELIRIUM-DEMENTIA AND COGNITIVELY INTACT CONTROLS. J. Neurol Neurosurg Psychiatry 81: 876-881. 2010**

CTD SSF	Positive	26	25	3
	Negative	14	15	17
	Total	40	40	20

Comments		Control patients were excluded from this analyses as they lacked cognitive impairment. Dementia and dementia with delirium patients were significantly older than delirium patients. The DRS-98 data and the full CTD test data were not analysed as they were not presented in a useful format. **Quality assessment** Patient selection: consecutive adult cases receiving care in the palliative care inpatient service Index test: Trained researchers carried out the tests and any difficult ratings were decided by consensus. DRS-R98 reviewed the previous 24hrs and CTD measured cognition at that time. CTD responses not used to rate DRS-R98 items. It is unclear whether the researchers were blind to the DSM IV results or the results of the other index test. Reference standard: Comorbid delirium-dementia was defined as the presence of both disorders. Dementia was diagnosed based on persistent cognitive impairment for at least 6 months prior to assessment, clinical case note, family/carer input and DMS criteria (unspecified). Flow and timing: DSM IV diagnosis then DRS-R98 followed by CTD.

Full citation		**Richardson SJ, PT, Davis DHJ, Bellelli G, Hasemann W, Meagher D, Kreisel SH et al: DETECTING DELIRIUM SUPERIMPOSED ON DEMENTIA: DIAGNOSTIC TEST ACCURACY OF A SIMPLE COMBINED AROUSAL AND ATTENTION TESTING PROCEDURE. International Psychogeriatrics 29: 1585-1593. 2017.**
Study details	Country/ies	Italy, Ireland, Portugal and Switzerland. .
	Study type	Cohort study
	Aim of the study	To validate the use of a combined test of arousal and attention to identify delirium in elderly patients

<table>
<tr><th>Full citation</th><th></th><th>Richardson SJ, PT, Davis DHJ, Bellelli G, Hasemann W, Meagher D, Kreisel SH et al: DETECTING DELIRIUM SUPERIMPOSED ON DEMENTIA: DIAGNOSTIC TEST ACCURACY OF A SIMPLE COMBINED AROUSAL AND ATTENTION TESTING PROCEDURE. International Psychogeriatrics 29: 1585-1593. 2017.</th></tr>
<tr><td></td><td></td><td>admitted to hopsital</td></tr>
<tr><td></td><td>Study dates</td><td>Not stated</td></tr>
<tr><td></td><td>Sources of funding</td><td>Grant to D. Meagher from the Health Research Board in Ireland; Alzheimer’s Society Clinical training fellowship for S. Richardson; Wellcome Trust Intermediate Clinical fellowship for D.Davis.</td></tr>
<tr><td>Participants</td><td>Number of patients</td><td>114</td></tr>
<tr><td></td><td>Inclusion criteria</td><td>Patients > 70 years old who were admitted to 5 acute or rehabilitation hospitals.</td></tr>
<tr><td></td><td>Exclusion criteria</td><td>Presence of aphasia; history of major stroke; coma at the time of admission; poor vision or hearing.</td></tr>
<tr><td></td><td>Eligible participants characteristics</td><td>21 patients with delirium
28 patients with dementia
31 patients with delirium superimposed on dementia (DSD)
34 patients without delirium or dementia
Mean age (SD): 82.6 years (6.5)
No. of men: 52 (45.6%)</td></tr>
<tr><td>Tests</td><td>Type of test</td><td>Attention test; Observational Scale of Level of Arousal (OSLA) test and the combination of the 2 tests</td></tr>
<tr><td></td><td>Reference standard</td><td>DSM-5 for delirium and IQCODE or SMMSE for dementia</td></tr>
<tr><td>Results</td><td>Sensitivity and Specificity</td><td>
<table>
<tr><th colspan="6">Delirium (including DSD) versus no delirium (dementia alone and no dementia)</th></tr>
<tr><td colspan="2">Scale of Level of Arousal (OSLA) (Cut off 3/4)</td><td colspan="2">Attention Test (Cut off 3/4)</td><td colspan="2">Combination of tests (Cut off 9/10)</td></tr>
<tr><td>Sensitivity</td><td>Specificity</td><td>Sensitivity</td><td>Specificity</td><td>Sensitivity</td><td>Specificity</td></tr>
<tr><td>85%</td><td>82%</td><td>90%</td><td>64%</td><td>84%</td><td>97%</td></tr>
</table>
<table>
<tr><th colspan="6">DSD versus dementia alone</th></tr>
<tr><td colspan="2">Scale of Level of Arousal (OSLA) (Cut off 3/4)</td><td colspan="2">Attention Test (Cut off 3/4)</td><td colspan="2">Combination of tests (Cut off 9/10)</td></tr>
<tr><td>Sensitivity</td><td>Specificity</td><td>Sensitivity</td><td>Specificity</td><td>Sensitivity</td><td>Specificity</td></tr>
</table>
</td></tr>
</table>

Full citation		**Richardson SJ, PT, Davis DHJ, Bellelli G, Hasemann W, Meagher D, Kreisel SH et al: DETECTING DELIRIUM SUPERIMPOSED ON DEMENTIA: DIAGNOSTIC TEST ACCURACY OF A SIMPLE COMBINED AROUSAL AND ATTENTION TESTING PROCEDURE. International Psychogeriatrics 29: 1585-1593. 2017.**
		74% | 96% | 84% | 73% | 94% | 92%
Comments		The attention test alone could not be included in our analysis as we were unsble to calculate a 2x2 table for the data.(There were 5 missing participants, but we could not match them to a reference diagnosis with the information provided.) We were forced to keep the comparisons used in the paper of delirium verusus no delirium (including dementia no delirium and no dementia no delirium groups) and DSD versus dementia alone as the data was not presented in a manner that would allow us to alter the comparisons. **Quality assessment** Patient selection: A convenience sample of patients recruited from 5 acute and rehabilitation hospitals across 4 countries. Index test: It is unclear whether the clinicians were blinded to the reference diagnosis. For the attention test the best-performing cut off was used in the absence of a published recommended threshold. Reference standard: DSM-5 carried out by experienced delirium clinician-researchers using all available clinical data. In non-delirious patients the SMMSE was used to assess dementia; in delirious patients the IQCODE was used instead. Unclear whether the clinicians were blind to the index test results. Flow and timing: The time intervals between diagnostic reference and index tests and the order of such tests are not explicitly stated. 5/114 participants did not complete the attention test.

Full citation		**Trzepacz, PT, Mittal D, Torres R, Kanary K, Norton J, Jimerson N: VALIDATION OF THE DELIRIUM RATING SCALE-REVISED-98: COMPARISON WITH THE DELIRIUM RATING SCALE AND THE COGNITIVE TEST FOR DELIRIUM. J. Neuropsychiatry Clin Neurosci 13: 229-242. 2001.**
Study details	Country/ies	Mississippi, USA.
	Study type	Case-control study
	Aim of the study	To validate the revised Delirium Rating Scale (DRS-R98); establish its reliability and ability to assess the severity of delirium.
	Study dates	5-month period in 1999

<table>
<tr><th>Full citation</th><th></th><th>Trzepacz, PT, Mittal D, Torres R, Kanary K, Norton J, Jimerson N: VALIDATION OF THE DELIRIUM RATING SCALE-REVISED-98: COMPARISON WITH THE DELIRIUM RATING SCALE AND THE COGNITIVE TEST FOR DELIRIUM. J. Neuropsychiatry Clin Neurosci 13: 229-242. 2001.</th></tr>
<tr><td></td><td>Sources of funding</td><td>Supported in part by the Mental Illness Research Education and Clinical Centre, Veterans Integrated Service Network 16 (MIRECC-VISN 16), Department of Veterans Affairs.</td></tr>
<tr><td>Participants</td><td>Number of patients</td><td>37</td></tr>
<tr><td></td><td>Inclusion criteria</td><td>Patients with delirium, dementia, depression, schizophrenia and other psychiatric disorders</td></tr>
<tr><td></td><td>Exclusion criteria</td><td>Unwillingness to be psychiatrically assessed.</td></tr>
<tr><td></td><td>Eligible participants characteristics</td><td>24 patients with delirium
13 patients with dementia
(Other groups excluded from our analyses were 9 schizophrenic patients, 12 depressed and 10 “other”.)

Mean age (SD): 68.0 years (14.0)
No. of men: 30 (81.1%)</td></tr>
<tr><td>Tests</td><td>Type of test</td><td>Delirium Rating Scale Revised 98 (DRS-R98) and Cognitive Test for Delirium (CTD)</td></tr>
<tr><td></td><td>Reference standard</td><td>DSM-IV</td></tr>
<tr><td>Results</td><td>Sensitivity and Specificity</td><td>Sensitivity and specificity of the DRS-R98 based on receiver operating curve analyses.
<table>
<tr><td>Delirium versus Dementia</td><td colspan="3">DRS-R98 Total</td><td colspan="3">DRS-R98 Severity</td></tr>
<tr><td></td><td>Cut off score</td><td>Sensitivity</td><td>Specificity</td><td>Cut off score</td><td>Sensitivity</td><td>Specificity</td></tr>
<tr><td></td><td>17.75</td><td>100</td><td>85</td><td>15.25</td><td>100</td><td>77</td></tr>
<tr><td></td><td>21.5</td><td>91</td><td>92</td><td>17.00</td><td>86</td><td>92</td></tr>
<tr><td></td><td>22.5</td><td>91</td><td>100</td><td></td><td></td><td></td></tr>
</table></td></tr>
<tr><td>Comments</td><td></td><td>The study did not include a category for patients with delirium superimposed on dementia and it is possible that comorbid patients were included in either group.
We excluded the depressed, schizophrenic and other psychiatric patients from our analyses.
The CTD data was not presented in a useful format for our analyses.</td></tr>
</table>

Full citation		Trzepacz, PT, Mittal D, Torres R, Kanary K, Norton J, Jimerson N: VALIDATION OF THE DELIRIUM RATING SCALE-REVISED-98: COMPARISON WITH THE DELIRIUM RATING SCALE AND THE COGNITIVE TEST FOR DELIRIUM. J. Neuropsychiatry Clin Neurosci 13: 229-242. 2001.
		Quality assessment Patient selection: Recruited from medical, surgical, rehabilitation and nursing home care in-patient units at the University of Mississippi Medical Centre affiliated hospitals over a 5- month period. Selected based on diagnosis into the 5 target patient groups. Index test: DRS-R98 was carried out by trained study psychiatrists blinded to patient diagnosis. Research assistants screened cases for suitability. The test covered a 24-hour period. Inter-rater reliability was examined and found to be very high. The CTD was carried out by a research assistant. It is unclear whether the research assistants knew the results of the other tests. Reference standard: DSM-IV carried out by referring service physician using all available clinical data. Unclear whether they were blind to the DRS-R98 results. Flow and timing: The time intervals between diagnostic reference and index tests and the order of such tests are not explicitly stated.

E.1.3 Case finding for people at high risk of dementia

- What are the most effective methods of case finding for people at high risk of dementia?

Bibliographic reference	van den Dungen P, Moll van Charante EP, van den Ven PM, van Marwijk HMJ, van der Horst HE, van Hout HPJ (2016). Case finding of mild cognitive impairment and dementia and subsequent care; Results of a cluster RCT in primary care. PLOS One, 11(6):e0156958.
Study type	Cluster RCT
Aim	To investigate the diagnostic yield of case finding and its impact on the mental health of patients and carers
Patient characteristics	People at high-risk of dementia. In stage 1: 647 people with possible cognitive impairment across 15 primary care practices. In stage 2: 145 of the patients from stage 1.
Inclusion/ exclusion criteria	Inclusion criteria: • Stage 1: All older people (≥ 65 years old) with possible cognitive decline but lacking a formal dementia diagnosis • Stage 2: People from stage 1 who consented to be included in stage 2 of the trial Exclusion criteria for stage 2: • Terminal illness of patient of informal carer • Permanent admission to a nursing home expected within 6 months • Insufficient understanding of spoken Dutch or inability to communicate
Intervention	• Randomization at practice level. • Intervention Stage 1: training of family physicians to diagnose dementia • Intervention Stage 2: assessment of cognition and functioning by study two practice nurses, with referral for formal diagnosis by a physician and subsequent care as necessary
Comparison	Comparator: no additional training for physicians and usual patient care
Length of follow up	12 months
Location	Netherlands
Outcomes measures	• Primary outcome: new diagnoses of MCI and dementia • Secondary outcome: assessment of the effects on the mental health and quality of life of patients and their relatives
Authors conclusion	The study found a non-significant increase in the number of new MCI and dementia diagnoses. A larger study is indicated to determine whether there is a clinically relevant effect.
Additional comments	No beneficial or harmful effects of the intervention were detected in stage 2 participants.

Bibliographic reference	van den Dungen P, Moll van Charante EP, van den Ven PM, van Marwijk HMJ, van der Horst HE, van Hout HPJ (2016). Case finding of mild cognitive impairment and dementia and subsequent care; Results of a cluster RCT in primary care. PLOS One, 11(6):e0156958.
	Limitations: • Only a quarter of the eligible patients agreed to participate in stage 2 of the trial. (A non-response analysis did not detect selective (non-) response, but it cannot be ruled out.) • 30% stage 2 intervention group participants were not assessed by the practice nurse. • Limited adherence of the family physicians to the study protocol- the intervention group physicians did not formally assess all patients referred to them by the practice nurses.
Source of funding	Governmental grant from the National Care for the Elderly Programme and a grant from the Stoffels-Hornstra Foundation (a non-profit organisation).
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? No, randomization was at practice level, but appears to have been well carried out. Possible issue of selection bias by patients as they had to agree to take part in the second stage of the study, but not expected to be different to using case finding in real life. • Were patients, health workers and study personnel blinded? The patients were blind to allocation at stage 2, but physicians and health workers were not blind to their allocation or the allocation of their patients as this was not possible in a study of this kind of intervention. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes, the practices were treated equally otherwise, but normal practice (usual care) may have varied across practices. • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

E.2 Involving people with dementia in decision about care

E.2.1 Barriers and facilitators to involvement in decision making for people living with dementia

- What barriers and facilitators have an impact on involving people living with dementia in decisions about their present and future care?
- What barriers and facilitators have an impact on how people living with dementia can make use of advance planning?

Full citation	**Bisson 2009. Developing a care pathway for advance decisions and powers of attorney: qualitative study. The British Journal of Psychiatry. 194, 55-61**
Study details	• Country/ies where the study was carried out: South Wales, UK • Study type: In-depth interviews • Aims of the study: When should advance decisions and lasting power of attorney be discussed? How should information regarding advance decisions and lasting power of attorney be delivered and by whom? How should capacity to execute an advance decision or lasting power of attorney be determined? Can a care pathway that is acceptable to service users and clinicians be developed? • Study dates: 2009 • Source of funding: Welsh Office for Research and Development
Participants	• Sample size: Modelling phase: Two people with symptoms of Huntington's disease, one carer, one asymptomatic person with who had the altered Huntington's disease gene, five clinicians working with individuals with symptoms of the disease, a lawyer with expertise in this area, a medical ethicist and two advisors employed by the Huntington's Disease Association. • Pilot phase: Six people with symptoms of Huntington's disease, nine carers or relatives and four asymptomatic people with the altered Huntington's disease gene. • Inclusion criteria: Aged 18 years or over, able to provide informed consent and in active contact with the South Wales Huntington's Disease Service. • Exclusion criteria: None • Sample characteristics: No further information was provided. However, the investigators wrote: "Theoretical sampling was used to ensure involvement of females and males, individuals of different ages and experience with different stages of Huntington's disease."
Methods	A prototype care pathway was developed through an initial modelling phase which was then piloted and evaluated. This led to a second prototype which was piloted and evaluated leading to the final care pathway. In-depth interviews of up to 2 hours were used to generate data from stakeholders who were service users or carers. Four focus groups of 1-2 hours with group sizes of between four and eight people were used to generate data from the other stakeholders. Two were conducted in the modelling phase and one after each pilot phase. Group interaction was encouraged and individuals were asked to clarify why they thought as they did. During the first pilot phase, two people with Huntington's disease and two asymptomatic individuals with the altered Huntington's disease gene

Full citation	Bisson 2009. Developing a care pathway for advance decisions and powers of attorney: qualitative study. The British Journal of Psychiatry. 194, 55-61
	completed an advance decision. Two individuals with the disease decided not to complete an advance decision after the initial discussion. During the second pilot phase, one individual with Huntington's disease and one asymptomatic individual with the altered Huntington's disease gene completed an advance decision. One individual with the disease and one asymptomatic individual with the altered disease gene decided not to after the initial discussion.
Thematic analysis	• Theme 1: (Facilitator) – Providing information is a facilitator to advance care planning for people with Huntington's disease. ○ Finding 1: Some confusion was apparent among people with Huntington's disease regarding what advance decisions and powers of attorney are, not least the difference between advance decisions and euthanasia. ○ Finding 2: Easy-to-follow, consistent verbal and written information was desired. "*The Huntington's Disease Association leaflet was actually the best one of all. It gave a lot of information but it's not too in-depth either*." – Service user "*The information in the [HDA] leaflet wasn't patronising. It was straight to the point and it was easy to understand*." – Service user ○ Finding 3: Information specific to Huntington's disease was considered vital, especially regarding percutaneous endoscopic gastrostomy feeding and choices about location of care to guide future decisions. ○ Finding 4: Participants felt that advance decisions would be optimally introduced through offering a leaflet at a clinic appointment with a brief verbal explanation. An individual could then choose to undergo further verbal education backed up by more detailed written information. ○ Finding 5: in both pilot phases. One individual with Huntington's disease and their carer described feeling upset for a few days as a result of discussing end-of-life decisions that resolved without the need for external help. They continued to consider the care pathway important. • Theme 2: (Facilitator) – A facilitator for advance planning is having an established therapeutic relationship with an expert in Huntington's disease. This was a dominant theme. "*I think it helped me having someone that I know explain these things to me. It needs to be somebody who's caring when you talk to them. It's a major thing to think about really… I think somebody who is an expert in Huntington's disease would probably be good. I don't think it has to be a psychiatrist*." – Service user "*It helped that we know him. I wouldn't have wanted someone I didn't know. It made it easier. We have a rapport with him*." – Carer ○ Finding 1: Personal qualities such as being approachable, caring and sensitive with good communication skills were felt to be important. ○ Finding 2: Participants also recommended the additional offer of home visits by a Huntington's disease Association Advisor. • Theme 3: (Facilitator) – A facilitator for advanced planning was having an early introduction to advance decisions in order to increase autonomy. ○ Finding 1: The above opinion of patients with Huntington's disease was different to professionals. Professionals were reluctant to approach service users too early, particularly asymptomatic individuals with the altered Huntington's disease gene, for fear of causing distress. ○ Finding 2: A strong theme emerged that the earlier discussions regarding advance decisions are introduced the better, subject to checking

Full citation	Bisson 2009. Developing a care pathway for advance decisions and powers of attorney: qualitative study. The British Journal of Psychiatry. 194, 55-61
	personal circumstances and support, to allow consideration of them before individuals develop symptoms or their symptoms worsen. "*I think if I had symptoms, then I'd be panicking to rush this thing through*" – Service user ○ Finding 3: The increased difficulty in determining capacity of more symptomatic individuals was an additional argument for early introduction. "*I think it would be fair to say that was the toughest part of it… She was getting really worked up and we had to stop a bit. For her it was difficult… I think the assessment part was the difficult bit because the later on in the disease you are then the more difficult it is to know what they are saying*." – Carer ○ Finding 4: A consensus was reached between individuals with Huntington's and professionals: It was considered important to have a minimum 2-week "cool off" period between an initial meeting and advance decision completion. "*Even though I went away from here thinking, "I don't really need this" I did actually find it useful [2-week 'cool off' period]. It made me think. The two visits were needed*." – Service user "*I was okay when I was in the room but then I went away to think about it that's when it hit me and I thought about what is to come. I know I've been through it before but it's the reality of it*." - Carer ○ Finding 5: A consensus was reached between individuals with Huntington's and professionals: The duration should be flexible allowing for as many sessions required to reach a decision. "*I think maybe people might need a bit longer because it's a big decision and there's lots of things to consider and think of. So from my point of view 2 weeks wasn't enough… Maybe 4 weeks would be good*." – Service user ○ Finding 6: Those who did not complete an advance decision during the pilot phases acknowledged the need for end-of-life issues to be raised to enable choice. • Theme 4: (Facilitator) – A facilitator for advanced planning was having a single, short, easy-to-follow advance decision form with space for personal statements and wishes. "*It's unfortunate that things like this hadn't been available for my mother and my grandmother, having seen them and all the family arguments that it has caused*." – Carer "*It's been exhilarating for me because it's put my life in order*." – Service user "*For me it was probably better than for her. I know that nobody can interfere with what we've put down. It's all written down and everybody knows what the score is*." – Carer "*Good. It's what I wanted and it's done*." – Service user ○ Finding 1: The main issues that people believed should be on the form were: life-saving treatments, percutaneous endoscopic gastrostomy feeding, location of future care, capacity assessment, witness details and a distribution list. A summary sheet for patient files and checklists for education, completion and review were considered important. ○ Finding 2: Participants suggested adding statements concerning organ donation and whether independent legal advice had been received.

Full citation	**Bisson 2009. Developing a care pathway for advance decisions and powers of attorney: qualitative study. The British Journal of Psychiatry. 194, 55-61**
	○ Finding 3: The need to fully consider issues around impaired quality of life when making decisions was considered important. "*Quality of life is very important is very important to be on the form… It's good because it gives you room for what you want to put down, which is more important because it's quite personal what people consider quality of life and what they want to be treated for… Everybody with Huntington's disease will want different things for themselves*." – Service user "*We weren't sure about the options on life-threatening conditions. I spoke to my family about it and we were saying about quality of life. Each of us had a different opinion on what a decent quality of life is. What we had to do in the notes was write there what I class as a decent quality of life. That's what this is about, quality of life*." – Service user ○ Finding 4: It was also felt that the advance decision form should state whether incapacity was Huntington's disease-specific or whether it applied whatever the cause of incapacity. • Theme 5: (Barrier) – The power of attorney information was considered to be too detailed to be included on the advance decision form. Therefore, a single booklet containing all the information was recommended.
Author's comments	• Individual choice and empowerment are emphasised. Optimal delivery requires significant clinical and administrative commitment. • Caution is required in generalising the results but the authors consider them likely to be broadly representative because of the strong methodologies including the continuity of recruitment until there was saturation of themes at each stage of the process. • With the full implementation of the Mental Capacity Act 2005, advance decisions will be of increasing importance and need to be part of the clinical process. This study offers guidance for a wide range of chronic disease management services. Incorporating the pathway into routine service provision would be likely to raise awareness in both staff and service users and increase confidence in making advance decisions. • There are resource and staff implications that result from such a process. The average time of education sessions was an hour and for capacity assessment and decision completion another hour. Continued review at two-yearly interviews would also lead to lengthening of appointments. A 2-hour+ per person clinician commitment is likely to be very significant to many services without accounting for the additional administration required.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Uncertain – recruitment ceased when saturation of themes was achieved. Nevertheless, it was a small study. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes

Full citation	**Bisson 2009. Developing a care pathway for advance decisions and powers of attorney: qualitative study. The British Journal of Psychiatry. 194, 55-61**
	• Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: High

Full citation	**Dening Karen Harrison, King Michael, Jones Louise, and Sampson Elizabeth L (2017) Healthcare decision-making: past present and future, in light of a diagnosis of dementia. International Journal of Palliative Nursing 23, 4-11**
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews Aim of the study: To ask people living with dementia and their carers about their past, present and future healthcare decision making Study dates: not provided Source of funding: not stated. The investigators were staff of Dementia UK and UCL
Participants	• Sample size: 6 people living with dementia and 7 carers • Inclusion criteria: They included people living with dementia who had a MMSE score of >20 out of 30 and the mental capacity to consent to and participate in the interview • Exclusion criteria: none • Sample characteristics: Mean age of the people living with dementia was 77.6 years (range 70-88), the mean age of the carers was 73.4 years (range 49-85). All of the carers were spouses. Mean MMSE of the people living with dementia = 24.8 (range 22-28)
Methods	Semi-structured interviews
Thematic analysis	• Theme 1: (Barrier, patient level) Often there was one partner more dominant in decision-making although this was not always acknowledged within the dyad. One interview was joined by an adult child and a constant theme running through this interview was the spousal carer's dominance: ○ Finding 1: A person living with dementia said: "...well, she is very bossy [regarding decisions]." (low agreement) • Theme 2: (Barrier, carer) Fear of stigma. Carers talked of how they tried to influence the person living with dementia to seek help. However, one carer felt there was little point as she felt nothing could be done afterwards, even when the diagnosis was confirmed, the carer decided they would tell no one for fear of stigma. She felt this decision was shared, although other family members saw this differently. ○ Finding 1: A carer said: "We decided we were not going to mention it to anyone outside... Only our son, possibly his wife..." (low agreement) • Theme 3: (Barrier, carer) Becoming the main decision-maker for some carers was wearisome and felt like a burden. ○ Finding 1: A carer said: "It is probably the practical... everyday decisions... day-to-day decisions that I have to make... it is very wearing for

Full citation	**Dening Karen Harrison, King Michael, Jones Louise, and Sampson Elizabeth L (2017) Healthcare decision-making: past present and future, in light of a diagnosis of dementia. International Journal of Palliative Nursing 23, 4-11**
	me... it is very stressful for me...” (medium agreement) ○ Finding 2: A carer said: “[The burden of decision-making]... to me... most of it... all of it really...” (Carer, Low agreement) ○ Finding 3: A carer said: “Day-to-day decisions that I have to make... it is very wearing... “ (medium agreement) • Theme 4: (Barrier, carer) Some had limited knowledge of the legal system to support decision-making when capacity was lost, including ACP and Lasting Powers of Attorney (LPA). ○ Finding 1: A carer said: “[LPAs]... I didn’t say not at all... I wouldn’t do it until much later on I think... I see it as something you hand over when it's necessary, not before...” (low agreement) • Theme 5: (Barrier, carer) Inability to plan. Limited knowledge about the course of dementia was a barrier to decision making. ○ Finding 1: An adult son of a person living with dementia said: “There are certain milestones... that people [with dementia] are going to go through... I am not sure we fully understand what we need to do... more difficult [in dementia] to plan and understand the progression... you don’t really know what is going on...” (low agreement) ○ Finding 2: A carer said: “I can’t make decisions... well, I can make decisions... but erm, really, I have to take each day as it comes...” (low agreement) • Theme 6: (Facilitator, structural) Social support. Many spoke of dementia being the first time shared decision-making was tested, feeling the diagnosis marked a transition, with historical decision-making roles being altered. One person living with dementia had been the main decision-maker but because of dementia he now deferred this to his wife and she sought the support of other family members: ○ Finding 1: A wife of a person living with dementia said: “When it is a difficult decision I ask my girls... [daughters]” (low agreement)
Author’s comments	Families require ongoing support and guidance on decision-making following a diagnosis of dementia. Signposting and the provision of information may not be sufficient to enable families to understand the changes dementia may have on their usual strategies for decision-making and to prepare for future eventualities. There is often a belief that carers and PWD speak with ‘one voice’, but this cannot be assumed. Families affected by dementia are likely to require ongoing support to develop plans and adapt to changes in decision-making patterns as the illness progresses. Families affected by dementia should have access to post-diagnostic support and counselling that takes into account changes that occur in decision-making patterns within their relationships. Clinicians, when considering how they may support families in building their resilience in living with dementia, need to understand previous relationship strengths and weaknesses and historic family decision-making processes as this may indicate qualities on which to maximise or may highlight areas for increased support. In supporting ACP for the person with dementia, clinicians will need to explore the couple’s approach and ability to make decisions (Boyle, 2013); this should consider any carer tendencies to dominate or assume that they know best. Carers require support for day-to-day decision-making that maximises the strengths of the PWD for as long as possible. This will need to take account of a PWD’s wish to retain a sense of control and dignity while at the same time balancing carers’ needs as the relationship changes because of dementia.
Quality	• Was there a clear statement of the aims of the research? Yes

Full citation	Dening Karen Harrison, King Michael, Jones Louise, and Sampson Elizabeth L (2017) Healthcare decision-making: past present and future, in light of a diagnosis of dementia. International Journal of Palliative Nursing 23, 4-11
assessment	• Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. There was no explanation as to why those specific 6 people living with dementia and their 7 carers were selected • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Unclear • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Moderate

Full citation	Livingston G, Leavey G, Manela M, et al. Making decisions for people with dementia who lack capacity: qualitative study of family carers in UK. BMJ. 341:c4184 (2010)
Study details	• Country/ies where the study was carried out: UK • Study type: Focus groups and individual interviews • Aim of the study: To identify common difficult decision made by family carers on behalf of people with dementia, and facilitators of and barriers to such decisions • Study dates: Interviews conducted in 2009 • Source of funding: BUPA foundation
Participants	• Sample size: 89 family carers of people living with dementia • Inclusion criteria: Adult family member or friend who gave unpaid support for the person with dementia and who regarded themselves as a family carer. Could be currently caring or recently bereaved. Purposive sample to get people of different sex, age, level of education, religion, ethnicity and stage of dementia caring for. • Exclusion criteria: None • Sample characteristics: Mean age of 63, 71% female, 53% spouses and 35% children.
Methods	• Phase 1 – focus groups of people with shared or similar experiences, with discussion facilitated by a topic guide about carers' experiences, attitudes, feelings and beliefs

	• Phase 2 – After transcripts were reviewed to identify subjects raised, semi-structured interviews were conducted on the five areas identified as the most common and problematic. Interviews covered choices, barriers and facilitators, including cultural, religious and spiritual beliefs and practices, and dilemmas, consequences and advice. Interviews were continued until data saturation The five identified areas were: • Accessing health and social services • Considering care home placement • Legal matters, including management of finances, power of attorney, and continuing driving • Deciding on non-dementia related healthcare • Making plans for the person with dementia if the carer was too ill to care
Thematic analysis	• Theme 1 (barriers – patient level) ○ Finding 1: Denial of problem "*The hardest decision that I've had to make was to convince my wife there was something wrong with her, she didn't want to know . . . she wouldn't talk to no one about it*." (husband of early onset patient) ○ Finding 2: Rejection of help "*He refused all help. He wouldn't let anyone come into the house, no form of carer. But then, he was wandering, a danger to himself . . . he was out all night, no idea where he had been*." (wife) • Theme 2 (barriers – professional) ○ Finding 1: Not recognising problems ○ Finding 2: Late diagnosis ○ Finding 3: Timing and quantity of information given ○ Finding 4: Confidentiality and data protection "*On the phone the people would say 'well we'd have to speak to your mother first to get permission to talk about her issues' because you know they couldn't say anything to me. . . I have to get my mother's permission to represent her*." (daughter) ○ Finding 5: Bureaucracy and rigidity (sticking to protocols) • Theme 3 (barriers – psychological) ○ Finding 1: Role conflict ○ Finding 2: Carer guilt "*And my husband said 'promise me one thing, you'd never put me into a home,' and I said, 'I promise'*." (wife) ○ Finding 3: Family conflict ○ Finding 4: Rigidity (solution fixed when circumstances change) • Theme 4 (facilitators – patient level)

	○ Finding 1: Deference to authority "*So long as you say . . . 'doctor' in the sentence . . . she will go along with that, she will listen to that authority so that's been good actually*." (daughter) • Theme 5 (facilitators – professional) ○ Finding 1: Suggesting interventions to facilitate agreement ○ Finding 2: Quality and timing of information "*We didn't realise what dementia meant, the implications. . . I think that people who are carers should receive some training . . . told what to expect and what to do, before it happens, not when it happens."* (widower) "*I found, when he was first diagnosed, it was an awful lot to take in, you're given all this information on what you should be doing, you don't really want to know it*." (wife of early onset patient) "*The advice that I would give is get as much information as possible, because information is really hard to get . . . but . . . is there."* (wife) ○ Finding 3: Ensuring the patient is asked to give permission for information to be given to carers ○ Finding 4: Access to legal advice "*I realised he couldn't, no longer sign cheques and things like that, and then we just put everything into joint, all our financial things are joint*." (wife) "*The only thing that could happen now is Court of Protection . . . because my wife can't sign*." (husband of early onset patient) "*I made wills, my advice is to get it done sooner rather than later*." (husband of early onset patient) • Theme 6 (facilitators – psychological coping strategies) ○ Finding 1: Carer accompanying patient to professionals ○ Finding 2: Social support (extended family, voluntary and community networks) ○ Finding 3: Resources for carer (financial and social) ○ Finding 4: Family cohesion ○ Finding 5: Re-conceptualisation of services as optimising independence "*He has to be at the day centre six days a week . . . just one day a week when he's home on Sunday, it's very difficult, so it's better than him being in a nursing home*." (wife of young onset patient) ○ Finding 6: Allowing services to develop slowly (rather than "all or nothing") "*She wasn't washing herself, she kept saying 'no, I don't want [carers].' She [healthcare professional] said 'you can try and help slowly.' I said 'yes we will try it once a week.' They started a care package and it is every day now*." (son) ○ Finding 7: Knowledge of what the patient wanted when competent ○ Finding 8: Sharing – for example, power of attorney being made for both the carer and the person with dementia
Author's comments	The following strategies helped with implementation of decisions: introducing change slowly; organising legal changes for the carer as well as the patient; involving a professional to persuade the patient to accept services; and emphasising that services optimised, not impeded,

	independence. To access services, carers made patients' general practice appointments, accompanied them to the surgery, pointed out symptoms, gained permission to receive confidential information, asked for referral to specialist services, and used professionals' authority to gain patients' agreement. End of life decisions were particularly difficult. They were helped by knowledge of the person with dementia's previous views, clear prognostic information, and family support. Information sheets to help carers to overcome barriers to proxy decision making have been developed; their impact in practice has yet to be evaluated
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? High value Overall quality: High

Full citation	**Lord K, Livingston G, Cooper C. A systematic review of barriers and facilitators to and interventions for proxy decision-making by family carers of people with dementia. International Psychogeriatrics. 27(8), 1301-12 (2011)**
Study details	• Country/ies where the study was carried out: Multinational systematic review • Study type: Systematic review of qualitative or quantitative research on barriers and facilitators to decision making • Aim of the study: To systematically review the literature around barriers and facilitators to carer proxy decision-making • Study dates: Included articles published before 1st February 2014 • Source of funding: None reported
Participants	• Sample size: 20 qualitative studies on barriers and facilitators, including semi-structured and unstructured interviews, focus groups and participant observation (also included 10 quantitative studies which are not reported on below) • Inclusion criteria: Qualitative studies reporting barriers and/or facilitators to decision-making around health and social care interventions by informal carers of people with dementia, or report the effectiveness of an intervention that sought to facilitate the decision-making process. • Exclusion criteria: Meeting abstracts, letters, literature reviews, editorials and correspondence
Methods	• Medline search for papers that contained either “dementia” or “Alzheimer”, together with at least one of “carer”, “caregiver”, “decision”,

	"decide" or "substitute judgement" • Single screening of titles and abstracts, followed by double screening of full-text articles retrieved (with consensus decision-making) • All included studies were quality assessed by two independent individuals
Thematic analysis	• Theme 1 (triggers to carer decision making) ○ Finding 1: Deterioration in the person with dementia/carer found it difficult to continue caring/deterioration in the carer's health ○ Finding 2: Carers were more willing to make decisions if they felt they could be reversed at a later point (example given is remaining at home versus entry to a care home) ○ Finding 3: Often precipitated by a crisis, such as a fall or hospitalisation, that let to contact with healthcare professionals • Theme 2 (barriers to decision making - emotional impact of decision-making on family carers) ○ Finding 1: Feelings of anguish and guilt over decisions made ○ Finding 2: Many carers reported the decision was against the care recipient's wishes, and signalled a major carer role transition. ○ Finding 3: Felt a responsibility to honour the recipient's previously expressed wishes and preferences ○ Finding 4: Journey towards a decision was directed by a mixture of fatigue and a lack of obvious or available alternatives ○ Finding 5: Carers often knew the person never wanted to live in a care home, but as circumstances changed they felt obliged to act against this knowledge ○ Finding 6: Feelings of guilt and failure were particularly strong for people obliged to cope alone ○ Finding 7: Cultural issues may place a particular strain on decision-making around future places of care • Theme 3 (barriers to decision making – role transitions and perceptions) ○ Finding 1: Carers report a shift in the dynamic to a "mother/child" type relationship. They struggled with being expected to relinquish their caregiver role and that friends and family perceived the dyadic relationship to be over ○ Finding 2: Struggle with knowing when to seek care home placement due to dementia being unpredictable and wait lists of institutions • Theme 4 (barriers to decision making – care recipient factors) ○ Finding 1: When the person with dementia was involved in decision-making, they usually expressed reluctance to move to a care home. This often led the carer either to delay the decision or exclude the person with dementia from decision-making ○ Finding 2: Carers tended to be more satisfied than patients on many criteria (information, being listened to, time allowed, potential to change one's mind), with people with dementia often feeling they have limited freedom to participate in decision making • Theme 5 (barriers to decision making – lack of information) ○ Finding 1: Feelings of guilt and distress for carers were often exacerbated by a perceived lack of support and information • Theme 6 (facilitators to decision making – role and support of healthcare professionals) ○ Finding 1: Collaboration with staff helped carers with decision-making, and this was facilitated by a trusted healthcare professional who consulted them and advocated effectively

	○ Finding 2: Carers felt that clinician's raising this discussion helped them with decision-making • Theme 7 (facilitators to decision making – severity of dementia) ○ Finding 1: Individuals with moderate dementia were still actively involved in decision-making, particularly decisions about daily activities rather than more complex decisions • Theme 8 (facilitators to decision making – whole family shared decision) ○ Finding 1: Carers found it helpful to hear the perspectives of other members of the family or professionals when making decision on behalf of the person with dementia – they felt it "gave permission" to make decisions ○ Finding 2: Carers often sought reassurance after decision making from other family members ○ Finding 3: Spousal carers tolerated more difficulties than adult children before resorting to care homes ○ Finding 4: Decisions with more serious perceived consequences were less likely to be shared
Author's comments	We recommend development and testing of decision aids targeting the decisions carers report finding more distressing, including those around where people should live, accessing services, and end of life treatments. Being provided with information to make decisions which have not previously been considered may increase feelings of conflict, suggesting these aids should be carefully targeted.
Quality assessment	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Single screening on title and abstract, duplicate full-text screening and quality assessment • Was a comprehensive literature search performed? PubMed database searched only • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? No • Overall quality: Moderate

Full citation	**Mackenzie 2006. Stigma and dementia: East European and South Asian family carers negotiating stigma in the UK. Dementia. 5(2), 233-247**
Study details	• Country/ies where the study was carried out: An unspecified city in the North of England, UK • Study type: Semi-structured interviews • Aim of the study: To investigate stigma towards dementia in Eastern European and South Asian communities. To investigate how this stigma influences family carers' decisions about seeking support or using services. • Study dates: 2001 - 2004 • Source of funding: Health Action Zone Innovations budget
Participants	• Sample size: 21 carers of people with dementia • Inclusion criteria: Carers, having an Eastern European or South Asian ethnicity, looking after a person with dementia. • Exclusion criteria: None • Sample characteristics: 11 Pakistani carers, five Indian carers, four Polish carers and one Ukrainian carer.
Methods	• In order to recruit carers, contacts were made with 167 people and agencies in the city who had established links with local minority communities. Local radio was also used. • Semi-structured interviews were used to explore carers' experiences of caregiving.
Thematic analysis	• Theme (barrier to decision making): In South Asian communities, there is a tendency to want to protect the person with dementia from ridicule by keeping them away from other people. The carers are concerned about being embarrassed by their relative: "…*you know father talks about those things that don't even exist… he makes us embarrassed in front of other people. Sometimes I tell him to stay in another room if someone comes into my house… but he just wants to be in the same room*." (Pakistani man caring for his father) The concealment process carers engaged in acted as a mechanism to protect the reputation of the person with dementia and also family reputation. The use of services by these carers was limited. The most common explanation for not using services was that help from outside agencies put an already precarious balance between shame and inner pride in jeopardy. It was the case that most carers interviewed thought of mainstream support services entirely as leading to residential/nursing home care, which carers felt would bring shame on the family, as they perceived outsiders would consider their actions as an indication that they intended to abandon their relative.
Author's comments	Stigma in the South Asian group tended to be linked to religious and magical explanations for the onset of dementia. These explanations ranged from being understood as a punishment from God, to dementia symptoms themselves being seen as evidence of a powerful curse. Dementia, therefore, could induce fear and jeopardise family honour and reputation.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Uncertain. The number of participants (21 carers) was chosen

	because the investigators were unable to recruit more people, e.g. – carers were not recruited continuously until there was no new information. However, the results seem to have been consistent. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Reasonable Overall quality: High

Full citation	**Murphy J, Oliver T. 2013. The use of Talking Mats to support people with dementia and their carers to make decisions together. Health and Social Care in the Community. 21(2), 171-180**
Study details	• Country/ies where the study was carried out: Scotland and the North of England, UK • Study type: A cross-over trial involving narrative interviews and a questionnaire. • Aim of the study: To explore whether Talking Mats could help people with dementia and family carers feel more involved in decisions about managing their daily living than using their usual communication methods. • Study dates: September 2008 to May 2009. • Source of funding: Joseph Rowntree Foundation
Participants	• Sample size: 18 couples (person with dementia and their family carer). • Inclusion criteria: The person with dementia must be: diagnosed with dementia, aware of their diagnosis and be comfortable with the terminology involved, be living at home and have a relative or friend who is knowledgeable about how they are managing their daily living activities, a native speaker of English, have sufficient vision to see picture symbols. • Exclusion criteria: None • Sample characteristics: Initially, 22 couples were identified and agreed to take part. However, one person with dementia was unable to use Talking Mats, two participants withdrew due to ill health and one person died. Of the 18 remaining people with dementia, 10 were men and 8 were women, with a mean age of 77 years (range 60-86). Three participants were judged to have early stage dementia, 13 moderate stage, and 2 late stage. Of the 18 family carers, 5 were men and 13 women, with a mean age of 69 years (range 44-89). The participants were from varied backgrounds and geographical areas.
Methods	Talking Mats is a simple low-technology communication system. It uses picture symbols, placed on a textured mat, that allow people to indicate their feelings about various options within a topic by placing the relevant image below a visual scale. Specific topics and the range of options within each topic were identified by using the WHO International Classification of Functioning, the literature and guidance from the

Full citation	**Murphy J, Oliver T. 2013. The use of Talking Mats to support people with dementia and their carers to make decisions together. Health and Social Care in the Community. 21(2), 171-180**
	project advisory group. The topics and options were converted into picture communication symbols. The four main topics of daily living were identified with a subset of options within each topic: personal care (e.g. washing, washing hair, getting dressed appropriately), getting around (e.g. getting into/out of bed, walking, driving), housework (e.g. cooking, washing dishes, laundry), activities (e.g. listening to music, reading a book/newspaper, watching TV). Nine couples used the Talking Mats framework during their first visit and their usual methods of communication during their second visit. The other nine couples used their usual methods of communication during their first visit and the Talking Mats framework during their second visit. For the Talking Mats discussion, the option symbols within each topic were laid out and each member of the couple took it in turns to choose an option to discuss. The researcher explained that the visual scale represented 'managing', 'needing assistance', 'not managing', and couples were encouraged to come to an agreement, if possible, as to where each option symbol should be placed on the mat under the visual scale. For the discussion using usual methods of communication, the researcher presented each option within a topic orally one at a time in random order. For each option, couples were asked to discuss if the person with dementia was 'managing', 'needing assistance' or 'not managing'. All interviews were video recorded and a photograph was taken of the Talking Mat at the end of the session. After the interviews, each participant was asked separately to complete a questionnaire to evaluate how involved s/he felt in each type of discussion.
Thematic analysis	• Theme 1: Discussing care was facilitated by using Talking Mats. Using a method of scoring between 5 and 20, the mean score for feeling involved when using the usual methods of communication for patients with dementia and their carers was 15.6 and 16.9 respectively. These values rose to 17.5 and 19 respectively when using Talking Mats. Using a Likert scale of between 0 and 6, the mean score for satisfaction when using the usual methods of communication for patients with dementia and their carers was 4.3 and 4.6 respectively. These values rose to 5.4 and 5.7 respectively when using Talking Mats. Patients with dementia reported that Talking Mats helped them to remember what they were talking about. It also helped them to remember words, thus enabling them to express their views more clearly: *"…it [Talking Mats] helped me remember what we were talking about."* *"The pictures are really clear; they helped me to remember when I couldn't find the right word."* *"…that is what I think, right in front of me; I don't have to rack my brain to remember."* *"I found it [Talking Mats] a big help, sometimes I get the words muddled and can't get out what I am trying to say."* *"…it is so difficult to tell [my wife] what I think when I can't remember the words, the pictures could help me a lot."* • Theme 2: Talking Mats allowed the participants with dementia to see what they could still do and what they enjoyed doing rather than just focusing on what they could no longer do: *"The mat shows that I am able to do much more than I thought."* *"I had forgotten all the things I like to do."* • Theme 3: Talking Mats helped the participants with dementia to be aware of what their family members were doing for them:

Full citation	**Murphy J, Oliver T. 2013. The use of Talking Mats to support people with dementia and their carers to make decisions together. Health and Social Care in the Community. 21(2), 171-180**
	"I didn't realise how much she [daughter] is doing in the house." • Theme 4: Talking Mats was seen as an enjoyable activity which improved communication between the person with dementia and his/her family: *"It was nice to talk about things. We never seem to do that anymore but the pictures really helped us to do it"* • Theme 5: Talking Mats makes carers feel they are being listened to: *"It really feels like he is listening to my point of view, even for that moment."* *"It never seems like he is listening to me, with this I can make him sit down and look at symbols and get him to understand what I am trying to say."* • Theme 6: Talking Mats improves understanding from the carer's perspective: *"It [Talking Mats] gives a focus to your conversation; it can be so difficult sometimes to find out what he feels."* *"Meals are a problem, I'm not sure if he likes what I give him, but it is so hard to know. We could use pictures of different foods and decide what we are going to have for tea each night."* • Theme 7: Talking Mats reduced confrontation and arguments: *"Feels less confrontational, we didn't argue."*
Author's comments	The people with dementia felt that Talking Mats helped to clarify their thoughts and enabled them to express their views. It helped them to reach a decision about how they were managing different aspects of their daily living. Family carers reported feeling more involved in discussions and more satisfied with the outcome when using Talking Mats. Family carers acknowledged the value of Talking Mats in encouraging and maintaining communication. It allowed a better understanding of the views of the person with dementia. This has implications for the stress and guilt often associated with having to make decisions for their loved one, not only on a day-to-day basis, but also those related to their future care. An unexpected finding was that the increased feeling of involvement was significantly higher for the family carers. Family carers repeatedly reported feeling "listened to" by the person with dementia and felt that their loved one could actually "see" their point of view. Talking Mats reduced anxiety on the part of both the person with dementia and their carer. The study demonstrates that Talking Mats could enable people with dementia and their family carer to jointly discuss and make decisions about how they are managing daily living. This is important for health, social service and care staff in assessing needs and providing care and support. Talking Mats is a method by which healthcare professionals could communicate with patients with dementia – even though their verbal communication skills have deteriorated. Talking Mats also offers a method for recording views to inform later decision-making.
Quality	• Was there a clear statement of the aims of the research? Yes

Full citation	**Murphy J, Oliver T. 2013. The use of Talking Mats to support people with dementia and their carers to make decisions together. Health and Social Care in the Community. 21(2), 171-180**
assessment	• Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Unclear. The number of participants (18 couples) seems to have been chosen on an arbitrary basis, e.g. – couples were not recruited continuously until there was no new information. However, the results seem to have been consistent, e.g. – there were no differing viewpoints. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? No – there was no mention of how recruitment took place. • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: Moderate

Full citation	**Parveen S, Blakey H, and Oyebode J R (2017) Evaluation of a carers' information programme culturally adapted for South Asian families. International Journal of Geriatric Psychiatry 02, 02**
Study details	Country/ies where the study was carried out: UK Study type: focus group interviews Aim of the study: The aims of the aspect of the evaluation reported here were to establish whether the Information Programme for South Asian families (IPSAF): 1. had an immediate and/or medium-term impact on the lives of those carers/relatives who attended with regard to knowledge of dementia and/or use of services; 2. had an immediate and/or medium-term impact on the wider families, including the person with dementia, of those who attended. Study dates: September 2014 and March 2015 Source of funding: This evaluation was funded by the Alzheimer's Society
Participants	• Sample size: 20 family carers of South Asian people living with dementia. There were an additional 22 people who were not carers but were family members. • Inclusion criteria: The evaluation was conducted across 7 of the 9 sites in England where IPSAF was delivered. Two further sites were

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	unable to take part because of unforeseen delays in their start dates. All who attended IPSAF were invited to participate, and they were able to cater for language requirements so that all could take part. • Exclusion criteria: none • Sample characteristics: The focus groups involved 42 participants of Indian, Pakistani, and Bangladeshi heritage. The majority were family carers, although 22 were not carers themselves but had an interest in how to support others in this role. Family interviews involved 17 participants and included 4 families of Pakistani heritage and 3 of Indian heritage. Thirty-seven participants completed the prequiz and 33 completed the postquiz.
Methods	**Information programme for South Asian families** In 2013, the Alzheimer's Society culturally adapted, in consultation with South Asian communities, an existing carers' information and support programme to develop an Information Programme for South Asian Families (IPSAF). Carers' information and support programme was mainly attended by white British carers, and the Society perceived the programme did not meet the cultural needs of south Asian families. The programme was adapted to be delivered in south Asian languages and included culturally specific examples. The aims of IPSAF are to improve the knowledge, skills, and understanding of South Asian carers supporting a relative with dementia. The programme is delivered by an Alzheimer's Society facilitator in partnership with a local South Asian community organisation and consists of 4 sessions addressing understanding dementia, legal and money matters, looking after others, and looking after yourself. **Knowledge quiz** To obtain a quantitative measure of change in participant knowledge of dementia and/or services, a social quiz was designed to overcome the linguistic and cultural barriers associated with a written questionnaire. This was conducted before the first and after the final sessions of IPSAF. Participants held up coloured numbered cards to show how much they agreed with each of 6 statements. The cards represented a Likert scale, from 1 (strongly disagree) to 5 (strongly agree). **Focus groups** After the final session of IPSAF, attenders were invited to stay on to participate in a focus group with one focus group being held at each of the participating sites. Approximately 66% of course attenders took part, with numbers ranging from 2 to 11. The focus groups were facilitated by 2 researchers, one of whom was multilingual, and discussion occurred in the language choice of participants (mainly Punjabi, Hindi, Urdu, and English). Participants were asked about their views of IPSAF, whether it had impacted on their daily lives, what they had found useful, and whether and how it could be improved. The focus groups lasted 30 to 60 minutes. **Family interviews** Attenders were also invited to participate in a family interview to include members who had not attended the Course, and the person with dementia, if appropriate. Seven semi-structured family interviews were conducted in the participants' home. People with dementia were included where they had capacity to provide informed consent. Family size ranged from 1 to 5 with a mode of 2, and 3 people living with dementia took part. Relationships to the person with dementia were varied (3 daughters and 1 son; son and daughter-in-law (2 families); 2 daughters; daughter and wife; wife; and daughter-in-law and granddaughter). Interviews lasted 25 to 100 minutes. Families were asked about

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	the impact of IPSAF, whether and how knowledge had been shared with the family, changes for the person with dementia, and how those who had attended IPSAF perceived the peer support aspect of the programme. Three of the families were followed up 6 months later to establish whether IPSAF had a sustained impact on the families. One family declined follow-up, and because of timescales, it was not possible to follow up the remaining 3.
Thematic analysis	• Theme 1: (Facilitator, intervention) All participants discussed being much more aware of services as a result of IPSAF and were able to give examples of services they could approach for support. Many placed particular value on knowledge gained about legal and financial aspects of supporting a person with dementia. There was evidence that a number of participants had made use of services as a result of IPSAF. Attenders who were non-carers reported that they felt confident they could signpost carers to services, as a result of IPSAF. Although some carers reported that they were not planning on using services at the present time, they valued having the knowledge of available services. A number of carers expressed an intention but had not yet accessed more social types of support such as wellbeing cafés and carer support groups. ○ Finding 1: A carer said: “I feel less isolated because I know who the service providers are now, so kind of things to do with health, housing, legal issues. So we now know where to go because initially we kind of found these things by chance and by accident really, by asking people, you know.” ○ Finding 2: Some reported making use of memory clinics; 3 reported applying for power of attorney as a result of what they had learned, 5 reported making use of their local Alzheimer's Society, and several had contacted social services and completed carers' assessments. ○ Finding 3: The quiz data supported these findings with the number of participants feeling confident they would be able to find support to help them tripling (23% to 76%), and the number who perceived they would know where to go for advice on legal and financial matters doubling (44% to 82%). • Theme 2: (Facilitator, intervention) The Information Programme for South Asian Families improved families’ coping and confidence. A significant number felt IPSAF had improved their understanding of the carer's role and given them confidence to support their relative with dementia. Some reported increased confidence in interacting with health care professionals, particularly as they felt more able to recognise the signs and symptoms of dementia. They also felt comfortable sharing information from IPSAF with their wider community. Two families reported feeling better able to cope with pressures from extended family members as a result of strategies they had learned. ○ Finding 1: A carer said: “We now understand that we need to make time for our self also a bit, so ok it's our duty to take care of our parents or husband, whoever is ill with the disease, we are devoted to that but the other important thing is I have to take care of myself also. If I get [a] cold, then who's going to take care of both of us.” ○ Finding 2: Almost all carers said they now better understood the need to look after themselves, one carer perceiving this “as the most important thing.” Many carers reported that IPSAF had validated the need for self- care and, as a result, felt less guilty. • Theme 3: (Facilitator, intervention) The Information Programme for South Asian Families provided social and emotional support. Participants were very positive about the opportunity IPSAF gave them to discuss their experience with others who understood and could relate to the shared cultural barriers experienced, particularly with regards to seeking support. The group was seen as an opportunity to form

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	connections, share information, and learn from one another. ○ Finding 1: A carer said: "When you experience something which devastates you emotionally, you know, big time, it's so important to find people in the same boat as you." ○ Finding 2: A number of participants reported that the peer group they had met during the Course had become a source of social support, and they no longer felt they were "on their own." Sharing and discussing their personal experiences with the group was seen as a form of "release." • Theme 4: (Facilitator, intervention) The knowledge and understanding gained by carers during IPSAF led to changes in how carers supported people with dementia. Many carers reported that they used shorter sentences and pictorial aids to facilitate communication, and some had developed a more organised routine for the person with dementia. Care practices were more centred on promoting independence and empowerment for those with dementia, who were provided with more choice of activities including a fresh opportunity to participate in previously enjoyed activities such as cooking. ○ Finding 1: A carer said: "We understand that she can't help forgetting things, but at the same time we are still trying to empower her, because we understand that, we still got to keep routine with her, to keep her, to try and help her to keep remembering things, so we help with a lot of stuff, but we still empower her."
Author's comments	At the follow-up interviews, it was evident that the metaphors used in IPSAF to aid understanding of dementia continued to resonate with the families. The families had continued to provide more person-centred care and promote the person with dementia's independence. Information sharing with extended family members had continued and become more widespread, with examples of sharing information with neighbours and colleagues. One family had remained in contact with another that they had met through IPSAF and were supporting one another whilst sharing information. All 3 families had engaged with services in relation to seeking practical support but had not accessed carer support groups. Although they were yet to attend carer support groups, the knowledge of their existence helped reduce their sense of isolation. Despite the families' improved awareness of services, they reported a number of barriers to access, for example, the lack of local services, or no culturally specific services being available in their vicinity.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes

Full citation	**Parveen S, Blakey H, and Oyebode J R (2017) Evaluation of a carers' information programme culturally adapted for South Asian families. International Journal of Geriatric Psychiatry 02, 02**
	• Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: High

Full citation	**Poppe 2013. Qualitative evaluation of Advanced Care Planning in Early Dementia (ACP-ED). PLOS ONE. 8(4), 1-5**
Study details	• Country/ies where the study was carried out: Two memory services in south London, UK • Study type: In-depth interviews • Aim of the study: This study was designed to evaluate the acceptability of a systematic dementia-specific approach to advanced care planning discussion. • Study dates: 2012 • Source of funding: Modernisation Initiative End of Life Care Programme 2008-2011, Guy's and St Thomas' Charity with support from the King's College Hospital Charity and South London and Maudsley NHS Foundation Trust Charitable Funds.
Participants	• Sample size: 12 people with mild dementia, eight carers, and six members of staff. • Inclusion criteria: People with mild dementia who had capacity to consent to this study, their carers and staff. • Exclusion criteria: None • Sample characteristics: 12 people with dementia, mean age 79, range 68-88 years, gender: four males, eight females, eight carers, three were either a spouse or partner, four sons or daughters, one son-in-law or daughter-in-law. Six members of staff (three community practitioners, one team manager, one clinical psychologist, and one assistant director of nursing).
Methods	The investigators developed an Advanced Care Planning in Early Dementia tool (ACP-ED). An initial draft was devised and then revised following discussion with people with dementia, carers and dementia practitioners. Overall, 18 patients, 25 carers and 150 members of staff provided feedback during its development. Advanced care planning (ACP) discussions were conducted by a senior nurse and by a clinical psychologist. The discussions were evaluated by in-depth qualitative interviews with the people with mild dementia, their carers, staff from a memory service and a community mental health team for older people. ACP discussions were held with 16 people with dementia, 14 agreed to be approached for the evaluation. Of these, 12 people with dementia and eight carers consented to be interviewed about their experience of the ACP discussion.
Thematic analysis	• Theme 1: (Facilitator) – Offering ACP to people with dementia is a facilitator for people with dementia to make use of ACP. ○ Finding 1: Only one third of patients interviewed had thought about any aspect of the future.

Full citation	Poppe 2013. Qualitative evaluation of Advanced Care Planning in Early Dementia (ACP-ED). PLOS ONE. 8(4), 1-5

- Finding 2: Out of the 12 patients, all but three considered ACP a positive and helpful experience and were satisfied with having the discussion:

"I was glad to have told her what I wanted."

"They covered everything I wanted to know and the questions they asked were the right questions."

Patients said that the ACP discussion gave them time to think about the future. Some stated that they were relieved and less worried after discussing their preferences for the future. They felt reassured about the support from their family and services and they found it important that their family and professionals knew their preferences for the future:

"I suppose really it was the wisest thing to do because there is no use leaving things like that too long before things are going to get worse. You don't know what you are doing. I would rather know what I am doing so that's why I decided to make arrangements and things so if anything happens now they all know, both of them know, what I want and what's happening and so it saves me worrying about it."

- Finding 3: Two carers out of eight mentioned they had tried to discuss the future with the patient before and had found it difficult. They felt that they probably would not have brought up the topic again without the ACP discussion being prompted by the memory service.

- Theme 2: (Facilitator) – The motivations to agree to the ACP were concern about their memory and wanting to plan for a time when they could no longer look after themselves.
- Theme 3: (Facilitator) – Some patients with dementia may want an ACP because of a dispute with a family member who is questioning the patient's capacity to make decisions.
  - Finding 1: This was the situation for one patient in the study. Having made his preferences for future care known, he felt more secure and considered the plan as a means of self-protection.
- Theme 4: (Facilitator) – Carers are a facilitator to how people with dementia can make use of ACP.
  - Finding 1: Carers said that ACP made them think about the future and that the initial ACP discussion prompted further discussions about the future with the person with dementia or other family members.
  - Finding 2: Carers considered it helpful to find out the person with dementia's wishes and to have a written record of it so that everyone knew that this was what the person with dementia wanted.
  - Finding 3: Carers said that they felt more confident that if necessary they would be able to make a decision that would reflect the person with dementia's wishes:

"The social worker doesn't know mum and doesn't know us and whereas we are actually quite a close knit family and we are very lucky because we can actually make those decisions and think yeah that isn't actually what mum would want, what she would want is x, y, z."

- Theme 5: (Facilitator) – Staff found the ACP-ED tool to be a facilitator.
  - Finding 1: Staff felt that the ACP-ED tool provided structure to guide them in the discussion.
  - Finding 2: Staff felt that it was helpful that the tool was open-ended. This is because the open-ended questions provided flexibility and the given questions could generate further questions.
  - Finding 3: Staff who had not yet conducted any advance care planning discussions themselves were unsure how to initiate the discussion

Full citation	Poppe 2013. Qualitative evaluation of Advanced Care Planning in Early Dementia (ACP-ED). PLOS ONE. 8(4), 1-5
	with those people with dementia who had not raised the issue themselves, but saw the tool as a potential way of facilitating this. • Theme 6: (Barrier) – Staff thought that the main barrier to ACP on the part of the people with dementia and carers was difficulty for some people with dementia or carers to accept the diagnosis. o Finding 1: For one person with dementia, some members of their family were disputing the diagnosis. This made discussing an ACP problematic. o Finding 2: Some staff said that some patients with dementia were worried that by discussing ACP, they would no longer be allowed to make decisions. • Theme 7: (Barrier) – Family may not want ACP to go ahead. o Finding 1: One staff member gave an example of a case where the patient would have agreed to ACP, but the carer was against it: *"I think the client would have been quite open to the discussion but the daughter was quite, that wasn't somewhere that she wanted to do and she was, so we didn't."* • Theme 8: (Barrier) – Some patients find discussing the future dispiriting. o Finding 1: This was the case for two out of the 12 people with dementia. • Theme 9: (Barrier) – Some patients find discussing the future difficult without knowing what the future will bring. o Finding 1: This was the case for one patient out of 12. o Finding 2: Staff felt that it was the uncertainty about the duration of the illness that made it difficult for people with dementia to plan for the future. • Theme 10: (Barrier) – Staff thought that a potential barrier to ACP was lack of capacity. Therefore, discussing ACP early in the dementia pathway was seen as the solution. • Theme 11: (Barrier) – Staff felt that a potential barrier was staff lacking in confidence to discuss ACP. Training and use of the ACP-ED were seen as ways of addressing this.
Author's comments	There was a consensus among the staff that that ACP should be offered to patients soon after diagnosis when patients had time to think about the diagnosis, when they were still in contact with the service, and where they were still able to make decisions about preferences for the future. There was overall agreement between staff that doing this at the point of diagnosis might be too stressful. It was agreed by all staff that time was needed to come to terms with the diagnosis before being able to start thinking about the future. Staff felt that it was important to give people with dementia and their carers detailed information about ACP before the discussion took place. This is so people with dementia would not feel threatened by the discussion and so they could decide whether to proceed. The authors felt that it is crucial that the topic of ACP is initiated by staff because people with dementia and their carers are unlikely to initiate the discussion with professionals spontaneously. Services need to see this as a core part of their work and part of providing a good diagnostic service. One of the main reasons why ACP has not has not been more widely implemented in practice is because there is a lack of clarity about who

Full citation	Poppe 2013. Qualitative evaluation of Advanced Care Planning in Early Dementia (ACP-ED). PLOS ONE. 8(4), 1-5
	should be delivering the intervention. The authors felt that their findings suggested that people with dementia, carers and staff believe that memory services and Community Mental Health Teams are well placed to initiate ACP discussions with people with dementia, provided they are properly trained and resourced. To enable implementation of the person with dementia's wishes, it is important that the ACP documentation is made available to the relevant health service providers, such as GPs, with the person with dementia's consent.
Quality assessment	Was there a clear statement of the aims of the research? Yes Is a qualitative methodology appropriate? Yes Was the research design appropriate to address the aims of the research? Was the recruitment strategy appropriate to the aims of the research? The number of participants was chosen arbitrarily, e.g. – carers were not recruited continuously until there was no new information. Was the data collected in a way that addressed the research issue? Yes Has the relationship between researcher and participants been adequately considered? Yes Have ethical issues been taken into consideration? Yes Was the data analysis sufficiently rigorous? Yes Is there a clear statement of findings? Yes How valuable is the research? Valuable Overall quality: Moderate

Full citation	Samsi K, Manthorpe J. 2013. Everyday decision-making in dementia: findings from a longitudinal interview study of people with dementia and family carers. International Psychogeriatrics. 25:6, 949-961
Study details	• Country/ies where the study was carried out: London, UK • Study type: Longitudinal interview study • Aim of the study: To ascertain how people with dementia make decisions in the present. The study does not include how people with dementia make decisions for the future. • Study dates: 2013 • Source of funding: National Institute for Health Research (NIHR)
Participants	• Sample size: 12 'dyads' (one person with dementia plus one carer. For example, not all were 'partners'). • Inclusion criteria: People with dementia who had a carer. • Exclusion criteria: Dyads were excluded if the person with dementia did not have capacity to consent to take part in the study.

Full citation	**Samsi K, Manthorpe J. 2013. Everyday decision-making in dementia: findings from a longitudinal interview study of people with dementia and family carers. International Psychogeriatrics. 25:6, 949-961**
	• Sample characteristics: The ages of the people with dementia ranged from 72 to 88 years. At the first interview, the time since diagnosis of dementia ranged from 3 to 11 months. Severity of the dementia was mild to moderate. All but one dyad were white British. The exception was a one uncle and his niece who described themselves as Asian/Indian.
Methods	Face-to-face interviews were conducted with people with dementia and their carers every three to four months for a period of a year. Interviews were recorded and transcribed. Every individual's opinion was treated as contributing to a common shared reality. No participant's account was verified for factual accuracy. An absence of discussion around dementia was seen as potentially significant and examined. The investigators explored how people were feeling about their current situation and how they were reacting to it.
Thematic analysis	• Theme 1: Decision-making is a continuum of five stages. However, not all participants start at the beginning and reach the end. Furthermore, the five stages are not absolute, nor do they represent a "pathway" – there is considerable nonlinear movement between stages. ○ Finding 1: Stage 1 is 'mutual decision-making'. When people with dementia and their carers make decisions jointly. The facilitators were the capacity of the person with dementia and their keenness to make decisions. Decisions were often made together – between the patient with dementia and the carer, with boundaries respected by spouses in particular. Joint decision making was considered normal if the dyad were long-term partners (some had been married for over 50 years). As many of these decisions were embedded in everyday conversations, they found it hard to distinguish who had made the decision. ○ Finding 2: Stage 2 is 'reductive decision-making'. The barrier is that people with dementia find it more difficult to make decisions. In many of these instances, the carer takes on a larger share of caring responsibilities, such as cooking meals and prompting washing and bathing. An important aspect is the keenness of the carer to use facilitators to reduce "cognitive overload". The following facilitators were used by the carers: posing a question at the "right" time, gauging when their relative was likely to be most engaged in conversation, and presenting a limited number of options. Most people with dementia told of their trust and faith in their relative or friend deciding for them. However, two reported not wanting their choices or autonomy to be compromised and a desire to remain closely involved in any decisions that concerned them. One carer was worried about the responsibility of having to take decisions for her friend. This is because her friend was doing everything she told him to do. Therefore, she was having to be very careful. ○ Finding 3: Stage 3 is 'restrictive decision-making'. At this stage, people with dementia and their carers describe their lives as having "shrunk", e.g. – they are doing less, eating simpler meals, and through successful adjustments, were managing with less. As a result, many talked of fewer decisions arising. A facilitator often used by carers to keep their relative with dementia engaged in decision-making was orchestrating the situation around them. For example, the carer makes the decisions for the small unimportant things, such as choice of meal. This "saves" their relative's decision-making capacities for bigger and more significant decisions. ○ Finding 4: Stage 4 is 'retrospective reflections for decision-making'. As time progresses or for some decisions, carers reported that they had to make decisions on behalf of their relative with dementia. Some carers expressed their frustration about this – they reported feeling strained and confused by being the person upon whom all such decisions rested. The facilitator in this situation was the carer's accumulated knowledge of their partner. Child carers were more likely to base decisions on previous conversations with their parent. In

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	three cases where an adult child carer had not had the chance to have such conversations with their parent with dementia, they seemed to lack confidence and were more worried about making proxy decisions. A potential barrier is if the carer is a friend, rather than a family member. This is because one of the carers who was a friend was happy to support her friend over practical tasks, such as taking her for shopping. However, she was very reluctant to make decisions with and for her friend with dementia: "…every time I go now, she's asking me if she should be in a home. Now I can't make that decision. Her son can't make that decision because he's too far away…" Out of 12 dyads, only one had made a Lasting Power of Attorney (LPA). Only two further dyads had heard of LPAs but were unclear about details. A barrier to decision-making for a person with dementia can happen if their needs conflict with the needs of the carer. For example one carer said: "Well, one of the big decisions was going to the day centre because he didn't want to go, but I said, well, it would be good for him and good for me. And then when he knew the other people from Friday mornings were going there, he went. But I made all the arrangements on that, because I really needed that break, you see?" ○ Finding 5: Stage 5 is 'best-interests decision-making'.
Author's comments	An important divergence in views between people with dementia and carers in this sample appeared to be that some people with dementia wanted decisions to be made on their behalves, while carers were more inclined to want to preserve their relative's autonomy through the use of strategies and cues. Only one-third of the dyads interviewed operated in isolation or mutual dependency. Most talked of being part of strong family networks with other family members actively involved in practical caring support and decision-making. Spouse couples often demonstrated the strongest mutual relationships in terms of their knowledge and intimacy of the person with dementia they were supporting. However, one of the dyads involved a niece – she also showed a deep understanding of her uncle's preferences and habits despite not living with him. She attributed this to close family ties in her family. This illustrates the importance of not overly simplifying marital partners or adult children as having privileged positions. Practitioners and support services should provide timely advice to carers and people with dementia around everyday decision-making, and be mindful of how situations may change.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. The number of participants (12 dyads) was chosen on an arbitrary basis, e.g. – dyads were not recruited continuously until there was no new information. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes

Full citation	Samsi K, Manthorpe J. 2013. Everyday decision-making in dementia: findings from a longitudinal interview study of people with dementia and family carers. International Psychogeriatrics. 25:6, 949-961
	• Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? It is valuable. Overall quality: Moderate

E.3 Care planning, review and co-ordination

E.3.1 Health and social care co-ordination

- What are the most effective methods of care planning, focussing upon improving outcomes for people with dementia and their carers?
- How should health and social care be co-ordinated for people living with dementia?

E.3.1.1 Qualitative evidence

Full citation	**Bunn F, Burn A M, Robinson L, Poole M, Rait G, Brayne C, Schoeman J, Norton S, and Goodman C (2017) Healthcare organisation and delivery for people with dementia and comorbidity: a qualitative study exploring the views of patients, carers and professionals. BMJ Open 7, e013067**
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews Aim of the study: The aim of this study was to explore the impact of dementia on access to non-dementia services and identify ways of improving service delivery for this population. Study dates: December 2013 to July 2014 Source of funding: a grant from the National Institute for Health Research
Participants	• Sample size: 28 people living with dementia and 33 family carers • Inclusion criteria: People living with dementia and at least one of the following three conditions: diabetes, stroke or vision impairment (VI). These conditions were chosen as they are common in older people, require external monitoring and collaboration between primary and secondary care, may exacerbate the progression of dementia and their management is likely to be complicated by the presence of dementia. They also recruited family carers and healthcare professionals (HCPs) who organise and deliver care for people with stroke, diabetes and VI in primary and secondary care. PLWD were recruited via dementia registries, GP practices, memory clinics and voluntary organisations in the South and North East of England. They were asked whether they received any significant help from a family/ unpaid carer. Recruitment was from primarily urban areas. • Exclusion criteria: none • Sample characteristics of the people living with dementia: Type of comorbidity: diabetes 31%, diabetes and vision impairment (VI 17%), stroke 24%, all 34%. Age median 82.5 years (range 59-94). 36% female. 85% white (majority white British). 78% lived with a carer. • Carers: age median 65 years (range 46-90). 82% female. 85% white (majority white British). 64% of carers were a spouse, 14% adult child.
Methods	In the light of the lack of previous research in this area, they took an exploratory qualitative approach involving in depth semi-structured interviews and focus groups.

Full citation	**Bunn F, Burn A M, Robinson L, Poole M, Rait G, Brayne C, Schoeman J, Norton S, and Goodman C (2017) Healthcare organisation and delivery for people with dementia and comorbidity: a qualitative study exploring the views of patients, carers and professionals. BMJ Open 7, e013067**
Thematic analysis	• Theme 1: Family members were often proactive in facilitating continuity and negotiating access to services for their relatives with dementia. This included acting as an advocate for their family member with dementia, noticing when something was wrong and seeking help ○ Finding 1: Carer Diabetes: "As a family member you're the person who knows that person better than anyone else so you can see when it's not, when it's not right, when it's going wrong." ○ Finding 2: Carer Diabetes/VI: "It was like when she had her cataract done, I actually went into the room with her… you know, because one nurse kind of looked at me and she said 'no, if you wait in the waiting room', I went 'well, no—my sister has a memory problem so I'll have to stay'". • Theme 2: Family members were often proactive in helping clinicians make treatment decisions, such as whether to thrombolyse a PLWD after a stroke. Family carers also had a significant role in coordinating their relative's care, navigating healthcare systems and facilitating continuity of care; for example, managing appointments, organising transport, keeping records of test results and medication ○ Finding 1: Carer Diabetes/VI: "Her feet were black and I was concerned, because we've got, in the paternal side of my family, she's got aunts and her mother was blind, aunt had amputation of the toes." • Theme 3: Family members were often proactive in actively transferring information between HCPs and different services. ○ Finding 1: Carer diabetes/VI: "and now I go with him for all his appointments…I have got a notebook there which I use to note everything, you know, when it started [sound of paper rustling] for myself, for my own, you know…I used to record everything, 'seen by so and so, what prescribe and when to be seen again' and all these things." • Theme 4: The availability of a family carer to act as a proxy, and provide consent, information and post-discharge support impacted on a PLWD's access to care. HCPs recognised that PLWD who lived alone, or did not have support from a family carer or advocate, were particularly vulnerable and may have poorer access to care ○ Finding 1: PLWD and Carer VI: "you see one person one time and then you'd have, tell them what they need to know and then you see the next person and they don't know, do they. You have to go all through it yeah, you have to start again. But I mean, that actually is a problem with the NHS all the way through, I mean, because it's a kind of, you know, you're not always treated as a whole person, you're treated as individual bits, aren't you." • Theme 5: Although HCPs in our study valued the role family carers played, there was little formal recognition of the carers' role, and no systems for negotiating how or when carers' views could be incorporated into care planning. This was reflected in the many examples provided by their interviews where carers felt undervalued or excluded from decision-making about their relative's care. ○ Finding 1: Carer Diabetes: "do you remember that mum, you know your method for testing your blood that you'd used for years, last Easter the nurse came on Maundy Thursday, the day before Easter and she gave you a new machine to do it…And you could not fathom it at all…No, no, none of us could, could we? It was chaos…" • Theme 6: There were many challenges for family carers. These included difficulty in understanding how health systems worked and who to

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contact, their own health problems, emotional and practical challenges of changing roles

- Finding 1: Carer Stroke: "gradually I took over the medication, each step was really painful, you know 'cos he always used, he was on by the time when he started sort of losing grip on things he was on a lot of medication, six or eight different pills a day and he would line them up and take them one at a time and so on, and then I started putting them in dosette boxes and then he started not remembering to take them and then he would take them at random so gradually I took over the whole thing and I mean there were a lot of tears and agony."

- Theme 7: Living at a distance and/or with work and family commitments that made taking on responsibilities for day-to-day care difficult. Caring at a distance may be particularly problematic for carers of PLWD as it is difficult for them to offer support or to monitor adherence to medication over the phone.
  - Finding 1: Carer Diabetes: "I know yesterday you had a bit of a problem because you thought, when I phoned you up in mid-morning you thought that the lady hadn't been to give you your medications and your Cornflakes but in fact she had, hadn't she?" PLWD diabetes: "she had, yeah." Carer and PLWD diabetes: "so mum ended up having two breakfasts yesterday."
- Theme 8: Support from social networks, such as extended family, friends and religious groups, and from third sector providers were clearly important to PLWD and their carers.
  - Finding 1: Carer Stroke: "the Alzheimer's Society have been fantastic…Oh the Alzheimer's Society, oh .. that's a godsend that is, absolutely godsend, yeah."
- Theme 9: Formal support from health and social care was often seen as inadequate.
  - Finding 1: Carers Diabetes: "they have a diabetic nurse and she rings up every now and again to get her readings." And: "I don't think that's very good, that's one of the services that I don't think is very good to be honest."
- Theme 10: PLWD and family carers valued continuity, in terms of relationships with practitioners but also in terms of encounters that factored in the impact of dementia, that built on earlier conversations and appointments and that included people with dementia and their carers in decision-making. Many PLWD and carers reported positive relationships with their GPs and recognised the role that GPs played in coordinating care.
  - Finding 1: Carer Diabetes: "[GP] yes, now she's gone ahead with loads of things because she says 'are you getting this, are you getting that,' we told her what we'd had and what you know what he doesn't have, so she says 'right I shall get in touch with these people' she said 'and help you'. Now as it happens she must have done very quickly, because we had a lady from the social services yesterday."
- Theme 11: How PLWD managed their care, for example, either independently, in tandem with a family carer or with external health and social care support, was linked to where they were on the dementia trajectory. Some people with early stage dementia were still able to self-manage their care. As the dementia got worse, the PLWD's ability to self-manage declined and responsibility moved, either partly or totally, from the PLWD to a carer. These transitions often happened when strategies to facilitate self-management, for example, memory aids, diaries and dosette boxes, ceased to be effective
  - Finding 1: Carer VI: "we had a timer at the beginning and it bleeped when he should take a tablet, well he would go and turn the bleeper off

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	and forget to take the tablet so." • Theme 12: Current infrastructure did not support the sharing of information across different specialities. ○ Finding 1: Carer Diabetes: "but obviously anywhere new that we go, like for this colonoscopy and all that sort of thing, I always mention, you know, 'he has dementia quite, quite severe dementia', I think when we went for a blood test for this colonoscopy it wasn't on his notes there, although it was on the original colonoscopy referral sort of thing. So it seems that within the hospital setup they don't always transfer all relevant information between departments." • Theme 13: For many participants, their comorbid health condition predated the diagnosis of dementia. Despite this, there appeared to be inadequate consideration by some services of the implications of a diagnosis of dementia on the management of existing conditions. ○ Finding 1: PLWD Diabetes/Stroke/VI: "memory loss, no, they're not interested in that, they're interested in treating the symptoms of diabetes not somebody else's, it's almost like somebody else's problem but I don't mean that hard heartedly, I mean that we are dealing with this bit, there's nobody, other than my GP looking at the whole picture."
Author's comments	HCPs' concerns about confidentiality meant that carers sometimes had trouble accessing the information they needed to manage their relative's care. For example, being refused copies of letters or details of hospital appointments. Although a number of carers and PLWD mentioned lasting power of attorney, this was seen as facilitating management of financial affairs rather than healthcare. What emerged from their analysis is that in order to facilitate access to care and improve continuity for PLWD and comorbid conditions, there is a need for coproduction of care in which HCPs, PLWD and family carers work in partnership, the matching of management to the needs of the individual (including ways of anticipating changes in needs and tailoring care appropriately), and improved collaboration across specialities and organisations. They found examples of good practice, but these tended to be about the behaviour of individual practitioners rather than system-based approaches; current systems may unintentionally block access to care for PLWD. Their study highlights not only how family carers are often responsible for negotiating continuity and access for family members with dementia but also how care systems often hinder rather than support their efforts. They found that fragmented care, clinical guidelines that focus on single conditions and poor communication and collaboration between different specialities were barriers to continuity and access to care for PLWD. Models of care designed to improve inter-professional working include components such as case management, specialist nursing support, comprehensive geriatric assessment and colocation of different specialities to promote integration and holistic care. Their study suggests that relatively minor changes to healthcare systems, such as ensuring that PLWD are identified in advance of visits to outpatient services and primary care, or for providers to make information sharing with family carers the default option while the person still has capacity to decide, could lead to improvements in care.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes

Full citation	**Bunn F, Burn A M, Robinson L, Poole M, Rait G, Brayne C, Schoeman J, Norton S, and Goodman C (2017) Healthcare organisation and delivery for people with dementia and comorbidity: a qualitative study exploring the views of patients, carers and professionals. BMJ Open 7, e013067**
	• Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: High

Full citation	**Brooker Dawn, Dröes Rose-Marie, and Evans Shirley (2017) Framing outcomes of post-diagnostic psychosocial interventions in dementia: the Adaptation-Coping Model and adjusting to change. Working with Older People: Community Care Policy & Practice 21, 13-21**
Study details	Country/ies where the study was carried out: UK Study type: focus group interviews Aim of the study: to assess the Adaptation-Coping Model Study dates: not provided Source of funding: not provided. The investigators were staff at the University of Worcester and University Medical Centre, Amsterdam.
Participants	• Sample size: 9 people living with dementia and 6 carers • Inclusion criteria: Two focus groups were undertaken with people living with dementia and their family carers who had attended one of the UK Meeting Centres. • Exclusion criteria: none • Sample characteristics: Average age of the 9 people living with dementia was 81 years (range 65-93). Average age of the 6 carers was 73 years (range 70-80). All focus group participants were white-British and came mainly from skilled professional backgrounds. A number had held professional positions (e.g. former engineer, bank manager, armed forces, architect, teacher); others had worked in the caring professions (e.g. care-home manager, GP, midwife) whereas others had been home makers.
Methods	The Adaptation-Coping Model recognises that when someone receives a diagnosis of a severe illness or a chronic condition, there are many changes to which the person and their family have to adjust. These changes are conceptualised as adaptive tasks or challenges. How the

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	person and their family deal with these tasks is based on their cognitive appraisal of them. The appraisal will be affected by the history of the person and their family, the specific symptoms of the condition and their social and material resources. How the tasks are appraised may lead to a straightforward automatic adaptation for some. Others will develop new coping strategies and behaviours, depending on the difficulties the person experiences. Family carers are confronted with adaptive tasks over time. The degree to which the carer is able to adapt to the situation depends on their personal attributes and the support they receive. Just as the person diagnosed with dementia goes through different stages so does the carer. In these different stages the carer needs different types of support. During the initial stages, when the carer realises that significant change is happening, all kinds of emotions and frustrations may be triggered. Families need to make decisions together about the future. What the carer needs most at this point is information about dementia, services and emotional support. At a later stage, the carer needs to get practical support as care tasks become more complex. They may need to step back in order to maintain their own emotional balance. Carers often experience feelings of guilt about this. Understanding why this is occurring, and providing emotional support can help the carer at this stage. The carer becomes re-involved in the care by learning skills to enable them to manage their day-to-day interactions with the person living with dementia.
Thematic analysis	• Theme 1: Family carers valued having the opportunity to learn more about dementia and see other people in the same situation. It enabled some carers to gain a broader perspective on their own experiences, and facilitate adjustment. By seeing how their relatives were treated at the Meeting Centre and responded to the interactions, some carers were able to reflect on the difficulties faced in their everyday lives. In particular, one carer commented on how their family inadvertently treated her husband: ○ Finding 1: A carer said: “When our family come round, they all find it quite difficult to deal with it, don’t quite know how to be, so I think they just, they have all their conversations going, [my husband] can’t keep up with it, so he just sits back and lets it all go on around him. And he gets forgotten. And I occasionally try to bring him in, as soon as he starts to talk he loses his words, so he just goes back into his shell. And they gabble over the top of him. They’re not being cruel, but they don’t know how to deal with it.” • Theme 2: Participants liked the warmth and friendliness of the staff. It gave them confidence. ○ Finding 1: A participant said: “I think my first impression was how friendly and warm, when you walk through the door. The friendliness and the warmth ‘cos friendliness and warmth mean safety to speak’” ○ Finding 2: A participant said: “it’s the atmosphere, it’s welcoming, warm, it’s safe, it’s, you can be you.” ○ Finding 3: A participant said: “it’s just nice to be here with other people, listening to what they think, so you don’t get too introverted.” ○ Finding 4: A participant said: “In lots of ways I feel I am drowning all the time, it gives you a chance to pick up a little bit. So it helps two people.” ○ Finding 5: A wife of a person living with dementia said: “I think that’s why they want to come, because they’re made to feel quite special. Where in the big wide world, they don’t feel special any more outside, they’ve lost all that”. She also commented that “[my husband] says ‘when I come in they all go morning [his name]’, he said ‘and I feel as though I matter, that I’m noticed again.’”

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	○ Finding 6: A carer said: "[…] every single person, without fail, who came in through the door went up to him, shook his hand and said 'I'm so and so, what's your name?' Every single one. And they all sort of came and sat round him and involved him in conversation. Well you know, that was really lovely and we really sort of noticed that didn't we? Rather than him just come in and be sitting in a corner, and nobody speak to him, instantly he was involved." • Theme 3: Some carers felt that they were unable to share their true feelings or experiences with family members for fear of judgement, and again the Meeting Centre provides a supportive space for those feelings to be aired: ○ Finding 1: A carer said: "So a very positive experience for [my wife] but also for me. Because I can talk to you folks about it, and you're not going to look back in horror. Last week, one of the family members came up, "I was absolutely frustrated the other day", he said "I got hold of two mugs and threw them on the floor". I've never done that, I've got close to it, I can understand it and not be judgemental about it." • Theme 4: The experience enabled some people to reflect upon their own emotional adjustment. ○ Finding 1: One person with dementia who had a military background reflected; "Perhaps I'm too organised like that. Perhaps I shouldn't be like that. Perhaps I've got to sit back and relax a bit more." • Theme 5: The planned activity provided a useful structure. ○ Finding 1: A participant said: "The Meeting Centre is a meeting centre I know, but sometimes I think you need to have an activity to focus on, otherwise we're always just coming here and meeting people." • Theme 6: The participants felt that they were not alone. ○ Finding 1: A participant said: "Well we've got nothing to compare it against have we? We've got preconceived ideas. If everybody else is feeling the same way, and expressing the same fears and contradictions, it's a relief in a way that you can share these opinions and not feel as though you're the odd one out." ○ Finding 2: The Meeting Centre was felt to be "a great benefit I think, socially" (A participant) ○ Finding 3: A participant said: "you can come and meet different people, find out different things that are happening." ○ Finding 4: a participant said: "it's almost like an instant friendship isn't it? You know, you see somebody a couple of times here, and they're your friend." ○ Finding 5: A wife of a person living with dementia said: "Brilliant, I would not like to be without it. It's a saving not only for me but for [my husband] as well, because he comes alive when he's with other people. He'll not necessarily remember what he's done, but he enjoys coming, and he wouldn't come if he didn't, you know. It's absolutely wonderful." • Theme 7: Seeing other people in similar situations and getting outside perceptions helped one carer to reassess how he views his wife's situation: ○ Finding 1: "And to me, one of the first things that struck me was half her behaviour, it's strange compared to the norm, whatever that

Full citation	**Brooker Dawn, Dröes Rose-Marie, and Evans Shirley (2017) Framing outcomes of post-diagnostic psychosocial interventions in dementia: the Adaptation-Coping Model and adjusting to change. Working with Older People: Community Care Policy & Practice 21, 13-21**
	might be, but in terms of dementia, it's not. And people say "oh, she's doing rather well now", and you think "no she's not", she is not, but then no she isn't, but I'm comparing her to how she was six, seven, eight years ago." (Husband) • Theme 8: The participants enjoyed attending and therefore the attendance was good. ○ Finding 1: A participant said: "It's noticeable though that people who start to come here carry on coming. There's very few people who drop out. So they must, there must be something here that's attractive." ○ Finding 2: A carer said: "He'll say 'when am I going to the Alzheimer's group?' Now that's the nearest I get to him looking forward to doing anything."
Author's comments	The framework can potentially be used directly by the person diagnosed and their family. It could also be utilised by the many statutory and third sector services and personnel who offer support in these early stages. It could be useful to dementia advisers, dementia support workers, peer support groups, carer support groups, memory assessment services and community workers to provide a shared language to clearly articulate the aims of their particular offer.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. UK Meeting Centre usage, recruitment and selection was not well explained. • Was the data collected in a way that addressed the research issue? Unclear. Some of the quotes are not appraisals of the intervention. • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Moderate

Full citation	**Faith Martin, and et al (2015) Qualitative evaluation of a self-management intervention for people in the early stage of dementia. Dementia: the International Journal of Social Research and Practice 14(4), 418-435**
Study details	Country/ies where the study was carried out: UK

<table>
<tr><th>Full citation</th><td>Faith Martin, and et al (2015) Qualitative evaluation of a self-management intervention for people in the early stage of dementia. Dementia: the International Journal of Social Research and Practice 14(4), 418-435</td></tr>
<tr><td></td><td>Study type: Semi-structured interviews with focus groups of people living with dementia.
Aims of the study: To explore the acceptability of self-management to participants. To explore how intervention components may fit with participants needs. To investigate views of intervention delivery in terms of timing of sessions, extra support required outside of the group time and tutors.
Study dates: Not provided. This study was published in 2015.
Source of funding: Warwick Coventry Primary Care Research</td></tr>
<tr><td>Participants</td><td>• Sample size: 6 people living with dementia
• Inclusion criteria: All were well known to the Alzheimer’s Society and were judged by their experienced staff, who were involved in intervention development to be in the ‘earlier’ stages of dementia and capable of coping with program requirements.
• Exclusion criteria: Illness and other engagements preventing attendance.
• Sample characteristics: 3 men, 3 women. The mean age of the participants was 68.9 years (SD 8.98) and all had a dementia diagnosis, with a mean of 3.5 years (SD 3.5) since diagnosis. 5 participants were White British and one was White Irish. All had co-morbid health conditions including hypertension, hernia, carcinoma, hearing difficulties, history of stroke, osteoporosis, cardiac conditions and a history of depression. One participant was concurrently attending a day care centre and two participants regularly attended an ‘Alzheimer’s Cafe´, which is where people living with dementia and their partners socialise and receive education and support from health care professionals. All participants were no longer in full-time employment and all participants were still living at home. Five of the six participants had a partner acting as a carer, with the other participant living alone and being supported by visits from his son.</td></tr>
<tr><td>Methods</td><td>This table provides the intervention objectives and content for each of the six sessions. One session took place per week for 2.5 hours each:
<table>
<tr><th>Session</th><th>Brief description</th></tr>
<tr><td>Session 1</td><td>Introductions, outline of participants’ responsibilities
Outline of course structure, content and aims.
Identifying and sharing experiences to be thankful for; generating and sharing positive emotions.
Introduction to diaphragmatic breathing.
Identifying goals that are pleasurable and meaningful and noting down and sharing goals (participants to share written copy of goal with family/friend and receive mid-week reminder phone call).</td></tr>
<tr><td>Session 2</td><td>Review of Session 1.
Practicing diaphragmatic breathing.
Discuss the information participants have used, what is more or less useful, remaining questions and explore ways to seek out information.
Discuss the importance of staying active and healthy, including diet and exercise, and problem solving around how to</td></tr>
</table></td></tr>
</table>

Full citation	Faith Martin, and et al (2015) Qualitative evaluation of a self-management intervention for people in the early stage of dementia. Dementia: the International Journal of Social Research and Practice 14(4), 418-435	
		stay active and healthy. Identifying goals that are pleasurable and meaningful and noting down and sharing goals (participants to share written copy of goal with family/friend and receive mid-week reminder phone call).
	Session 3	Review of Session 2. Practise diaphragmatic breathing focusing on one word associated with relaxation. Based on Seligman's (2002) suggested activity, present participants with list of strengths and then discuss which strength they identify with most. Express emotions around dealing with memory loss and share these experiences; share strategies participants use, which help reduce negative emotions around memory loss. Identifying goals that are pleasurable and meaningful and noting down and sharing goals (participants to share written copy of goal with family/friend and receive mid-week reminder phone call).
	Session 4	Review of Session 3. Sensory relaxation activity with imagery of, for e.g. walking through a garden on a summer's day (or, if participants request more practice, practise diaphragmatic breathing focusing on one word associated with relaxation). Share the idea of a memory box and how to make one (box of personal mementoes and photos important to the individual, often accompanied with brief written description); encourage to again share emotions associated with memory loss and positive past memories. Building on personal strengths activity, discuss idea that doing activities we are good at can increase happiness, discuss continued importance of enjoyment in life, encourage participants to focus on strengths and set goals around this. Identifying goals that are pleasurable and meaningful and noting down and sharing goals (participants to share written copy of goal with family/friend and receive mid-week reminder phone call).
	Session 5	Review of Session 4. Discuss changes in personal relationships and emotions associated to this, guide consideration of reasons for this, consider importance of maintaining activity and how this may impact on relationships (may illustrate with a story of a couple or family taken from tutor's experience or Alzheimer's Society online resources). Consider the advantages and disadvantages of talking about emotions and difficulties with family/friends/carer, for example negotiation required around who does household chores, encourage participants to discuss any difficulties openly and plan how communication could be improved. Identifying goals that are pleasurable and meaningful and noting down and sharing goals (participants to share written copy of goal with family/friend and receive mid-week reminder phone call).

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Session 6	Review of Session 5. Sensory relaxation activity with imagery of, for e.g. walking through a garden on a summer's day (or, if participants request more practice, practise diaphragmatic breathing focusing on one word associated with relaxation). Explore aspects of relationships with health and social care that work and do not work so well, present and discuss list of commonly used improvement strategies including, e.g. booking double appointments and definitely asking questions when information provided is too complex. Tutor first models and asks participants to think of some of their negative characteristics and then some of their positive characteristics and then review the idea that we are all a mixture of positive and negative. Share recent successes, including attending the course, enjoying the sessions, being more active and achieving goals, for example. Review course material, collect feedback and thank participants.

Delivery was guided by a structured tutors' manual. It includes commonly used self-management activities such as relaxation, goal setting, action planning, goal feedback, problem solving, identifying personal strengths and maintaining a focus on engaging in pleasurable activities. Participants received handouts and mid-week phone calls to remind them of their goals.

There is a strong social element promoting the experience that one is not facing unique problems but experiencing similar issues to others, known as 'universality'. The intervention draws from self-efficacy theory, positive psychology and curative factors of group programs.

An experienced 'lay' self-management tutor and a clinical psychologist, specialised in older adults' mental health, were trained to deliver the intervention reflecting the innovative 'co-delivery' model that has been successfully used in self-management. In addition to the two tutors, the 'course champion' role ensured a person with dementia was involved in delivery. This role was designed to incorporate personal experience of living with dementia into the delivery of the intervention, in addition to eliciting this from participants. The 'course champion' is also able to role model living well with dementia. Involvement of 'expert patients' is common in self-management interventions and acknowledges the experience that people have in managing their own conditions and showcases how active people can be in their own care. Research has identified that people with dementia may perceive themselves (or be perceived) as no longer able to contribute to society in a meaningful way. The 'course champion' role challenges this by directly including a person living with dementia in the intervention delivery. Their level of involvement is self-selected and supported by the two tutors. The course champion was a man living with Alzheimer's dementia for around 5 years at the time of the course. He was verbally able and gave consent to take part in the role. He selected intervention activities he felt able to deliver and provided a positive role model during goal setting and the 'Staying active and health' activities.

Tutor and course champion training

The two tutors and course champion attended two half day training events (led by an experienced volunteer, lay-self management tutor and co-author AT, an experienced self-management researcher and tutor). Initially, the intervention targets were reviewed and a brief explanation concerning how the intervention had been developed was given. Next, we worked through the tutor manual that had been developed, outlining

Full citation	Faith Martin, and et al (2015) Qualitative evaluation of a self-management intervention for people in the early stage of dementia. Dementia: the International Journal of Social Research and Practice 14(4), 418-435
	each activity, role-playing delivery and exploring how to respond to challenging situations, for example if participants do not want to goal set or become disruptive, dominating and angry. As each activity was discussed, the course champion provided input, for example including potential areas where further explanation may be needed or activities where language may be simplified. Additionally, he worked with the trainers and tutors to select activities he felt comfortable inputting into and planned how he would do this, for example by modelling goal setting and sharing his experience of using the memory box. Support needed for the course champion was planned, including prompts to invite his input and scheduled reminders for him to bring materials to the group. Finally, training covered motivational interviewing skills, group facilitation skills and the practical aspects of the tutor role, handling the materials and IT equipment used to display prompts to participants. **Data collection and analysis** Course participants attended a post-intervention focus group, having given informed consent. The focus group schedule was designed to explore experiences, any perceived benefits, most/least useful program activities and perceptions of tutors and course champion. It was semi-structured with a 'lead in period', allowing participants to describe their experiences, highly collaborative and with a joint agenda, meaning the researcher allowed participants to talk about topics they desired to and worked to validate participants' experiences. The focus group began with open-ended questions regarding the course and their views and impressions of it. Then, prompts were used to remind participants of each course activity to promote discussion of their experiences or views of individual activities. Prompts were brief descriptions of the activities and visual prompts of some of the course materials. For the goal setting activity, the interviewer reminded people of the goals they had set to help prompt discussion. No other reminders or prompts were given. The focus group was led by one of the researchers who they had previously met. The course champion was unable to be interviewed due to unrelated unforeseen personal circumstances. The two tutors were also interviewed. Interviews and focus group were audio-recorded, transcribed verbatim and analysed thematically. Two researchers independently analysed the data, searching for potential themes. Transcripts were read and re-read and initial codes generated and these were collated into initial themes. Where participants provided differing perceptions, this was noted in the coding and is reflected in the reported analysis. No a priori coding frame was used, although study aims were kept in mind. Themes emerged from the data. Themes from the two researchers analysing the data were compared and disagreements discussed and resolved by a third researcher where necessary. The structure of overarching themes and sub-themes was created through discussion.
Thematic analysis	• Theme 1: Although participants said they could not recall all of the activities, they had enjoyed the program: o Finding 1: A person living with dementia said: "It has been very enjoyable. I'll miss it. . . I have enjoyed, I must have enjoyed it because I wanted to come back". o Finding 2: A person living with dementia said: "I know everything is going in, but it doesn't always come out at the same time. So I know at certain stages, something from this meeting will come back to me". • Theme 2: The participants felt empowered:

Full citation	**Faith Martin, and et al (2015) Qualitative evaluation of a self-management intervention for people in the early stage of dementia. Dementia: the International Journal of Social Research and Practice 14(4), 418-435**
	○ Finding 1: A person living with dementia said: "Get on with life, like normal. You can't get up in the morning and say ''oh God. I've got Alzheimer's and I can't go out''. Give me my golf clubs and I'm off up in that field". ○ Finding 2: A person living with dementia said: "Everybody should set themselves goals to achieve, I feel, rather than just stagnate". • Theme 3: Peer support was considered valuable by participants: ○ Finding 1: A person living with dementia said: "I think a key (benefit) has come out at the end, is just that bonding. That group identity. Being with other people in a similar situation". ○ Finding 2: A person living with dementia said: "You know you're not alone". ○ Finding 3: A person living with dementia said: "We all have one thing in common. It, sort of, puts you at rest, really". • Theme 4: Participants found the relaxation activity of diaphragmatic breathing relaxing: ○ Finding 1: A person living with dementia said: "That's one thing which has really changed [worked]. I find it very hard to relax. I have always worked. I have always been quite dynamic and been always doing things". ○ Finding 2: A person living with dementia said: "It was actually brilliant, and I adapted it, and I use it on a day-to-day basis". ○ Finding 3: A person living with dementia said: "It's about minimizing the stress, because when you can't find the thing you are looking for, you stress about that".
Author's comments	Participants were able to attend, complete activities and reported some benefits from this.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? No. Data was collected straight after the course ended. There was no follow-up period. • Was the research design appropriate to address the aims of the research? No. There was no significant follow-up period. • Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Unclear. There are follow-up period issues. • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Fairly valuable. Overall quality: Very low. There was no follow-up period as such.

Full citation	**Gethin-Jones Stephen (2014) Familial perceptions of the impact of outcome-focused homecare with older people experiencing dementia and living alone. Working with Older People: Community Care Policy & Practice 18(2), 90-96**
Study details	Country/ies where the study was carried out: UK Study type: before-and-after qualitative study of standard care and then outcome-focused care. Semi-structured interviews Aim of the study: to discuss whether the use of outcome-focused homecare improves the subjective well-being of the familial carers of older people with dementia. It also discusses familial carers' perception of whether this intervention has improved the well-being of their relative. Study dates: not provided. The paper was published in 2014. Source of funding: not provided. The investigator was a Senior Lecturer at the University of Central Lancashire, Preston, UK.
Participants	• Sample size: 20 familial family carers. • Inclusion criteria: All 20 participants were recruited by a voluntary process and all had relatives living on their own in the community and experiencing dementia that meant they would be unable to live independently without the support of paid carers in addition to their friends and family. • Exclusion criteria: None • Sample characteristics: The sample of familial carers (n=20) was distributed as females (16) and males (four) all females were married (n=10) having dependent children under the age of 16. The four males were divorced or single and lived on their own. All participants were in employment of more than 16 hours per week. The mean age of the sample was 51.
Methods	Prior to the commencement of this study the older people had been receiving the standard model of care which is classified as the time and task model of homecare, which may be defined as: "The division of assessed care needs into time allocated components and is measured by the completion of tasks rather than assessed outcomes". This care tended to be purchased from a number of providers and was allocated within set time limits of 15-minute slots. Outcome focused care may be defined as: "Outcomes are defined as the impact, effect or consequences of a service or policy. Outcome-focused services are therefore those that meet the goals, aspirations or priorities of individual service users." For this definition of the outcome-focused care model to be applied, care and outcomes were agreed in consultation with the paid carer, the older person and their family and was reviewed on a daily basis. The first semi-structured interview with the carers took place at the commencement of the use of outcome-focused care and another semi-structured interview with the carers six months into the intervention. During the interview, the carers completed the individual Likert rating scales for their self-identified subjective well-being and also their ratings for the subjective well-being of their older relative receiving the outcome-focused model of care. The relatives were also asked to express the two main concerns they had about caring for their dependent relative or friend. These themes were then analysed by the use of thematic analysis. The carers were asked to identify their two main concerns they had about their relative experiencing dementia. They were all asked the following question: "In the last month what has caused you the most concern about caring for your relative/friend? Could you please give me two, one that is your main concern and one that is secondary?" The responses to the question were placed into four broad categories displayed in the tables below (inability to cope, feeling isolated, inability

<table>
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<tr><td></td><td>to get help and fear of harm coming to the sufferer).</td></tr>
<tr><td>Thematic analysis</td><td>

Theme 1: Standard care: The most common concern of familial carers is the feeling of not being able to cope.

Finding 1: Table 1 shows the carers' main concern. Table 2 shows the carers' secondary concern:

Main concern
<table>
<tr><th>Description of concern</th><th>Number of participants</th></tr>
<tr><td>Inability to cope</td><td>12</td></tr>
<tr><td>Feeling isolated</td><td>3</td></tr>
<tr><td>Inability to get help</td><td>3</td></tr>
<tr><td>Fear of harm coming to the sufferer</td><td>2</td></tr>
</table>
Secondary concern
<table>
<tr><th>Description of concern</th><th>Number of participants</th></tr>
<tr><td>Feeling isolated</td><td>8</td></tr>
<tr><td>Inability to get help</td><td>6</td></tr>
<tr><td>Inability to cope</td><td>3</td></tr>
<tr><td>Fear of harm coming to the sufferer</td><td>3</td></tr>
</table>

Finding 2: One carer said before the use of outcome-focused care: "I dread the phone, it's either the homecare saying they called but couldn't get in, or the police saying they have found dad again. Dad is a little chaotic now, but the care is so structured a set time and if you miss it that's it! That means I have to fill the gaps or get up in the middle of the night. I have a full-time job and two kids at school; it's a living nightmare at times I just feel I can't carry on." This comment was reiterated by most of the carers.
Finding 3: One carer said before the use of outcome-focused care: "The pressure is relentless, mums condition will continue to get worse, and everyone looks to you to sort it, when what I really want is some support. It is more difficult than you think." This comment was reiterated by most of the carers.

Theme 2: Standard care: The sense of isolation expressed by the participants came over very strongly in the interviews. Most of the

</td></tr>
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Full citation	Gethin-Jones Stephen (2014) Familial perceptions of the impact of outcome-focused homecare with older people experiencing dementia and living alone. Working with Older People: Community Care Policy & Practice 18(2), 90-96

respondents were family members who had social workers, district nurses and homecare workers involved in the older persons care. This isolation appeared to come from their sense that they were on the outside with little control because the care was planned by the other professionals. Family carers felt that they were isolated as they had all the responsibility and in their eyes and potentially all the blame when things went wrong. This sense of isolation is summed up in the following responses:

- Finding 1: One carer said: "Dad had a really difficult week last week. He didn't let the homecare workers in and he didn't cooperate when they did get in so they ran out of time. The social worker rang me to let me know. But what am I supposed to do I am left on my own then with all the pressures."
- Finding 2: One carer said: "I sat in the park for hours last week to get away; I felt so alone. Everyone expects me to sort things and I have nowhere to go or no one to help me."

In common with the other participants, the two participants above had a lot of input from homecare agencies and social workers. What came across was their sense of disconnection from the care package and how things were done, over which they had little control or even consultation. This sense of powerlessness impacted upon the carers' own sense of control and led them to feel helpless and unable to control events.

- Theme 3: Outcome-focussed care: There was an improvement in the carers' self-reported subjective well-being, six months into the outcome-focused homecare intervention.
  - Finding 1: This is demonstrated by the table below. The participants were all asked the following question: In the last week how would you rate the impact of your caring responsibilities on your subjective well-being?

Subjective well-being response

Self-reported subjective well-being score	First interview number of responses	Six-month interview number of responses	Overall change ±
1. As good as it gets	0	0	0
2. Very good	0	0	0
3. Good	1	10	+9
4. Neither good nor bad	7	9	+2
5. Poor	7	1	-6
6. As bad as it gets	5	0	-5

Therefore, there does appear to have been an improvement in the carers' self-reported subjective well-being, six months into the intervention. These findings were followed up in the interviews to ascertain what had changed for the respondents; these were some of the responses:

<table>
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<tr><td></td><td>

Finding 2: One carer said: “Well it feels more supportive and there is the consistency. The same four staff delivers the care, they have my mobile and we communicate. It feels more like I am part of a team rather than an outsider.”
Finding 3: One carer said: “Having the same people – they know mum even though she doesn’t really remember them, so they know her idiosyncrasies and her temper and they manage her well between them.”
Finding 4: One carer said: “The care is very flexible if they can’t get in they go back so things aren’t left to me alone, we sort it between us.”

Theme 4: Outcome-focussed care: All the carers felt the subjective well-being of their relative had improved after the six month outcome-focused care intervention.

Finding 1: This is demonstrated by the table below:

Subjective well-being response
<table>
<tr><th>Self-reported subjective well-being score</th><th>First interview number of responses</th><th>Six-month interview number of responses</th><th>Overall change ±</th></tr>
<tr><td>1. As good as it gets</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>2. Very good</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>3. Good</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>4. Neither good nor bad</td><td>0</td><td>17</td><td>+17</td></tr>
<tr><td>5. Poor</td><td>9</td><td>3</td><td>-6</td></tr>
<tr><td>6. As bad as it gets</td><td>11</td><td>0</td><td>-11</td></tr>
</table>
The participants were all asked the following question: “You have indicated that there has been an improvement in the subjective well-being of your relative, can you tell me why you think this is the case?” Two of the responses are below:

Finding 2: One carer said: “Mum just appears more settled in herself, things tend not to become a crisis as they did before. When things went wrong before, it would take days to settle mum down again. The consistency of the care staff has made a huge difference.”
Finding 3: One carer said: “Mary [relative] has some ability to remember faces and people. Before, the carers kept changing and this just made Mary’s agitation worse as she constantly tried to make connections between all the different people. Now that it’s mainly the same four people, Mary is more settled and her agitation appears to have decreased.”

</td></tr>
<tr><td>Author’s comments</td><td>The Authors report that the carers experienced ambient stress that was constantly around them and especially the need to balance work and numerous care commitments. This was particularly the case for the female participants who, in addition to the responsibility they felt themselves, also felt that that the male members of the family expected that they should be responsible for the older relative and the childcare. The minority of male respondents who were single reported feeling isolated rather than unable to cope and reported that the pressure of caring for a relative whose behaviour was unpredictable, limited their ability to build a life outside of their caring role.</td></tr>
</table>

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	The inability to get help and the fear of harm coming to the older relative were quite closely linked in the interviews to the main themes. All the participants were in employment which meant that it was difficult for them to attend meetings or to have contact with care staff, especially social workers and homecare managers who also tended to work Monday to Friday. This often meant care was planned without their presence or with only a very limited input. Therefore, working relationships which could have been used to gain help and support were not established. This was acutely felt at weekends and bank holidays when only skeleton staff were available, who had little or no knowledge of the older person's case. The fear of harm coming to their relative was present throughout the interviews and although it was not reported as the major concern by the participants it was a major concern that caused them a great deal of anxiety and stress. The sense of being a team was echoed by a number of the respondents. The fact that the care process was a continual negotiation and they knew who they were speaking to helped them to feel part of the team. The continuity and flexibility of the care assisted the carers in feeling more supported and provided them with a sense of inclusivity. Consistency of the outcome-focused care provided the relatives with the ability to intervene before crises occurred. This early intervention appears to have limited the episodes of agitation and confusion experienced by the older service users. It has also lessened the need for the relative to plug the gaps left by the previous system, especially where staff were unable to gain entry on their first visit and therefore unable to deliver care. Therefore, the ability to micro manage the care at a relatively informal level appears to have improved both the well-being of the carers and their relatives. Outcome-focused care as a model, provided consistency and flexibility that allowed the formation of relationships between the carer and the paid care staff. This relationship allowed the carer to feel less isolated in the care process and in their opinion assisted in the improvement of their relatives' subjective well-being. This study also found that the relatives felt that the subjective well-being of the older person receiving the care had also improved. This study shows that it is the consistency of the care provision combined with the ability to form relationship between carers, paid care staff and the older person experiencing dementia that has the greatest impact.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Unclear. The author did not say whether saturation of themes had been achieved. • Was the recruitment strategy appropriate to the aims of the research? Unclear. The selection of the participants is unclear. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Unclear. The relationship was not stated. • Have ethical issues been taken into consideration? Unclear. The source of funding was not mentioned. • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes

Full citation	**Gethin-Jones Stephen (2014) Familial perceptions of the impact of outcome-focused homecare with older people experiencing dementia and living alone. Working with Older People: Community Care Policy & Practice 18(2), 90-96**
	• How valuable is the research? Very valuable. Overall quality: Moderate

Full citation	**Gibson G, Timlin A, Curran S, and Wattis J (2007) The impact of location on satisfaction with dementia services amongst people with dementia and their informal carers: a comparative evaluation of a community-based and a clinic-based memory service. International Psychogeriatrics 19(2), 267-77**
Study details	Country/ies where the study was carried out: UK Study type: comparison of a clinic-based service and a community service. Qualitative interviews. Aim of the study: This study reports the findings of an evaluation study comparing a clinic-based and a community service. Study dates: Not provided. This study was published in 2016. Source of funding: Two of the four investigators' positions were funded by a research project grant from Pfizer/Eisai. These two investigators were staff at the Division of Primary Care, University of Liverpool. The other two investigators were staff at the School of Human and Health Sciences, University of Huddersfield.
Participants	• Sample size: 10 people living with dementia and their carers. The sample was split equally between the community-based and memory clinic services. • Inclusion criteria: people with dementia and their main informal carer receiving treatment either via a hospital-based memory clinic, or via a community-based nursing service. • Exclusion criteria: none • Sample characteristics: not provided
Methods	**The two services** The first service was community-based. As part of its care pathway, initial assessments took place at home, followed by diagnostic assessment within a hospital outpatient's clinic. Service users were subsequently monitored and assessed by community psychiatric nurses at six-monthly intervals within their own homes. Nursing staff were supported by consultant geriatric psychiatrists. The second service was a traditional memory clinic based within a hospital outpatients department. Service users initially attended the clinic for a baseline assessment and diagnosis, followed by subsequent six-monthly monitoring and efficacy assessments. In both services, efficacy was monitored using Mini-mental State Examination (MMSE). Each service also used different activities of daily living assessments. The memory clinic provided a more prolonged assessment compared to the community service. **Sample**

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	In-depth qualitative interviews took place with a sample of 10 dyads (people with dementia and their main informal carer) receiving treatment either via a hospital-based memory clinic, or via a community-based nursing service. The sample was split equally across the two services. Both sites were located in two distinct urban areas within the county of West Yorkshire in the UK. Service users were assigned to each site on the basis of their geographical location and which of the two services they were currently using. Sampling was based on a convenience sample: suitable participants already using each service were identified and recruited with the assistance of healthcare professionals and charitable agencies within the study area. In all cases, participants were living together in their own homes. Criteria for inclusion in the study were based upon NICE guidance for the provision of anticholinesterase drugs; including a diagnosis of mild–moderate dementia of Alzheimer's type. **Interview process** The semi-structured interviews involved an open-ended agenda relating to personal experiences of using the two services, and to the impact of the services on health and well-being. Interviews were designed to enable people to discuss areas of importance to them, and for the interviewers to probe and explore emerging issues. Interviews lasted between 30 minutes and 1.5 hours, and took place in the person's own home. Interviews were transcribed and coded prior to data analysis. Transcripts were subsequently analysed using template analysis. Data were coded into general domains that were highlighted as important during interviews. On subsequent readings, each domain was further expanded into themes and sub-themes. Here we report domains relating to perceptions of treatment location amongst service users and their carers.
Thematic analysis	• Theme 1: (Community-based service) Meeting health and social care professionals at home was more relaxing and less stressful. ○ Finding 1: One carer said: "I think it is more friendly if it's in your own home… and especially for my husband because he is in his own environment, and he will be more relaxed, whereas I think if you go to a clinic, you can all be very tensed up… …it is on more of a friendly basis, and that is what I like about it." ○ Finding 1: One carer said: "The nurse is excellent and she could not be better at the job because she is casual, she is not formal, she is completely informal, and she has a good laugh with you, and makes a joke of it." • Theme 2: (Community-based service) Being at home facilitated communication with health and social care professionals. ○ Finding 1: One carer said: "If you are in the hospital you are in a different place altogether; [at home] you are sitting on your own settee, with your own carpet and your own furniture all around you, you can be yourself . . . But in hospital, [. . .] you are not as relaxed, tense, wondering what they are going to say next. [. . .] When you are in your home, no matter what the outcome is, you feel you can take it better in your own home." • Theme 3: (Community-based service) For some, exposure to others at more severe stages of the illness within the clinic was a potent contributor towards anxiety, illustrating what could be expected as the disease progresses. Appointments at home removed this exposure. ○ Finding 1: One carer said: "[I] think if you went into the hospital you would be sat in a waiting room. You are going to see people far worse

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	than what my husband is. I would not want him to think, well am I going to end up like this, [. . .] that can be very distressing in itself, I mean going down to [hospital] you see people in a worse state than yourself, which is distressing. No, I am satisfied with people coming." • Theme 4: (memory clinic) Difficulty and effort in accessing treatment. ○ Finding 1: One carer said: "I mean the treatment is limited, as you know, so it makes you wonder sometimes if you are going through a lot of hoops for no reason at all, if you understand my logic." • Theme 5: (memory clinic) Memory clinics provoke anxiety for people living with dementia. ○ Finding 1: One carer said: "It may all be completely new once again so they go through the initial anxiety each time again. I have found with [May] that if she is anxious… she will almost become like a headless chicken you know, things are going round in the mind, which are completely unrelated to what is going on around her…"
Author's comments	In the current study, participants were generally satisfied with both services, with many being happy to be in receipt of any kind of effective intervention, particularly drug treatments. However, when discussing the services, the cognitive benefits of the treatments were often secondary to the psychosocial support they often gained from the service. Receiving treatment at home gave a person a greater perception of control and empowerment over their own treatment, transcending their common experiences of health-care services. The community service was highly regarded, with the home focus being thought of as the main advantage of this service. Being at home made people feel valued as individuals, rather than being perceived as nondescript "patients". Receiving treatment at home raised important issues in terms of access to services, reinforcing the perception that the community service met the patients' needs. Participants strongly appreciated the fact that they did not need to travel to a clinic in order to access services. Being visited at home by the community nurse eased the burden felt by carers by removing the additional tasks of arranging transport, and removing much of the physical and emotional difficulty of attendance. Feelings of anxiety and distress were linked to the experience of traveling to the clinic, either as a result of the actions and behaviour of others, or from feelings of stigma from exposure to the public gaze. Carers' own fears regarding the actions of people with dementia in public settings were an important element in their general unwillingness to use public transport. In contrast, home was viewed as a safe, secure and comfortable place, which removed the burden of attendance on the part of the service user and carer. Participants commonly felt that they were had to work according to the requirements of the memory clinic system, rather than it operating to meet their own needs. This was influenced by the experience of having to wait in the clinic, and of difficulties relating to traveling to and from the clinic. Although appointments with different staff in the clinic were designed to run concurrently, they often failed to operate in this way, occasionally resulting in lengthy waits between appointments. Traveling to the clinic was also described as problematic, particularly where people had to rely on public transport, or on ambulances, which took a long time. Such delays heightened the perception that service users had to operate within the confines of a system that was not designed to meet their specific physical and psychological needs. Satisfaction with memory clinic personnel was high, but was based on experiences of the clinic as an institutional system. Therefore, issues such as waiting times and areas within the clinic, and stress caused to service users during appointments and when traveling to and from the

Full citation	**Gibson G, Timlin A, Curran S, and Wattis J (2007) The impact of location on satisfaction with dementia services amongst people with dementia and their informal carers: a comparative evaluation of a community-based and a clinic-based memory service. International Psychogeriatrics 19(2), 267-77**
	clinic were of key concern. Such issues were expected to occur within the context of an institutionally based system. These are particularly important given the negative impact that anxiety and stress can have on the cognitive, emotional and behavioural state of people with dementia.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Unclear. The authors did not state whether saturation of themes had been achieved. • Was the recruitment strategy appropriate to the aims of the research? No. It was not clear how recruitment was achieved. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? No • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: Moderate

Full citation	**Gladman J R, Jones R G, Radford K, Walker E, and Rothera I (2007) Person-centred dementia services are feasible, but can they be sustained?. Age & Ageing 36(2), 171-6**
Study details	Country/ies where the study was carried out: UK Study type: non-participant observation and semi-structured interviews. Aim of the study: to evaluate a specialist person-centred community-based dementia service to establish whether high quality care was being delivered and the conditions for doing so. Study dates: February 2013 to August 2014 Source of funding: The College of Occupational Therapists, UK funded this study
Participants	• Sample size: 15 carers of people living with dementia • Inclusion criteria: All 15 cases had been living alone and had been at a point of crisis when they were referred to the Daisy Chain service. Examples of crises included wandering or behavioural disturbance, and lack of self-care including inadequate eating, drinking or personal

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	hygiene, or suspected alcohol abuse, each of which required consideration of the need for institutional care. These problems were often associated with the person with dementia being unwilling to accept care. • Exclusion criteria: None • Sample characteristics: Not provided. The carers were children, nephews or nieces, or family friends.
Methods	Two researchers observed the Daisy Chain team at work, its meetings, documentation and database. Field notes were kept and compared between researchers. Interviews were semi-structured: respondents were asked to describe the health and welfare issues arising with the patient, describe the involvement of the Daisy Chain service, and comment upon its value. While analysing the first set of interviews, the investigators became aware that several of the patients had moved from their home into long-term care. In view of the fact that reducing institutionalisation was a core objective of the service, they chose in their second set of interviews to interview as many of the first cohort as possible instead of a new cohort. Fifteen interviews were undertaken in the first set of interviews, and repeat interviews were performed in seven of these (seven others declined and one was in long-term care at the first interview). All field notes, focus groups and interviews were tape recorded and transcribed.
Thematic analysis	• Theme 1: The person-centred community-based dementia service was well received. ○ Finding 1: One carer said: “It is an excellent service on the whole. I hope everyone gets the same service who find themselves in a similar situation.” ○ Finding 2: One carer of a person living with dementia who lived alone said: “I think it is an excellent organisation, I think they do the job that they are asked to do and Mother is happy and I’m happy.” ○ Finding 3: One carer of a person living with dementia who lived alone said: “She liked them all. She enjoyed their company.” ○ Finding 4: One carer of a person living with dementia who lived alone said: “Motivation is the biggest thing. She hadn’t been in the bath or had a shower or anything for, I would think, years rather than months. I knew that Mother would feel uncomfortable if I was to say ‘come on strip off I will help you wash’. She would not want that. Although she felt it was quite difficult at first she is quite happy for the carers to do that.” • Theme 2: The person-centred community-based dementia service provides a personalised service. ○ Finding 1: One carer said: “They are very good. They try to make up for the fact that she no longer had the car, she was still able to move around, you know, mobile so they used to take her out, help her with her medication. I think they called every day and did something different every day. You see, Mum used to be a hairdresser, she loved being with people, still does, you know she’s chitty chatty, likes hustle and bustle.” • Theme 3: The person-centred community-based dementia service helped carers to cope. ○ Finding 1: One carer of a person living with dementia who lived alone said: “Without Daisy Chain I think I would have gone under a long time ago and then what would have happened to Mum?”

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- Finding 2: One carer of a person living with dementia who lived alone said: “After the assessment, the carers started going to see Aunty. They were fantastic. It was a weight off my mind. They were efficient and professional but gave Aunty all the time she needed. They visited three times a day to keep an eye on Aunty’s mental health and diet and tablets they were concerned that she ate and drank properly.”
- Finding 3: One carer of a person living with dementia who lived alone said: “They’re much more patient than me, Mum gets upset sometimes which upsets me and then things seem to get really tense and things start to go wrong. She gets upset and then I get upset and that’s how it goes on. I don’t know how to deal with her sometimes, she just goes on and on and it grinds me down.”

- Theme 4: The person-centred community-based dementia service kept the people living with dementia and their accommodation clean.
  - Finding 1: One carer of a person living with dementia who lived alone said: “She’s cleaner and the flat is cleaner too. That’s so important. You don’t like to think of your Mum being dirty and smelly, do you?”
- Theme 5: The person-centred community-based dementia service enabled people living with dementia to stay at home.
  - Finding 1: One carer of a person living with dementia who lived alone said: “She wants to stay at home. They make that possible. She wasn’t looking after herself properly and now she’s doing more. You know, she’s better. They spend time with her, you see. They don’t rush her. They have increased her visits from one to three a day. It’s been great . . . I found it difficult when she became incontinent. I can’t talk to mum about this. She used to have carers from social services going in 1 h a day. This wasn’t working. Well it wouldn’t, would it? Mum needed more than that. They tried using bigger pads for her ‘problem’. They just weren’t able to give her any more time.”
  - Finding 2: One carer of a person living with dementia who lived alone said: “The House Manager [warden] suggested I look for somewhere else [for the person with dementia to live]. A registered home. However, the Daisy Chain view was very different.”
- Theme 6: The person-centred community-based dementia service had good communication.
  - Finding 1: One carer of a person living with dementia who lived alone said: “They’re very patient, always give Mum time, don’t rush her, reassure her and all that. I like the way you always know what’s happening.”
- Theme 7: Residential care homes are value for money at £1,600 per month.
  - Finding 1: One carer of a person living with dementia who had recently moved into a residential care home said: “We pay £1,600 a month and it’s worth every penny.”
- Theme 8: Residential care homes are convenient.
  - Finding 1: Family friend of a bereaved man with alcohol abuse and who was living with dementia, who had lived alone, about the change in him when admitted to a residential home: “He’s really happy. We’re happy. He has his own room but doesn’t have to worry about bills and eating. It’s all done for him. We see him regular and it suits us.”
- Theme 9: Residential care homes are liked by residents.
  - Finding 1: Nephew of a lady living with dementia who lived alone, was happily supported by Daisy Chain at the first interview but who had moved to a residential care home at the second interview, and had then died: “She loved it and it became her home.”
- Theme 10: There is a ‘right time’ for someone living with dementia to move to a residential care home.

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	○ Finding 1: One carer of a person living with dementia who lived alone said: "I would like to think she can stay there [at home] until she becomes a danger to herself." ○ Finding 2: Nephew of a woman living with dementia, second interview, at which point his aunt had moved to a residential home, and then died a few weeks later: "It was the right thing to do. She wasn't alone when she died. That's important to me. Long-term care is OK when the time is right. It would not have been right a couple of years ago, but was then." ○ Finding 3: Second interview of daughter of a woman living with dementia who had lived alone at the first interview: "The time was right . . . without Daisy Chain [names of personnel] this would have happened a long time ago." • Theme 11: Some carers would prefer the person living with dementia to remain in their own home. ○ Finding 1: One carer of a person living with dementia who lived alone said: "I want Mum to remain at home for as long as possible and will try and do everything in my power to make sure that happens. I don't want to see her in a home, it would break her heart, I can't do that to her." • Theme 12: There are sometimes differences of opinion between people living with dementia, paid carers and familial carers. ○ Finding 1: At the first interview with the daughter of a woman living with dementia who lived alone: "I didn't, and don't want, Mum to go into a home, she'd hate it. Daisy Chain means she can manage to stay at home. It's all a bit fragile though." At the second interview, the woman living with dementia had died while awaiting placement in a residential care home. Referring to Daisy Chain's reluctance to move her mother to a residential care home the daughter said she was: "Let down by them in some ways…"
Author's comments	Carers deemed the service good because the care workers were kind, showed patience and understanding, and enjoyed the company of the person with dementia. Good communication with carers was reassuring and another mark of success. A well-used communication book in the patient's home for staff and carers was cited as an example of this. Carers contrasted their experiences of the Daisy Chain service with those of previous care services, where specific care tasks were undertaken in fixed periods of time and where little pleasure appeared to be drawn from doing so. The prevention of unwanted institutionalisation was acknowledged as one of the Daisy Chain service's core objectives. At the point of referral, most carers wanted the person for whom they cared to remain in their own homes. However, avoiding institutionalisation per se was not the objective. The reason for the change in peoples' opinions over time appeared to be that as time went by the awareness of the person with dementia deteriorated to the extent that they no longer seemed to take overall pleasure from being at home or when the risks of being alone were unacceptable. Avoiding institutionalisation when unwanted was an objective at one point in time, but facilitating a smooth move into an institution could be an objective later on in the same person's care. This specialist dementia service delivered a different style of care from standard service provision to people with dementia. Instead of impersonal, task-focussed and time-limited interventions, this dementia support service provided a personalised and flexible package of care, which involved pleasurable social interaction. It appeared to deliver a service that was in accord with modern advice about good dementia services. This care was highly appreciated and preferred by carers.

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Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. Recruitment is not well explained. The investigators do not mention if saturation of themes has been achieved. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Unclear • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Unclear. The data was originally presented using vague themes. • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Moderate

Full citation	**Górska S, Forsyth K, Irvine L, Maciver D, Prior S, Whitehead J, Flockhart J, Fairnie J, and Reid J (2013) Service-related needs of older people with dementia: perspectives of service users and their unpaid carers. International Psychogeriatrics 25(7), 1107-14**
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews Aim of the study: this study aimed to develop a deeper understanding of the lived experience of people with dementia regarding their service-related needs. Study dates: not provided. This study was published in 2013. Source of funding: not provided. The investigators were staff at: School of Health Sciences, Queen Margaret University, Edinburgh; Mental Health and Wellbeing, NHS Lothian, Edinburgh; Care of the Elderly Team/Primary Care Dementia Team, Bonnyrigg Health Centre, NHS Lothian, Bonnyrigg; Midlothian Council, Fairfield House, Dalkeith; Midlothian Community Hospital, NHS Lothian, Bonnyrigg.
Participants	• Sample size: 12 people living with dementia and 19 carers. • Inclusion criteria: People living with dementia: dementia symptoms, experience of dementia services, ability to participate in interviews. Caregivers: experience of supporting someone with dementia symptoms daily life, experience of supporting someone with dementia symptoms to access appropriate services. Participants were approached by community mental health nurses and asked to consider participation in the study.

Full citation	**Górska S, Forsyth K, Irvine L, Maciver D, Prior S, Whitehead J, Flockhart J, Fairnie J, and Reid J (2013) Service-related needs of older people with dementia: perspectives of service users and their unpaid carers. International Psychogeriatrics 25(7), 1107-14**
	• Exclusion criteria: none • Sample characteristics: In all 92% of the participants with experience of dementia were females; with the unpaid carers' gender being 74% female and 26% male. The average age of those with experience of dementia was 84 years (range: 77–93 years), and unpaid carers 65 years (range: 40–84 years). The majority of the participants with experience of dementia were widowed (59%), with 33% being married and 8% divorced. The unpaid carers' employment status was as follows: 58% were retired; 21% were unemployed; 5% were in full-time employment; 11% were in part-time employment, and 5% were self-employed. • The average time between the onset of symptoms and formal diagnosis of dementia was 2.5 years (range: 1–5 years). In all 58% of the participants with lived experience of dementia relied on informal support provided by their adult children, 42% of unpaid carers were their spouses. Altogether 68% of the people with experience of dementia included in this study lived within the community, 32% were users of residential care. The average time spent living at the current address for community-dwelling participants was 48 years (range: 27–58 years), whereas the average time of living within residential care setting was 19 months (range: 5–47 months). The percentage of dementia severities were as follows: mild 40%, moderate 25%, severe 35%.
Methods	This study made use of the data gathered through individual semi-structured, narrative interviews of people with experience of dementia and their unpaid carers residing in Midlothian, Scotland. The aim of data collection in this study was to elicit detailed stories, thoughts, and feelings from participants. It was the researchers' intention to facilitate an interaction which permitted participants to tell their own stories in their own words. Therefore, the interview comprised two components. The main narrative aimed to encourage participants to recount their experience since the onset of dementia. This was followed by further questions to explore areas of enquiry not covered during the narrative account. The first author conducted all interviews. The interviews were arranged to take place in venues most convenient for the participants. Most were conducted in participants' own houses; however, in two cases Queen Margaret University counselling rooms were used as an interview site. In nine cases the interviews with the person with lived experience of dementia and the unpaid carer were conducted separately, in one case it was the person with experience of dementia and the unpaid carer's wish to be interviewed together. The average interview time with service users was 40 min (range 17–75 min), and 79 min with carers (range 35–118 min). Total average interview time was 70 min. Interviews were transcribed prior to data analysis.
Thematic analysis	• Theme 1: Poor coordination of services. The participants particularly emphasized poor communication between existing services, which results in unsatisfactory case management and delays in service provision. The need for a single point of access to information and service coordination was expressed as a means to manage these challenges and to facilitate more efficient and effective service delivery. Participant reports also highlighted inconsistencies in care provision and suggested the need for well-defined care pathways. It was indicated that introducing a care pathway managed by a single service would enable services to provide care more consistently allowing continuous monitoring, appropriate and timely actions, and the same standards of care to be applied to all patients. Carers commonly believed that they were expected to manage the care provided to their loved ones. This included facilitating communication between the various services involved and ensuring that appropriate actions are undertaken, such as arranging

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	appointments and ensuring they were kept. ○ Finding 1: One carer said: "I'd just like a joined-up service, it's the main thing… …I know it's an overstretched system, but I think it maybe needs checklists that are not there. Just to tick off, right, this is where we are." • Theme 2: Some experienced lack of continuity of care. Continuity of care, particularly in relation to the involvement of health and social care personnel was seen as essential for providing high-quality care, ensuring its efficiency, and giving people with dementia a sense of familiarity and security. It was felt that, due to the nature of the condition, failure to ensure continuity of personnel involved often causes anxiety and distress for people with dementia who may experience difficulty memorising and recognizing new individuals. In the unpaid carers' opinions this affects the quality of care as people with dementia often take time to develop positive working relationships with health and social care personnel. Lack of time to develop such relationships is exacerbated by frequent changes in staffing and may result in distress and poor response to care efforts. By contrast, those people with dementia who experienced long-term, consistent professional involvement were reported to enjoy social interaction with their paid carers and to respond positively to their caring efforts. Another issue linked to the lack of service continuity was poor communication, which was also perceived as a factor reducing the quality and efficiency of care. There was a general appreciation among the participants that securing continuity of staff can be extremely challenging for service providers. Despite expressing their understanding of the factors impacting on this aspect of service provision, the need for greater consistency of health and social care personnel was identified as one of the priority requirements for this client group. ○ Finding 1: One carer said: "You were getting different people coming in which I really objected to… …because of the changing, information was not passed on." • Theme 3: Lack of mental stimulation. ○ Finding 1: One carer said: "I had kept seeing my mother is deteriorating, she's bored, she's doing nothing, she's sleeping all day. She's lost interest in everything. I want to try and get some kind of stimulation for her. She needs mental stimulation." ○ Finding 2: One carer said: "If they had more day centres… …which my mum really enjoys and it gets her away from this environment instead of just being stuck [at home] all the time."
Author's comments	Although participants were generally satisfied with the services received, they identified a number of unmet needs in relation to post-diagnostic support. The need for a single point of information and service coordination as a means to improve the efficiency of care was highlighted by the participants. One of the challenges raised by the participants in relation to dementia services was inadequate continuity of the personnel involved. This study indicates that such continuity is essential as it provides people with dementia with a sense of security, helps to establish trusting relationships, promotes their cooperation and active involvement in treatment, and results in more efficient, higher quality of care. Although the participants appreciated that, due to the limited resources and staffing problems, achieving continuity of personnel can be challenging, they stressed that it should be aimed for whenever possible. The findings suggest that people with dementia would benefit greatly from enhanced access to non-pharmacological interventions such as

Full citation	**Górska S, Forsyth K, Irvine L, Maciver D, Prior S, Whitehead J, Flockhart J, Fairnie J, and Reid J (2013) Service-related needs of older people with dementia: perspectives of service users and their unpaid carers. International Psychogeriatrics 25(7), 1107-14**
	psychology, occupational therapy, physiotherapy, and speech and language therapy as well as increased access to day services and other services promoting activity and facilitating social involvement.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. The participants were hand-picked. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Unclear. The authors do not say whether saturation of themes had been reached. • Is there a clear statement of findings? Yes • How valuable is the research? Valuable. Overall quality: Moderate

Full citation	**Hean S, Nojeed N, and Warr J (2011) Developing an integrated Memory Assessment and Support Service for people with dementia. Journal of Psychiatric & Mental Health Nursing 18(1), 81-8**
Study details	Country/ies where the study was carried out: UK Study type: interviews Aim of the study: to compare a new service to an old service. Study dates: not provided. This paper was published in 2011. Source of funding: not mentioned. The investigators were staff at the School of Health and Social Care, Bournemouth University, Dorset, and Crystal Centre, Essex (this is the base of the service).
Participants	• Sample size: An unspecified number of people living with dementia and their carers. • Inclusion criteria: not mentioned. • Exclusion criteria: not mentioned. • Sample characteristics: not mentioned. Statistics on the number of service users in one year are provided. However, it is not mentioned how the participants for this study were selected.

Full citation	**Hean S, Nojeed N, and Warr J (2011) Developing an integrated Memory Assessment and Support Service for people with dementia. Journal of Psychiatric & Mental Health Nursing 18(1), 81-8**
Methods	A pilot Mid-Essex Memory and Support Service (MASS) compliant with the national model was initiated in January 2009. The stated aim and role of the service is to offer a comprehensive assessment of the individual's current memory abilities and attempts to determine whether the individual has experienced a memory impairment that is greater than that to be expected, given their age. It aims to identify the cause of memory loss and if necessary discuss any possible treatments with the patient and their relative or friend. The service also offers support for carers of people with memory problems. MASS appointments can be in outpatient clinics or in the patient's home. This service has gone beyond the recommendation of the dementia strategy by being non-age-specific and the initial assessment is preferably carried out in the patient's own home. The base for the service is The Crystal Centre, Broomfield Hospital in Chelmsford and publicity has been carried out with local general practitioners (GPs)/voluntary services to encourage referrals. The service is staffed by doctors, nurses (three band 6 and one band 5 nurse and three support workers one of whom is from the Alzheimer's Society) and a whole time equivalent administrative support and psychology staff. It utilizes existing medical staff to feed into the memory assessment on a sessional basis and one of the consultant psychiatrists has taken the clinical lead for the service. An occupational therapist is brought into the service as and when needed. The work of the team is to identify the cause of memory loss and to discuss possible treatments. Physical examinations and blood tests are currently being undertaken in primary care settings and if a brain scan is required this is arranged at another time at the local acute hospital that is on the same site. Treatments may include memory enhancing medication, attendance at day centres and attendance at therapy groups. Support for carers is an integral part of the service. Figure 1 outlines the previous arrangements in terms of a patient pathway: The new service aims to streamline these arrangements by offering the following: • A timely 1-h appointment in response to referral for any patient irrespective of age. Referrals are normally received from GPs as agreed within the pathway. The first appointment is preferred to be carried out in the patient's own home, to get a holistic picture of the patient's situation in a familiar surroundings. • The assessment visit is carried out by two members of the team, so that the family/carer is also seen/assessed. This begins a profile building of the patient and his/her carer's need. • Being seen by a qualified practitioner to assess memory, medical history, psychiatric history and other information. A physical examination and blood tests will have been carried out by the GP. Memory tests will be carried out at the centre and a brain scan may also be requested. • Feedback is given to the patient (the referrer) and family or friend in the form of a disclosure meeting with relevant staff who have been involved in the assessment process. The family is also seen immediately after this disclosure meeting by the support workers for further clarification, information giving and identified appropriate on-going support. • If appropriate, a range of services are offered to minimize the difficulties arising from poor memory, e.g. memory enhancing medication, therapy groups and attendance at day centres. • Follow-up support to assess coping and offer specialist advice and support for the patient and carer including referral to other professionals. • In term of the overall care pathway, MASS is the single point of access where initial assessment takes place. Once the assessment is carried out and treatment (medical or non-medical) initiated, depending on the individual patients' needs, they are linked in with the integrated

Full citation	**Hean S, Nojeed N, and Warr J (2011) Developing an integrated Memory Assessment and Support Service for people with dementia. Journal of Psychiatric & Mental Health Nursing 18(1), 81-8**
	community mental health teams for older adult or generic health and social care services.
Thematic analysis	• Theme 1: The memory service was well received. ○ Finding 1: One carer said: "I have no negatives. Felt service was great. I do not know where Mum and I would be without it." • Theme 2: The coordination of care was valued. ○ Finding 1: One carer said: "My 85 year old mother was diagnosed with dementia through the memory service in September 2009. Our family have found this service to be first class. The co-ordinated aspects are valued by my parents." • Theme 3: The service and nature of the staff made carers and service users feel supported and reassured. They felt the service had improved their quality of life and they write of the indispensability of the service in their lives. ○ Finding 1: One carer said: "Even after my mother was admitted to Manor Lodge (residential care home) – Anne continued to advise. My family and I are so very grateful for the support advice and reassurance provided by the service… …Anything else I could do to support the service – please let me know – my family and I are happy to do so." • Theme 4: The language used was not quite right. ○ Finding 1: One carer said: "When you are retired and no longer in regular employment, times, dates are of less importance and in the grand scheme don't matter. I feel the questions are designed by much younger people to whom every last minute must, these days be accounted for." ○ Finding 2: A person living with dementia said: "The use of the word Alzheimer's. Also English spoken with a strong foreign accent and having to ask them to repeat the question several times before being able to understand them." ○ Finding 3: A person living with dementia said: "I found the questions asked of patient rather strange." • Theme 5: People living with dementia felt pressure of time because the psychiatrist was busy. ○ Finding 1: A person living with dementia said: "When with a psychiatrist felt the pressure of time [felt the need to take as little of the psychiatrist's time as possible] because of the amount of people wanting to be seen." • Theme 6: Some found it difficult to get to the right people and get the answers needed. ○ Finding 1: A person living with dementia said: "I found it difficult to get to the right people and get the answers needed." • Theme 7: People living with dementia and their carers liked seeing the same person throughout treatment. ○ Finding 1: One carer said: "We have enjoyed seeing the same person throughout the treatment. My father has benefited greatly from the referral to the Alzheimer's staff who are part of the unit. As a result, my mother is receiving excellent medical treatment and, as a couple, my parents are managing to cope with the aid of practical aids and benefits. Congratulations on this initiative." • Theme 8: People living with dementia and their carers thought that home visits were very good. ○ Finding 1: One carer said: "The first visits relating to the memory service were as hospital appointments. The home visits were very good and the only visit to the Crystal Centre was very interesting as much better surroundings. If only all appointments could be in such pleasant

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	places with such helpful staff. We do hope your service continues."
Author's comments	The integrated service, within a purpose-built unit has distinct advantages, emphasised by the positive comments from service users, carers, family and staff. There are increased costs associated with the service, not least because of initiating and monitoring treatment, especially anti-dementia drugs to a larger population, based on earlier diagnosis. The MASS approach appears to meet its stated aims and has improved the service for people with dementia, their carers and families through its streamlined and integrated pathway.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? No. The method of recruitment was not mentioned. Saturation of themes was not mentioned. • Was the recruitment strategy appropriate to the aims of the research? No. For example, recruitment numbers are not mentioned. The investigators give how many people used the service in one year but this is not the same thing. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Low

Full citation	**Iliffe Steve, Waugh Amy, Poole Marie, Bamford Claire, Brittain Katie, Chew-Graham Carolyn, Fox Chris, Katona Cornelius, Livingston Gill, Manthorpe Jill, Steen Nick, Stephens Barbara, Hogan Vanessa, and Robinson Louise (2014) The effectiveness of collaborative care for people with memory problems in primary care: results of the CAREDEM case management modelling and feasibility study. Health Technology Assessment 18(8), 1-148**
Study details	Country/ies where the study was carried out: UK Study type: Interviews Aim of the study: To adapt the Collaborative cARE for people with DEMentia (CAREDEM) intervention used in a promising case management project in the USA and test its feasibility and acceptability in English general practice. Study dates: 1/6/12 to 1/12/12 Source of funding: National Institute for Health Research Health Technology Assessment

Full citation	**Iliffe Steve, Waugh Amy, Poole Marie, Bamford Claire, Brittain Katie, Chew-Graham Carolyn, Fox Chris, Katona Cornelius, Livingston Gill, Manthorpe Jill, Steen Nick, Stephens Barbara, Hogan Vanessa, and Robinson Louise (2014) The effectiveness of collaborative care for people with memory problems in primary care: results of the CAREDEM case management modelling and feasibility study. Health Technology Assessment 18(8), 1-148**
Participants	• Sample size: 6 people living with dementia and 10 carers (in the nested qualitative study). • Inclusion criteria: 1) People with a diagnosis of any type of dementia, confirmed by secondary care assessment. 2) Living independently in the community at the time of baseline assessment and with a spouse, close relative or other informal carer who maintains regular contact and who can be approached as a potential participant and informant. Case identification using the Quality and Outcomes Framework (QOF) dementia register was supplemented by searches of electronic medical records to identify those taking cholinesterase inhibitors who were not on the QOF dementia register. Additional searches for patients with symptoms suggesting possible dementia (memory loss, confusion) allowed medical records to be checked for evidence that a formal diagnosis had been made but had not been added to the patient record. • Exclusion criteria: receiving palliative care, no carer or carer uncontactable, unavailable or unable to contact, already case managed, other including practice reasons • Sample characteristics at baseline: Mean age of people living with dementia (SD) = 80.2 (8.5). Mean MMSE (SD) = 19.44 (6.436). Mean age of carers (SD) = 66.0 (13.8).
Methods	Case managers systematically followed up people living with dementia under regular supervision and provided brief psychological therapy and medication management. The components of a collaborative care model were: 1) A multi-professional approach to care. This was provided by a case manager working with a GP under supervision from specialist mental health medical and psychological therapy clinicians. 2) A structured management plan of medication support and brief psychological therapy. 3) Scheduled follow-ups. Frequency and location of meetings was client led. People living with dementia were followed up at 5 months. 4) Enhanced inter-professional communication with written feedback to GPs via electronic records and through personal contact. CAREDEM also involved the use of a manual for case managers.
Thematic analysis	• Theme 1: The case manager was good at identifying needs and providing the right support. People living with dementia and their carers felt that the case manager brought a more detached perspective. Therefore, the case manager was in a better position to identify their needs through regular contact and monitoring. Many participants reported that their greatest need for information was at the point of diagnosis and shortly afterwards when they face navigating the system without support. They felt the lack of information at this point had compounded the difficulties of coming to terms with the diagnosis. However, those patients and carers who were still at the early stages often felt that they did not need any support at the moment but could see a point in the future when they might have needs requiring input. This mismatch in the views of people in the early and later stages of the illness trajectory may reflect the possibility that patients and carers are able to see their needs more clearly retrospectively than at the time.

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	○ Finding 1: A carer said: "You need somebody to be able to look at the bigger picture who knows where you're going, who's seen it before and [who could] deem and assess your situation to be stable and tenable or not. And either talk to you about it, get you the right support or what have you. But you can't be the judge of your own situation. I mean, obviously you know it's bad but sometimes you just don't know what to do." • Theme 2: Carers expected case managers to provide information about dementia and services. ○ Finding 1: A carer said: "Professional carers that's their vocation they understand it – they've been trained for it. If you're a son – the child – who's been doing something else, you don't know what the nature of the beast is. And if you misunderstand it, you can say 'Well, that person is just being difficult.' Even though they've never… they've been a beautifully loving person up until that point, when they sort of change. If you don't – if you haven't been counselled – it hasn't been explained to you, you misinterpret. That can cause for stress. The more you understand this disease and the behavioural symptoms, then the better you are to deal with it. So again, somebody like [case manager] you know being a point of contact." • Theme 3: Case managers should be proactive in asking carers and people living with dementia if they feel they need assistance. This is because participants frequently expressed a reluctance to initiate contact with the case manager, which undermines the concept that they could ask for help when needed. ○ Finding 1: A person living with dementia said: "I wouldn't personally ask. I'm happy to accept it all if somebody points me in the right direction. I just won't initially ask. I mean, I wouldn't say to you, 'I'm struggling with this. Can you help me with that?' I just wouldn't do it – I've never done it. I just don't feel comfortable with it." • Theme 4: A common reason why people living with dementia and their carers do not initiate contact with case managers is because they associate case managers with assisting with 'major' problems such as arranging residential care homes. They do not associate case managers with assisting with day-to-day issues. ○ Finding 1: A carer said: "The things that [case manager] had to offer were perhaps something that I would have found very useful at the beginning of my mum's Alzheimer's and not so much [now] because I've learnt by trial and error on how to deal with it." ○ Finding 2: A carer said: "At the moment, you see… with my wife… things are in early stage, aren't they?... So you know… we might be very very glad of [case manager] in months… years… a couple of years to come. You know, I hope she's still about to help us. Of course, with her doing this she's the person you want to help you." • Theme 5: People living with dementia and their carers preferred to have their case manager based at their GP's surgery. This is because there was the perception that their GP's surgery would then be a 'one-stop shop'. In addition, having the case manager at the GP's surgery provided an additional opportunity to talk to the case manager while visiting the GP's surgery. ○ Finding 1: A carer said: "Because it's more linked with doctors and any service that I need it's all linked through the GP. So [case manager] will know us and they must have meetings there if there's anything that sort of crops up she can say that she knows us and can actually

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	trace things happening through the system if she feels there is a need for that and it's the centre rather than have her placed in a different area… It's the most appropriate place that she's there attached to the GP, and let's face it, I can't get any service for mum or any care unless I go through that point so it's very important." ○ Finding 2: Interviewer: "What are the advantages [of case manager being based at the surgery]?" Carer: "Well, probably because she's got other medical staff there that she can, if there's a bigger problem, then she can discuss it with them and then." ○ Finding 3: A carer said: "At the moment, I can just ring [case manager]. You know, we've got so used to [case manager] now – seeing her at the surgery, seeing her coming here. I think she's going to come round and see us again, which she said yesterday, didn't she? She said, 'I'm going to pop round and see you'. So another little moment I can have, you see. So this is handy, isn't it?" • Theme 6: From the perspectives of some people living with dementia and their carers, nurses as case managers were perceived as providing a more direct link to the GP and advice and support around comorbidities and minor ailments. ○ Finding 1: Interviewer: "And obviously [case manager] is a nurse and is that important to you that she's got a nursing background, a medical background?" Person living with dementia: "Yes! Oh yes – it's always very important. Yes. It's because, as I say: I have got different things wrong with me but I feel pretty good most of the time. I don't feel like an invalid – not yet, anyway." • Theme 7: From the perspectives of some people living with dementia and their carers, a direct link to the GP was not a priority because they preferred their case manager to have expertise in social services. The inference is that they would prefer a social worker to be the case manager. ○ Finding 1: A carer said: "I don't think the clinical side probably comes into it. It's probably more having access to knowing what services are available and more helpful in that way. I mean, obviously the doctors would be the ones that would be doing the medical side of things as regards the illness. But it's more about managing the problem and it wouldn't make any difference to me where it came from and what department or whatever. So no, it's not a problem." • Theme 8: People living with dementia and their carers emphasised interpersonal skills such as empathy. ○ Finding 1: A carer said: "I think the most important thing is the care. That's what I think. Because having worked in that sort of industry, there were people who came along that obviously had fantastic qualifications to see the people that I was looking after. But they didn't seem to have any empathy." • Theme 9: Case management made access to services easier including GPs, benefit checks and links to other services. ○ Finding 1: A carer said: "What was very useful was when I told her that trying to get appointments is really difficult. She's actually used a pop-up system now in the surgery to get the earliest appointment without me having to say 'Is it possible? Can you bring the appointment a bit forward?' Because I might be off on a particular day. She used the pop-up system so it comes up on the screen to let us have, without debating, the earliest appointment in view of me being a carer and at work. And mum being not been able to wait a long time for an appointment."

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	○ Finding 2: A carer said: "At the minute, we're going through a care plan [for a personal budget], and that's where you get an amount of money and it's done through the council, which we never knew about. It was [case manager] who directed us in that way and we can go and spend it like. [Patient] basically, can go out and spend it. It covers your care needs and everything. And that's something we never knew about. It was just [case manager] directed us in that, and checking that our benefits were in place." • Theme 10: Case managers should respond as quickly as possible to questions from people living with dementia or their carers. ○ Finding 1: One carer was waiting for information on whether or not her mother could keep a cat in sheltered accommodation. This carer said: "It's the one thing that my mum said that she *really*, *really* would love to happen. But as I say, I don't know whether it would be possible." Interviewer: "And has there been any follow up with [case manager]?" Carer: "We haven't heard anything. No, we haven't heard anything yet. But it wasn't that long ago so maybe she's tried to get in touch with them." • Theme 11: A key aspect of case management valued by patients and carers was the idea of background support that could easily be called on at a time of need. This was described as providing a sense of back-up, a safety net, security and knowledge that help was available if needed. This concept of contingency was considered key to avoiding or averting crisis. ○ Finding 1: A carer said: "She [case manager] was good. She said if there was anything, 'Don't sit there worrying. Pick up the phone and we'll sort something out.'" Interviewer: "Did you ever have the opportunity to pick up the phone and call her?" Carer: "No, no, but it was just nice to have that safety blanket there because I've got her number in my phone now. So if there's anything that comes up or anything like that, I know the phone number is there to get in touch with [case manager]. So it's really good." • Theme 12: For patients and carers to feel comfortable about contacting the case manager in the event of difficulties, there needed to be time and opportunities to develop a deeper relationship. Regular contact, the provision of case management from the early stages of the condition and continuity were seen as crucial for establishing a good relationship. ○ Finding 1: Carer: "I think it needs to be regular." Interviewer: "Right, even from that early stage?" Carer: "I think so." Person living with dementia: "Yes." Carer: "So that then when it gets to a stage when we really do need help, we've got the confidence in the person you've been seeing all along." ○ Finding 2: People living with dementia and carers who were recruited later in the study commented on the lack of time to build up a relationship with the case manager, although first impressions had generally been positive. A person living with dementia said: "She is… very nice. I could only say as I… She's amazing. She's nice. She's a lovely person. Well, she came over as lovely to me. As I say, I don't know her very well. Sometimes, it does take a while to get to know people." • Theme 13: Face-to-face and telephone contact were both considered acceptable, although face-to-face contact was often preferred as it facilitated relationship building better than telephone contact. One participant would have preferred more face-to-face visits at regular intervals rather than just telephone follow-ups: ○ Finding 1: A carer said: "I was hoping that we'll get regular support and I think visits on a regular basis… It would be nice to think that I

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	know that we are going to have another visit… say… every 3 months or something like that." • Theme 14: However, some people living with dementia and their carers appreciate the service that case managers provide and also appreciate how hard they work. Therefore, they do not mind contact by telephone. ○ Finding 1: A carer said: "I think [case manager] is a very busy woman. So to pile things onto her would be wrong. But it's lovely knowing she's there if I need her – I can pick that phone up. I can even ring her at the surgery and she'd listen, which is nice. But I wouldn't want to say to you 'Oh, I'd like to see her two more times a week' or something like that, where at the moment she's running – she'll get here at a gallop, won't she? If I want to see her too much. So it's just nice her being there so I can ring." • Theme 15: Case managers should explain to carers, and where appropriate to people living with dementia, what support they can provide. ○ Finding 1: Interviewer: "Do you think a case manager could have helped to support you in that role or…" Carer: "Eh, I don't know. Is it their job to do that, is it?" Interviewer: "Well, case managers can support the carer and the person with dementia as well. Did you feel that you navigated it fine by yourself?" Carer: "Well no. I didn't. I had to go to the… I'm still going to the council. I was there yesterday." • Theme 16: Participants found case management more useful than dementia advisors. This is because case management offers continuity of care but dementia advisors do not. This is what participants had to say about the dementia advisor service that was piloted at one site: ○ Finding 1: A carer said: "It was just like: We'd got the diagnosis, go to the doctors' appointments and things, and then that was it. We were just sort of left." ○ Finding 2: A person living with dementia said: "Because very often you can't get in to see a doctor." Interviewer: "Right. Is it difficult?" Person living with dementia: "It can be. It is, yes. I mean, I just see whoever. Not like the old days when you used to see your doctor."
Author's comments	The benefits of a case manager from the patient and carer perspective included acting as a first point of contact and also as a 'safety net' for all concerns, potentially providing a one-to-one, therapeutic relationship for future ongoing support and offering information and direct links to the practice and other services. Some participants suggested that the case managers should also be able to take on a more active role in negotiating or brokering with local services. Participants valued the ability of case managers to address both health-care and social care problems. Patients and carers were generally satisfied with their experience of case management and several participants were clear that they wished the service to remain in place (both for their own benefit and to benefit others). The service created feelings of security or comfort for some patients and carers.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Unclear: there was no mention of saturation of themes. The report mentions that there were recruitment difficulties. Six people living with dementia and 10 carers were included in this study, which is not a big

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	number. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: High. The relatively large number of quotations and themes provide relatively good detail.

Full citation	**Anthea Innes, Paulina Szymczynska, and Cameron Stark (2014) Dementia diagnosis and post-diagnostic support in Scottish rural communities: experiences of people with dementia and their families. Dementia: the International Journal of Social Research and Practice 13(2), 233-247**
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews Aim of the study: to investigate the experiences of people living with dementia and their families with regards to post-diagnostic support in Scottish rural communities. Study dates: September to November 2010 Source of funding: This study was funded through a Knowledge Transfer Partnership administered by the Technology Strategy Board with funding from the ESRC and NHS Highland.
Participants	• Sample size: 6 people living with dementia and 12 family carers. • Inclusion criteria: Not provided • Exclusion criteria: Not provided • Sample characteristics: People living with dementia: age range 58-82 years; 3 women, 3 men; 3 in a small rural town, 2 in a village, 1 on an island. Carers: age range 45-80 years; 11 women, 1 man; 8 were spouses/partners, 3 were children, 1 was a sibling; 8 in a small rural town, 3 in a village, 1 on an island.
Methods	This study was designed to help the Health Board reach the Government dementia target. A service user consultation was undertaken to explore the experiences and views of people with dementia and/or their family member who had experienced the diagnostic process and post-

Full citation	**Anthea Innes, Paulina Szymczynska, and Cameron Stark (2014) Dementia diagnosis and post-diagnostic support in Scottish rural communities: experiences of people with dementia and their families. Dementia: the International Journal of Social Research and Practice 13(2), 233-247**
	diagnostic support in the six months prior to the interviews.
Thematic analysis	• Theme 1: Carers generally expressed satisfaction with support received but said they required more help. ○ Finding 1: A carer said: "…that was [name of agency], which was brilliant. I mean if you could have more it's better, but an hour-and-a-half was great." • Theme 2: The lack of alternative options sometimes led to provision of no support at all. ○ Finding 1: A carer said: "He liked going on the bus to the [day centre]… …He was denied it once. …he went once and then he was told that it wasn't suitable and he couldn't go again." • Theme 3: Poor coordination of services sometimes occurred. At other times, there was good communication. ○ Finding 1: A carer said: "There should've been a social worker involved but they weren't co-ordinated: One didn't know what the other was doing… Now there's four people involved but one doesn't seem to know what the other's doing…" ○ Finding 2: A carer said: "And they do communicate… …so it's the people in it and the people really do communicate with each other." • Theme 4: Lack of continuity of care: Having different clinicians involved in delivery of care and support was reported as confusing. ○ Finding 1: A carer said: "I'm not sure now who is in charge of [husband]. Is it the GP or is [consultant]?... I don't know. Is it my GP that I consult or is it the psychiatrist who has the say?" • Theme 5: Some people living with dementia do not want to make use of day centres. ○ Finding 1: A carer said: "I do realise that people, many people, you know, might like to go to them [day centres], they might already be doing things like that, we haven't spent our lives in that way." • Theme 6: Participants who lived in remote areas had to travel long distances to use some services. ○ Finding 1: A person living with dementia said: "And I've to go back down which I'm not awful happy about really because it's so far from there with me…" ○ Finding 2: A carer said: "There's these ambulances but [my wife] and [our daughter] went by train and a taxi… …and then that was a whole day. They went on the eight o'clock and got home at half-past-nine at night." ○ Finding 3: A carer said: "I missed two or three [caregiver] meetings because I had nobody to sit with him and [name of agency] were charging us £13 an hour… I would probably have paid that but I thought 'Well, it's just a meeting. We're just sitting there yabbering about different situations.'" • Theme 7: One interviewee pointed out that some GPs have a specific interest in dementia and this improves communication. ○ Finding 1: A carer said: "I think his knowledge came through the fact that he had a friend that had dementia. So he had the basic knowledge there. Whereas, I'm sure there's a lot of doctors there that have never experienced it, so they don't know to pass on that information."

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	• Theme 8: There were high satisfaction levels with the support received from the Community Mental Health Team staff. ○ Finding 1: A carer said: "Well in that he [community psychiatric nurse] comes formally to see all is well and he will appear just like a friend." ○ Finding 2: A carer said: "She [community psychiatric nurse] has been my main help and I'll say to her, 'What do you think I should do about this?' Or 'What do you think I should do about that?' And she never… as you know, she always helps." • Theme 9: Participants discussed the importance of staff building a rapport with the person with dementia. This facilitates communication. ○ Finding 1: A person living with dementia said: "And [psychiatrist] is extremely open. I mean, if you ask him something, he gives you an honest answer. I mean, I've asked the really difficult ones: I've said, 'What's the prognosis?' Which is very difficult – almost impossible. But I've asked the questions… …that as a patient actually makes you feel better when people treat you that way instead of just that lump of meat sat in the corner." • Theme 10: When it was available, a carers' group (caregiver support) was appreciated. ○ Finding 1: A carer said: "There was a carers' group on the go then, and I used to go. (. . .) We used to go, and I found that really, really helpful at the time." • Theme 11: Practical support was important to most carers who received help from private or voluntary services on a regular basis. Carers perceived this type of support as an opportunity to take a respite from caregiving responsibilities. Many used the respite time to rest, run errands which required getting out, or to attend carers meetings. ○ Finding 1: A carer said: "I had carers but they stayed here with [person with dementia], see, and I went out… The carers came in night and morning." • Theme 12: Other sources of post-diagnostic support were from family, friends, and neighbours. ○ Finding 1: A person living with dementia said: "Well, one of my daughters come, either granddaughters or grandson. There's always somebody that will take me down to the shop . . . Well, we do it between us when we're there, you know. [Grandson] will say to me, 'You're needing that grandma.', 'You're needing this.'" ○ Finding 2: A carer said: "I have a friend – she comes in… and she'll help me out with [the dog] for that half-hour to take her for a wee walk. And I've another friend – she'll phone over, 'We're going up to Tesco's. Are you coming up with us? Do you want a run to [local town]?' She'll take [husband]." • Theme 13: Some carers have difficulty leaving their relative with someone else. ○ Finding 1: A carer said: "But he doesn't like me going out… and leaving him…. I don't think it's that he's frightened or anything – it's just he wants me there." • Theme 14: Information was not always in a format appropriate for the person with dementia or carers. ○ Finding 1: A person living with dementia said: "The written form is difficult for me." ○ Finding 2: A carer said: "…a leaflet is a leaflet. You say to yourself, 'Oh, I'll read it later.' And later never comes sometimes…"

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	• Theme 15: The way information was delivered was important. Participants preferred a direct approach with the opportunity to ask questions. ○ Finding 1: A person living with dementia said: "And [consultant] is extremely open. I mean, if you ask him something, he gives you an honest answer… I think that's great." ○ Finding 2: A carer said: "I personally would prefer somebody to tell me bad news like that totally straight forward: 'This is it, okay...', 'Here it is – I'll explain it to you… …What questions do you want to ask?'" • Theme 16: One carer stressed that some questions may develop as a result of experience. This implies that care managers should be proactive in anticipating the needs of people living with dementia and their carers and provide relevant information. ○ Finding 1: A carer said: "…if you don't ask the questions, you don't get the information. However, you don't know the questions to ask, so how can you get the information?"
Author's comments	Lack of co-ordination has been reported from a service provider perspective in remote and rural Scotland, where more joint working was seen as a way to improve the delivery of services. However, despite this policy driver to change practice it was apparent that small rural teams often located in different physical locations contributed to ongoing issues of communication difficulties. The difficulties encountered appear to reflect difficulties with delivering dementia care in rural areas rather than the failings of individual staff members. The need for clear information has long been identified yet is still lacking for our participants despite policy developments.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? No. Inclusion and exclusion criteria were not provided. • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. The methods of recruitment were not mentioned. Saturation of themes was not mentioned. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? No. There was no mention of the recruitment method. • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Low

Full citation	**Fiona Kelly, and Anthea Innes (2016) Facilitating independence: the benefits of a post-diagnostic support project for people with dementia. Dementia: the International Journal of Social Research and Practice 15(2), 162-180**
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews Aim of the study: this study reports on key findings from an evaluation of a post-diagnostic support pilot project in Scotland addressing local service gaps. Study dates: January 2010 to April 2011 Source of funding: the Dementia Services Development Trust.
Participants	• Sample size: 8 people living with dementia and 8 family carers. • Inclusion criteria: Posters advertising the evaluation were distributed in participating memory clinics inviting people newly diagnosed with dementia and/or their family members to contact the researchers if they were interested in taking part in the study. To maximise responses, participants were also approached by the post-diagnostic support project team to inform them of the evaluation and their details passed to the researcher with their consent if they wished to discuss the evaluation in more depth with them before deciding whether or not to participate. • Exclusion criteria: none • Sample characteristics: People living with dementia: mean age (range) = 71 (52-83) years; women = 43%, men = 57%. Carers: women = 43%, men 57%; wife = 17%, husband = 58%, daughter = 25%.
Methods	The post-diagnostic support pilot project aimed to provide person-centred, personalised support to people who had recently received a diagnosis of early stage dementia and their families. Support was offered for the duration of the project by two project workers employed by a national Alzheimer's association and with training in mental health and expertise in dementia, with the type and intensity of support varying in intensity according to assessed need. The project workers' roles were complimentary to the work carried out by existing services delivered, for example, by community psychiatric nurses, physiotherapists or home care workers. Their work ranged from one-off enquiries, to participation in the workshops, and/or ongoing support mostly in the form of drop-in cafe´s, one-to-one face-to-face and telephone support, through to much more intensive casework, which included planning for the future and/or exploring self-directed support. Self-directed support allows people to choose the types of social care support they receive and the level of control they have over their support arrangements; the project workers supported five people with dementia to put in place personalised support packages. The number of hours of support ranged from a minimum of 1 hour for a one-off contact to a maximum of 182 hours for someone who was supported by the project for its duration. The mean number of hours of support received was 27 hours. The key evaluation questions guiding interviews with participants with dementia and their family carers were as follows: (1) What difference, if any, does the post-diagnostic support service make to service access and service use for people with dementia and their carers? (2) What difference, if any, does the post-diagnostic support service make to promoting independence and choice for people with dementia and their carers?

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Thematic analysis	• Theme 1: For memory services that do not have post-diagnostic support, many participants expressed feelings of abandonment or 'being sent away' by professionals on receipt of diagnosis. This was particularly the case for those diagnosed with vascular or mixed dementia, who had little or no regular contact with the memory clinic or other services. ○ Finding 1: For example, this carer recalled how, on the day her mother was diagnosed with vascular dementia, there was no discussion or arrangement for follow-up appointments: "We were just really told that Mum had mixed dementia. And the doctor explained to me what that meant and then they were sort of 'Cheerio!' And basically, to be quite honest, that really was… that really was it". The same carer said at the second interview: "She [psychiatrist] explained what vascular dementia was. That's all I remember about her visiting there… I'm thinking a year, maybe longer. It could be two years [since her mother had had a medical review]." ○ Finding 2: this carer of her husband with mixed dementia (Alzheimer's disease and vascular dementia) said: "If you need them [memory clinic staff], phone them. That's all. That's it. Nobody pops in, you know, you're kind of just left on your own. To get on with it!" • Theme 2: Those who received post-diagnostic support from the project workers had quite different experiences. A key point raised was the value of having support as soon after diagnosis as possible and the importance of skilled, knowledgeable, sensitive project workers to deliver support. ○ Finding 1: This carer describes how the project workers helped her husband and herself come to terms with the diagnosis: "But they came in and just kind of threw open the door that there's another world out there: 'Yes, you've got it – we can't get away from it – but you've got a life. You've got things to do." And it was just their whole approach. Their whole approach. The things they were telling you. The information they gave you and the way it was done was the boost or the kick that he needed to get him kind of going again." • Theme 3: Carers frequently reported positively on the help received from the project workers with claiming benefits. Most of the carers who reported positively on this had not known of their entitlements and were therefore delighted with the extra income received. ○ Finding 1: For this carer and her husband, this was a valuable exercise, as they had no idea of their entitlements and benefits and the 'wee bit of extra money' was welcomed: "So the girls [project workers] came out and they actually helped with filling in forms and things like that." • Theme 4: Several carers also spoke of receiving support with arranging Power of Attorney and valued the input from project workers in negotiating the process. ○ Finding 1: A carer said: "Tomorrow we've got a lawyer coming in to give me the power of attorney sort of thing so they gave us all that information." • Theme 5: Family members and one person newly diagnosed with dementia found the information they received (books and leaflets) along with general advice useful. ○ Finding 1: A carer said: "Oh no, she was very nice, she really was and right away with . . . we were just coming back, within about two weeks, we got a social worker to give us advice on what to do to get any benefits, or whatever." ○ Finding 2: A carer said: "It was very good, aye. I think getting started initially down at the clinic down there, conversing with somebody

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rather than having to read through it all you seem to pick up an awful lot more. So we had a better understanding when we left that day and how things might work out. But the nurses… they were quite good. They were very good as well."

- Finding 3: A carer said: "But I'd never heard of self-directed support again until [project worker] came on board. I'd never heard of anything like that. I really just kind of thought that we had to put up with what we had. So they were instrumental in putting that across that 'No, there are other options out there… you can employ someone of your own to come in and do what you want to do.'"
- Finding 4: A carer said: "When you were first diagnosed, one of the questions he kept asking is, 'How long have I got? How long have I got?' He literally viewed it as a death sentence. And the project workers and the group have been good at both saying to him 'It's not a death sentence.' You know, think positive and get on. And then seeing people and meeting people who, you know… You realise that it's not the end of the world for you… So that's been good. Because… I think it just sort of drags you down."

- Theme 6: However, there were also accounts of receiving no information, or insufficient or inappropriate information following diagnosis.
  - Finding 1: One carer stated that she did not receive any information following her mother's diagnosis, nor did she look for any: "I never really… I never looked for information. I just thought 'Well, we'll carry on as we are.'"
- Theme 7: Some carers expressed discomfort with some of the information they received. Some felt that it was too much to face too soon. Many participants stated that a 'one size fits all' approach was not what they wanted.
  - Finding 1: A carer said: "The first one [carers' group] I went to I wasn't going back because some of the things. And I'm glad that [husband] wasn't there. And I don't really want to repeat some of what I heard there, quite frankly, terrified me and made it ten times worse. And I wasn't going to go back."
  - Finding 2: One person with dementia stated that he did not want to read the information that was available to him: "But I don't really want to read about it."
- Theme 8: Participants valued that information was delivered by the project workers on a one-to-one basis and specifically targeted to individual needs and wishes. This minimised the likelihood of becoming overwhelmed with the volume and content of information received. Thus, a key point raised by several participants was the value of having a single dedicated contact point.
  - Finding 1: A carer said: "…is probably one of the biggest things that people who are new into this require: Somebody that you can talk to without having to think am I annoying them, am I being a nuisance, you know. Never get any impression like that from them. They're always open to talk to you."
  - Finding 2: This younger person with dementia appreciated the openness and honesty from the project workers when they visited him: "I feel she talks straight to me, so I can handle that, you know what I mean."
  - Finding 3: For some carers, information on specific entitlements was welcomed as they had not known of this previously: "But, as I say, there's been one or two things that have came up that's kind of helped and things that probably we would never have thought about. We never thought about the rates, getting a cut in rates. It's only because it was mentioned."
- Theme 9: A key issue for some participants was their increasing difficulties with travelling. This had the potential to isolate them as their means of travelling diminished, either through difficulty accessing public transport due to increasing frailty, or through having to give up

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	driving due to increasing cognitive impairment or for financial reasons. One of the ways the project workers supported participants with travelling was to arrange and pay for a taxi or by using their own cars to transport participants to the dementia cafe´ or other social events. Providing transport not only alleviated concerns about how to get to the events organised but also maintained social contact. ○ Finding 1: A person living with dementia who had to give up driving, described the positive impact of a bus trip organised by the project workers: "So, yes, we had a lovely day up at [place], so little things like that just brighten up your life, don't they?" ○ Finding 2: Another participant enjoyed the social element involved in being driven to events by the project workers, indicating the dual nature of this service: facilitating attendance at events they would not otherwise be able to get to, while also providing a measure of social contact. This person living with dementia said: "But [project worker] is one of the best taxi drivers going, that's for sure. She's jolly, you can talk to her and have a wee laugh about whatever. So she's really worthwhile talking to." • Theme 10: The main area in which the project did not achieve its intended outcome was in supporting people to think about what services and supports they might want in the future (advance care planning). This was not necessarily because the project workers did not broach the topic – they did with many participants. Interviews over the two time periods revealed no shifting in thinking from those who just did not want to think ahead. The responses below highlight the highly sensitive nature of the topic, the fear of what the future holds and the lengthy timescales required to support people to think ahead, if they do actually wish to. ○ Finding 1: A person living with dementia said: "Well, see I don't like to plan ahead, because I can't say how I'm going to feel." ○ Finding 2: A carer said: "We know that things are not going to improve, we know that. It's not like a physical illness that can get better. We know that but maybe I'm just like an ostrich and sticking my head in the sand, I don't know." • Theme 11: The post-diagnostic support project aimed to promote independence for participants. The findings revealed that, through individualised, one-to-one support, some participants with dementia began to re-engage socially or with old hobbies. ○ Finding 1: One carer who wished her mother could become more independent, even though her mother had regular trips to the shops or her church with a volunteer organised by the project workers, was pleased that, over time, her mother had become more outgoing and participated in conversations with other people in the project more often than before: "I think they're great [project workers]. My mum, whenever I used to take her anywhere, she didn't speak. Now, she… you know, she… You don't just speak whenever you're asked a question, you… She actually joins in the conversation... I think if you hadn't have been going to those things, I don't think she would have." ○ Finding 2: Another person with dementia surprised his wife by going to the shops with one of the project workers: "But what he has done is because of the nice way they've gone about it. He has gone out for lunch with them and he's popped in for a cup of coffee because it's on his shopping route, you know. He shops at X's so when he goes in has, you know . . . he would do that. That's the one thing I'm quite surprised about, that he's done that."
Author's comments	These findings indicate there is a variation in 'usual' support offered to people with dementia and family members post-diagnosis, with some receiving sufficient support and some receiving none at all. The post-diagnostic support pilot project has served to fill these gaps, offering individualised support as soon after diagnosis as possible to everyone regardless of type of dementia diagnosis. There was the sense that, with the support of the project workers, their needs would be addressed when required, there was always the named person to contact and

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	there was assurance of a response from the project team. This has been particularly important for those with vascular or mixed dementia who received little or no 'usual' support following their diagnosis. The availability of information from 'usual' services for people with dementia and their carers varied in type and amount, with most information being in verbal or written form. However, it is also clear that people's desire to know varied, particularly their desire to know what lies ahead and this was the case for both people with dementia and their carers. While written information seemed to be fairly accessible for carers, it was not seen to be so for some people with dementia who expressed discomfort with the process of reading and who struggled with information overload. This was particularly the case for participants with dementia having to take in information on other illnesses such as diabetes or heart failure. In a move away from a 'one size fits all' approach, the project workers aimed to deliver individualised information according to a need and desire to know basis. Their approachableness meant that participants felt able to contact them at any time, knowing that they would receive the information they required. The post-diagnostic support project enabled people with dementia and their carers to continue activities, to meet new friends and to fill a gap in service delivery following the diagnosis until the dementia progresses and intensive service provision is required. Several participants felt that the level of 'usual' support dropped off once the person with dementia was stable (medication or functioning) and this seemed to be an area of concern, particularly for carers who wanted a regular point of contact. We identified that the post-diagnostic support project had the potential to fill possible gaps (declining networks, reducing clinical input) by offering ongoing, long-term support, whether through social events, advice, information or help with planning as needed and wished. The authors felt that their findings aligned with Gilmour 2011 who proposed five key pillars of post-diagnostic support to be worked towards in any post-diagnostic service. These are: (1) Understanding the condition and managing symptoms (2) Supporting community connections (3) Peer support (4) Planning for future care (5) Planning for future decision making.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes

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	• Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: High

Full citation	**David Moore, and Kirsty Jones (2011) Promoting self-directed support for people living with dementia: overcoming the challenges. Social Care and Neurodisability 2(2), 66-70**
Study details	Country/ies where the study was carried out: UK Study type: interviews Aim of the study: this study aims to discuss the use of self-directed supported as a way of empowering people living with dementia to have greater control over the support they need. Study dates: not provided. This study was published in 2011. Source of funding: not provided. The authors work for the Adults' Services, West Sussex County Council, Chichester, UK.
Participants	• Sample size: Not provided • Inclusion criteria: Not provided • Exclusion criteria: Not provided • Sample characteristics: Not provided
Methods	The authors interviewed people living with dementia and their carers about their use of self-directed support. Within local authorities, such as West Sussex County Council (WSCC), self-directed support is being used as the process to enable personalisation to happen within social services. Self-directed support refers to the system that is used to give people control over how they use and shape the support that they need to meet their social care needs. Self-directed support aims to empower those, who are eligible for adult social care, through a number of key ways. One of the most significant ways is through a personal budget. This is a pot of money that is given to a person to use to purchase services that will meet their social care needs. Furthermore, individuals have control over their budget to find the support that they feel meets their needs. A person's budget can be received in the form of a direct payment. This is a cash payment that comes from the local authority to a person who has agreed to receive their budget in this way and is able to make arrangements to have their social care needs met. Until recently a person who could not give their consent was not able to have a direct payment (Section 57 of the Health and Social Care Act

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	2001 required a service user to 'consent' to receiving direct payments). Consequently, this ruled out a number of people with dementia from receiving a direct payment. However, changes to legislation in 2009 meant that a suitable person could be chosen to receive these payments. This has meant that direct payments can be open to many more people with dementia via a suitable person. However, this has meant that a number of areas have needed to be looked at including: • Following the guidelines to enable a 'suitable' person to be chosen. • Finding ways of supporting the 'suitable' person. • The issues around safeguarding. If a person does not wish to or is unable to receive a direct payment themselves or through a suitable person then the council can look after their personal budget and commission services on their behalf or find a suitable organisation to do this.
Thematic analysis	• Theme 1: Some carers felt a greater sense of empowerment. This is because they had access to a budget. ○ Finding 1: A family carer said: "I feel for me it has been a complete life line because I think I am someone who likes to have a certain amount of control to what is happening to us." ○ Finding 2: "I now have control over who comes through my front door." ○ Finding 3: "When you live with somebody with dementia you naturally slow down. Controlling the budget has helped me to keep my mind active." ○ Finding 4: "We got mum back, mum with Alzheimer's, but we got mum back." • Theme 2: Funding for respite was useful for carers. ○ Finding 1: A carer said: "I use respite in different ways. Respite is sometimes having a personal assistant here for the day, while I go off and pursue something I enjoy. Sometimes, it gives me the chance to go and visit my daughter." • Theme 3: Finding suitable individuals to become personal assistants was difficult for some people: ○ Finding 1: A carer said: "Although I advertised in the local paper a number of times only one person applied for the job." • Theme 4: When suitable individuals became personal assistants, there were positive results. ○ Finding 1: A carer said: "It has provided me with the flexibility to try and create a quality of life for Ian in terms of having people he enjoys being with and shares interests. Some of those people we have known historically as friends who have those skills and whom clearly Ian feels comfortable with already. We have formalised that in terms of a contract which I feel more comfortable about and saves any sense of exploiting the friendship." ○ Finding 2: A carer said: "I could choose the people I felt had the right chemistry."
Author's comments	There still needs to be a greater drive towards empowering people living with dementia through self-directed support. This aims to be done in West Sussex by learning from reports such as 'Let's get personal'. This document produced by Alzheimer's Scotland (2010) has suggested a number of ways that the successful development of personal budgets can be facilitated by:

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	• Increasing awareness through publicity and the provision of impartial information. • Improving understanding within social work departments. • Streamlining systems and reducing bureaucracy, with a quicker process for putting in place a direct payment. • Improving support and information and making reporting requirements more straightforward. • Working with local authorities to ensure parity across different areas on the flexibility regarding the ways in which direct payments can be spent. • Introducing a straightforward process for health money to be included in direct payments (Alzheimer's Scotland 2010). For transformation of services to truly happen there needs to be a fundamental shift in how people without dementia see people with dementia. It does not matter how much social care changes its structures and paperwork, if staff do not see the person as an individual with skills and knowledge who has the ability to take control of their life despite the difficulties they face because of having dementia, then nothing will change.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? No. No recruitment methods were given. No details of participants were given. • Was the research design appropriate to address the aims of the research? No • Was the recruitment strategy appropriate to the aims of the research? No • Was the data collected in a way that addressed the research issue? No. No details of the interview methods was given. There are no details of the duration of experience with the service that people living with dementia had or their carers had. • Has the relationship between researcher and participants been adequately considered? No • Have ethical issues been taken into consideration? Unclear • Was the data analysis sufficiently rigorous? Unclear • Is there a clear statement of findings? Unclear • How valuable is the research? Unclear Overall quality: Very low

Full citation	Carolyn Popham, and Martin Orrell (2012) What matters for people with dementia in care homes?. Aging and Mental Health 16(1-2), 181-188
Study details	Country/ies where the study was carried out: UK Study type: interviews with people living with dementia and focus groups of carers.

Full citation	**Carolyn Popham, and Martin Orrell (2012) What matters for people with dementia in care homes?. Aging and Mental Health 16(1-2), 181-188**
	Aim of the study: to determine to what extent the residential care home environment met the requirements of people living with dementia. Study dates: not provided. This study was published in 2012. Source of funding: This research was conducted as part of the University College London, MSc in Ageing and Mental Health.
Participants	• Sample size: 25 people living with dementia in 5 residential care homes. There were 5 focus groups. 11 family carers took part in three focus groups. • Inclusion criteria: At each of the 5 homes, residents who were aged 65 years or over were recruited to focus groups if they had lived in the home for six months or more and had a diagnosis of dementia. Care home managers were asked to assist the researcher to identify those residents with probable dementia using the Noticeable Problems Questionnaire. Potential participants were screened by the researcher with the Mini Mental State Examination, case notes and a clinical assessment to see if they met DSM IV diagnostic criteria for dementia. • Exclusion criteria: none • Sample characteristics: People living with dementia: 22 female, 3 male; mean age was 87.9 years; mean MMSE score = 8.8 (SD 5.9). Carers: 7 female, 4 male
Methods	Five care homes within Greater London were recruited as a convenience sample through the researcher's networks. Three were nursing homes, of which two had specialized dementia beds. One was a residential home with no specialized provision and one was a large care home providing residential, nursing and specialized dementia care. Size varied between 35 and 250 beds. All had access to a safe, enclosed garden.
Thematic analysis	• Theme 1: The need for activities, interaction and outings was the most prevalent theme overall. o Finding 1: A person living with dementia said: "I would like to go shopping." o Finding 2: A person living with dementia said: "I like people… and talking." o Finding 3: A family carer said: "In an ideal world one would not allow the patients to sleep all day" o Finding 4: A family carer said: "I have seen them (the staff) sitting around the table writing when I would have thought it might be better to be trying to socialise with the residents." o Finding 5: A person living with dementia said: "…being listened to when you are speaking – not walking away." o Finding 6: A family carer said: "Communication I think is very important – at a respectful and consistent level." • Theme 2: Participants spoke about having the freedom to be able to carry out normal everyday activities and domestic chores. o Finding 1: A person living with dementia said: "It would be good to make yourself a cup of tea when you wanted…" o Finding 2: A person living with dementia said: "They won't let me have scissors. 'You can't go here.', 'You can't go there.'…" o Finding 3: A person living with dementia said: "I haven't been in the garden much… this lovely weather." o Finding 4: A family carer said: "The patio garden is absolutely safe but they still don't go out on their own."

Full citation	**Carolyn Popham, and Martin Orrell (2012) What matters for people with dementia in care homes?. Aging and Mental Health 16(1-2), 181-188**
	○ Finding 5: A person living with dementia said: "There should be a small kitchen." • Theme 3: Rooms with views were highly valued. ○ Finding 1: A person living with dementia said: "I like the lovely view." ○ Finding 1: A family carer said: "What was really needed was lots of windows – low down, panoramic views."
Author's comments	Many studies have highlighted that activities are important to care home residents (Hancock et al., 2006; Harmer & Orrell, 2008; Reilly et al., 2006, Schreiner; Yamamoto, & Shiotani, 2005). This was the most important theme, with many residents complaining of boredom, spending much time sitting doing nothing, despite the fact that the homes studied all had organised programmes of activities. Staff mentioned exercise groups, games, arts and crafts and cookery. In contrast, the residents and their carers wanted to go out for walks or to the shops and to help with domestic chores. People recognised that residents' wishes were not being met but staff often felt they were too busy to spend time with the residents identifying what their wishes were. So although staff knew about person centred care (Kitwood, 1997) it was seen as an ideal rather than a realistic goal. Whilst many residents participated in activities, many others did not and a number of carers expressed concerns that residents were not actively encouraged to join in. Instead of following good practice by trying to incorporate meaningful activity into each resident's everyday life, group activity sessions were often regarded by staff as an adequate provision for the residents' needs. Organized activity may be easier to arrange but may not meet the residents' needs. Staff training and the use of standardized assessments such as the Pool Activity Level (Pool, 2007) may help in tailoring activities to the individual. For people with dementia the most important factors in the care home environment were not the layout or design of buildings but the ability to make choices, engage in activities, and the staff approaches to care. Freedom seemed highly constrained and residents were rarely allowed to take any risk, however minimal. There is a danger that care home life may be becoming over regulated (with a corresponding increase in paperwork at the expense of promoting choice and person centred care).
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: High

Full citation	**Rothera I, Jones R, Harwood R, Avery A J, Fisher K, James V, Shaw I, and Waite J (2008) An evaluation of a specialist multiagency home support service for older people with dementia using qualitative methods. International Journal of Geriatric Psychiatry 23(1), 65-72**
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews, focus groups and small group interviews Aim of the study: To establish whether a specialist multiagency home care service for older people with dementia delivered better quality care than standard services, and how any improvements were achieved. Study dates: not provided. This study was published in 2007. Source of funding: NHS Executive Trent Regional Office Research & Development Group Award under the Supporting Research Careers Scheme supplemented by some funding from the Mamroth-Fabisch Donation.
Participants	• Sample size: 27 people living with dementia and 18 family carers • Inclusion criteria: The investigators obtained the names of clients aged 65 and over receiving Social Services commissioned home care. For both services, clients with a diagnosis of dementia or known to the service as having memory problems were identified by home care managers. • Exclusion criteria: none • Sample characteristics: People living with dementia: 21 women, 6 men; 16 mild/moderate, 11 severe. Carers: 12 women, 6 men; 3 spouses, 8 daughters, 3 sons, 4 other relatives.
Methods	The specialist service was introduced in two areas of Nottingham City (Clifton, population 26,000 and Bridge, population 9,000). This service was compared with the standard service in a demographically similar area (Bestwood, population 15,000). The specialist multiagency home care support service's aim was to reduce high levels of care home placement. Specialist service care workers were given additional training in dementia care. They had licence to perform tasks flexibly, including undertaking visits outside the home or providing respite for family carers, and roster design ensured maximum continuity. Weekly meetings covered debriefing, supervision and support from a service manager, occupational therapist and community psychiatric nurse. The specialist service focused on clients' overall needs, requirements and preferences, rather than specific physical care tasks. Through multi-disciplinary health and social services support, care was individually designed to meet clients' assessed needs and their on-going requirements, with a 'needs-led', not 'provider-led' philosophy. Continuing multi-disciplinary review of provision enabled care workers to monitor clients' needs closely, adjusting care plans as necessary. When capacity was reached a waiting list operated. The standard service was provided by Local Authority in-house services or independent sector agencies. Social worker assessments identified tasks that care workers would undertake and available staff supported however many clients were identified with needs, even if these could not be fully met (no waiting list operated). Administrative meetings were held monthly. Continuing review and flexible service delivery were not described.

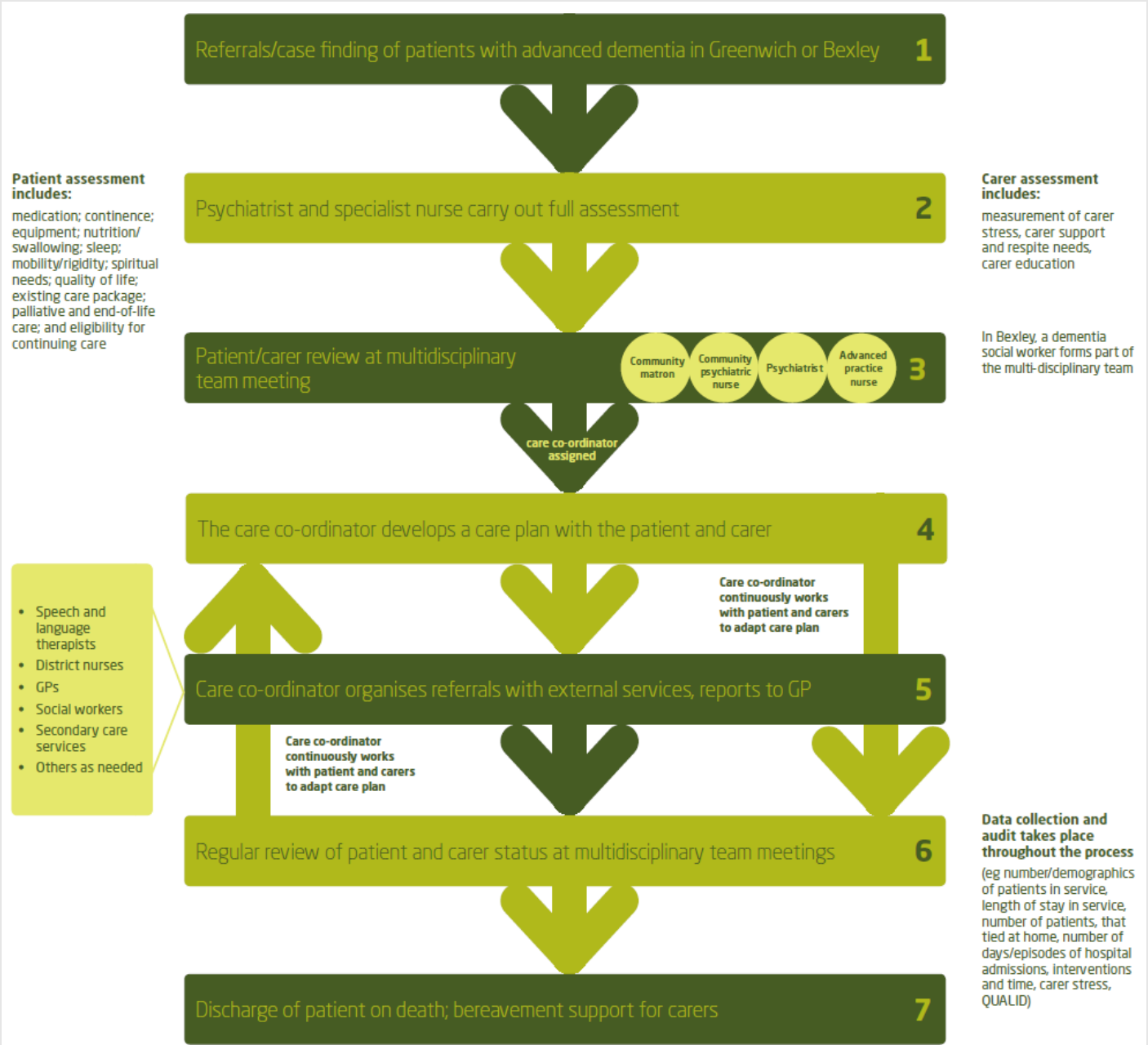
Full citation	**Rothera I, Jones R, Harwood R, Avery A J, Fisher K, James V, Shaw I, and Waite J (2008) An evaluation of a specialist multiagency home support service for older people with dementia using qualitative methods. International Journal of Geriatric Psychiatry 23(1), 65-72**
Thematic analysis	• Theme 1: The specialist service helped reduce carers' burden by focusing on their needs as well as those of the person with dementia. ○ Finding 1: Sharing the responsibility of care alleviated the pressure experienced by many carers who had other competing roles, such as that of wife or mother, and helped prevent crisis situations: "It was the relief that I could keep my mother at home and she was being well looked after because I realised that the time would come when I couldn't cope with the dual role of three relatively young sons and my husband and my mother and do the best for both of them. I was doing the best for my mother and, you know, neglecting them and if I was doing the best for them I was neglecting her."
Author's comments	The specialist multiagency home care service was superior to standard care.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Unclear. Saturation of themes was not mentioned. • Was the data collected in a way that addressed the research issue? No. The aim was to compare standard care to needs-led care. There was only one quotation from a carer. There were no quotes from people living with dementia. Therefore, from a service-user perspective, the data was not collected and/or presented in a way that addressed the research issue. • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? No. There was only one quotation from a carer. There were no quotes from people living with dementia. • Is there a clear statement of findings? Yes • How valuable is the research? Unclear Overall quality: Low

Full citation	**Sonola, Thiel, Goodwin, Kodner (2013) Oxleas Advanced Dementia Service: supporting carers and building resilience. (URBA)**
Study details	Country/ies where the study was carried out: UK Study type: focus groups with relatives, Relative Stress Scale, QUAlity of Life In late-stage Dementia scale (QUALID) Aim of the study: The Oxleas Advanced Dementia Service aims to help patients with advanced dementia to live at home for as long as

Full citation	Sonola, Thiel, Goodwin, Kodner (2013) Oxleas Advanced Dementia Service: supporting carers and building resilience. (URBA)
	possible in the last year of life with support from family and/or carers. Study dates: not provided. This report was published in 2013. Source of funding: The Greenwich team did not receive any direct funding; it was run as a part of the services provided by the Older People Community Mental Health Team in Oxleas Foundation Trust, using existing staff time. The Bexley project was initially funded through a 12-month clinical fellowship in 2011 worth £60,000 which paid for the clinical fellow's specialist input into the service. The APN time was allocated as part of an existing role and the dementia social worker's time was funded by Bexley Council. Once the fellowship ended, the service continued with discretionary funding of £52,000 from Oxleas Foundation Trust for a community psychiatric nurse (CPN) working three days a week until September 2013. The report is published by The King's Fund.
Participants	• Sample size: 9 people living with dementia and 9 carers • Inclusion criteria: This approach is targeted at complex patients with advanced dementia towards the end of their lives. Eligible patients were classified as suffering from severe or very severe cognitive decline (stage 6 or 7 of the Global Deterioration Scale for dementia) with accompanying physical ailments such recurrent infections or fevers, incontinence, pressure ulcers, ongoing pain or general physical frailty. Many patients became bed bound, requiring help with daily activities such as eating and dressing. In addition to physical symptoms, people with advanced dementia may display severe, persistent psychological or emotional distress including agitation, aggression, anxiety and restlessness. In addition, the people living with dementia had a primary carer (normally a family member) because care co-ordination took place at home. • Exclusion criteria: none • Sample characteristics: The majority of the caseload is aged over 65, with an average age of 75 years.
Methods	The Oxleas Advanced Dementia Service aims to help patients with advanced dementia to live at home for as long as possible in the last year of life with support from family and/or carers. The service consists of a consultant in old-age psychiatry, several specialist nurses and a dementia social worker. The core team works with GPs, secondary care and social services to support carers in providing ongoing and palliative care. Staff respond to crises at home to prevent unnecessary hospital admissions where possible and reducing the likelihood that patients are placed in residential care. The Oxleas service caters for people with a diagnosis of moderate to severe advanced dementia, complicated by complex mental and physical comorbidities requiring social care input, who are being supported to live at home (by family or paid carers). These patients tend to be in the last year of their lives with an average age of 75. The service has capacity to support up to 25 patients, as staff co-ordinate care in addition to their substantive roles. **Approach to care co-ordination** In Greenwich, care co-ordination is led by a consultant old-age psychiatrist based in the local mental health trust, working alongside specialist nurses called community matrons. In Bexley, the same psychiatrist works with a community psychiatric nurse (CPN), an advanced practice nurse (APN) and a social worker specialising in dementia. Staff in the service liaise with community mental health services and GPs to provide

Full citation	Sonola, Thiel, Goodwin, Kodner (2013) Oxleas Advanced Dementia Service: supporting carers and building resilience. (URBA)
	care in patients' own homes, focusing on supporting the carer and/or family to provide palliative care for the patient. **Organisational structure** Although the service is integrated, the approach to co-ordinating social care differs between the boroughs. In Greenwich, patients known to the social services department in the local authority have a care manager in that service with responsibility for organising care packages, respite care and equipment. If the patient is not known to social services, a care co-ordinator from the advanced dementia service can carry out these tasks directly. In Bexley, a social worker with a special interest in dementia organises all the care packages. **Primary care and other external care providers** Liaising with services in primary care and in the community is integral to the Oxleas model. Staff have developed strong links with other professional groups including district nurses, social workers, occupational therapists, physiotherapists and relevant specialist services such as the speech and language team. However, engagement with local GPs is variable and generating referrals has been problematic. This may be due to a lack of understanding or awareness of the service. The service has attempted to actively engage GPs, presenting to GPs at the launch of the new memory service in 2011 and visiting GPs; however, levels of engagement have not improved. **The process of care co-ordination** Step 1: Referrals/case finding Oxleas Advanced Dementia Service model and care process

Full citation	Sonola, Thiel, Goodwin, Kodner (2013) Oxleas Advanced Dementia Service: supporting carers and building resilience. (URBA)



Full citation	Sonola, Thiel, Goodwin, Kodner (2013) Oxleas Advanced Dementia Service: supporting carers and building resilience. (URBA)
Thematic analysis	• Theme 1: The people living with dementia generally experienced an increase in their quality of life. • Theme 2: Familial carers' stress scores improved or remained stable for all the carers measured: • Theme 3: Carers valued the co-ordinator's role as the person responsible for organising care, and as problem-solvers. ○ Finding 1: A son said: "…[the service] was very good but without your influence, when you try to call services you find yourself up against a wall." ○ Finding 2: A daughter said: "[Before the service] we had all these people involved in mum's care and she was going to the day centre and seeing all these professionals but the responsibility was no-one's." • Theme 4: Supporting carers was another strong theme emerging from the focus groups; having a named person to contact in times of crisis, and the security that they would not left to manage alone. ○ Finding 1: A husband said: "You really need someone like this because even if at the moment you are coping, the time will come when you will find it very very hard." ○ Finding 2: A daughter said: "What a [relief] to have someone to check on her and make sure all the other services are connected with each other as well. And not discharge her, as [other services] sometimes think: I haven't heard from them for a while they must be doing really well." ○ Finding 3: A daughter said: "With this service, in the last year, everything is now on the board… [Dad] knows who to expect, when they are coming and who everybody is. For me, this is a very positive thing and I know it is for mum [the person living with dementia], she feels more secure."
Author's comments	An internal audit of the service has shown that 70 per cent of patients die at home, compared to figures for England and Wales of 6 per cent for dementia patients in 2010 (Alzheimer's Society 2012). Analysis of the first year of the Bexley project observed improvements for the majority of patients on the quality of life in late stage dementia (QUALID) scale and reduced stress levels for carers using the Relative Stress Scale. The existence and continuing success of the Oxleas service is due to a small number of dedicated individuals who have sought to deliver an integrated service for patients and families who often experience a disjointed health and social care system. It has run for eight years, a long time compared with other models of care co-ordination. Despite this, attempts to develop an economic case for funding within the service have proved unsuccessful. The lack of dedicated management support has impeded their ability to produce a long-term business plan and robustly evaluate the benefits of this model. Clear, systematic and on-going evaluation of clinical outcomes, patient experience and the costs associated with care co-ordination projects should be viewed as an essential element of any programme. While the service has succeeded in becoming more embedded as a way of working within the trust as a result of the quality of care it provides, it remains a small service with a limited caseload despite growing demand. Elements of the care processes used by the Oxleas service are relevant to other models of care co-ordination. **Building resilience among carers** Carers underpin the Oxleas model with team members providing specific care and advice to help them to cope while under enormous stress.

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	Case finding and relationship building Staff identify suitable patients through their other roles in the mental health or community teams. A supportive culture surrounds all staff working within the service, and members of the team have built strong links between physical and mental health services. **Multiple referrals into a single entry point** Referrals are accepted from a wide range of health care professionals and a standardised referral form is used to capture information which flows into a single system for assessing and allocating cases to care co-ordinators. **A holistic care assessment and a personalised care plan** A single comprehensive assessment of the patient and carer addresses physical, mental health and social care needs. Following the assessment a personalised care plan is produced to put in place the services required and an emergency plan is put in place to deal with times of crisis. **Dedicated care co-ordination** The care co-ordinator takes on the role of primary contact with the patient and family. This role is filled by a specialist nurse with physical or mental health skills, e.g. a CPN, APN or community matron. They do not receive any formal training, but are all experienced case managers. **Rapid access to advice and support from a multidisciplinary team** The patient and carer are given a phone number for the care co-ordinator; if a crisis occurs (in working hours) or they need advice over the phone the coordinator will respond or delegate to another member of the team. **Split care assessment and co-ordination functions** Care assessment is led by the consultant psychiatrist working alongside a specialist nurse. Once a care plan is agreed, care co-ordination is led by a specialist nurse. Access to the right equipment, support for relevant medication, food, and social care needs were essential elements of caring for advanced dementia patients at home. Carers were often blocked from accessing support due to a poor understanding of the needs of advanced dementia care. As a result, they valued regular visits from a care co-ordinator who understood these pressures and could give advice if needed.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Unclear. Saturation of themes was not mentioned. • Was the data collected in a way that addressed the research issue? Unclear. Focus groups may not be as thorough as individual interviews. • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Unclear. Saturation of themes was not mentioned.

Full citation	Sonola, Thiel, Goodwin, Kodner (2013) Oxleas Advanced Dementia Service: supporting carers and building resilience. (URBA)
	• Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: Moderate

Full citation	Toms Gill R, Quinn Catherine, Anderson Daniel E, and Clare Linda (2015) Help yourself: Perspectives on self-management from people with dementia and their caregivers. Qualitative Health Research 25(1), 87-98
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews Aim of the study: to explore the attitudes toward self-management held by people with early stage dementia and their family caregivers. They examined their views and perceptions of self-management and explored factors that could make self-management difficult. Study dates: not provided. This study was published in 2015. Source of funding: National Institute for Social Care and Health Research grant.
Participants	• Sample size: 13 people living with early stage dementia and 11 carers. • Inclusion criteria: Participants were recruited from a memory clinic serving a semirural population in North Wales. People were recruited if they had early stage dementia, as indicated by a Mini-Mental State Examination score of 20 or above, or were the caregiver of someone experiencing early stage dementia (defined as a family member or close friend who provided day-to-day support). • Exclusion criteria: A history of significant neurological conditions, brain injury, or psychiatric illness; inability to provide informed consent; or risks to researchers visiting the participant at home. There were no exclusion criteria for caregivers. • Sample characteristics: People living with dementia: 9 women, 4 men; mean age (SD) = 75.54 (8.40); 11 living with partner, 2 living alone. Carers: 5 women, 6 men; mean age (SD) = 74.18 (6.97); 11 spouses.
Methods	Interviews were conducted by the first author, and in most cases the participants with dementia and their caregivers were interviewed separately. This procedure was chosen so that participants could talk openly without being influenced by the presence of family members. In three cases this was not possible, and although separate interviews were conducted, both parties were present throughout. Two interviews were conducted at the memory clinic, but most participants opted to be interviewed at home. Interviews were semi-structured and a topic guide was followed. Respondents were asked about the following topics: how they were self-managing with regard to memory problems at the moment; what advice, information, and support they thought would benefit people with regard to self-managing memory problems; their understanding of self-management; and their perception of its usefulness in managing memory problems. These questions were informed by the study aims and an overview of the relevant literature. Interviews were conversational and participants could introduce new areas of discussion if they wished.
Thematic	• Theme 1: The caregivers felt responsible and burdened. This left the person with dementia feeling disempowered.

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analysis	○ Finding 1: A carer said: "'Cos when you're married to somebody like that you [have] got to take the whole responsibility, haven't you?... They can't do, you know, nothing at all, so you've got to take over everything." ○ Finding 2: A person living with dementia said: "I don't like being checked for little things." • Theme 2: One particular source of self-management support that received unanimous endorsement from people with dementia and caregivers was providing support groups, which could offer companionship as well as information. It was felt that support groups provided a social outlet and a venue where information could be shared. In particular, respondents indicated that sharing practical tips and strategies among themselves would be beneficial. ○ Finding 1: A carer said: "A group would be useful in the fact that, I'm sure that [people] would benefit from knowing that other people are going through the same thing, because sometimes you feel isolated and having a group of people having the same problem and being able to talk to other people with the same problem, and I reckon it will be encouraging." ○ Finding 2: A person with dementia said: "With having the others to talk to as well, we've realized that that everybody's in the same boat and you could compare ideas and err and, you know, tell how each other felt. And err the interesting thing I, we, found out; that everybody seems different as well. Everybody's got their own set of problems and err ways that helps [them]. Ways of coping with it." • Theme 3: Additional support, such as a support group, was available, but these were often time-limited, which led both caregivers and people with dementia to the question of what happened when such support ended. ○ Finding 1: A caregiver said: "You also need somewhere for that to continue afterwards, and that, that does need a formal setting." This implies that respondents did not want to be left to cope with the condition by themselves but wanted formal support to help them manage. • Theme 4: People living with dementia and their caregivers felt that there was a lack of support. ○ Finding 1: A person living with dementia said: ""I don't think there is, because it's your life and you have to live it, and if you don't live it, well, who is there to pick you up? Who's there to pick you up? Nobody; only yourself." ○ Finding 2: A carer said: "It's learning on a daily basis. I mean we're not equipped, we haven't been trained… so you learn as you're going along… You see a deterioration and how do you manage that deterioration? Because actually, you don't realize you're managing it – you're just doing it." • Theme 5: Respondents thought that professional support was important for effective self-management, and valued this resource. They thought that this help was necessary because not everything could be self-managed within the family. As illustrated in the quote below, most respondents talked positively about the specialist services they received and some talked similarly about wider services, such as the support of general practitioners. Respondents often focused on the information they had received, noting especially how understandable it was. Respondents also commented on the lack of services available to them. In addition to medical/support services, this could include access to transport. Caregivers especially expressed a desire for "simple advice" to help them deal with the difficulties they experienced. This could include filling in forms, finding out about services that were available, and looking at the "hurdles" they might face.

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	○ Finding 1: A person living with dementia said: "Well, they were marvellous in [the memory clinic]… Everyone was very supportive, and the staff nurse [who] was with me was very good, and everyone was, the consultant, everybody." • Theme 6: Many respondents were unsure how to access the services that were available, and reported finding them limited and poorly integrated. This made it harder to self-manage the condition. ○ Finding 1: A caregiver said: "When I've mentioned it to our own GP or a GP down there, erm, I've just said about the tablets and that, 'Oh you'll, have to see [the memory clinic].' They feel that… Alzheimer's is to do with [the memory clinic]. That's the impression I get from them. But it's a sort of division." • Theme 7: Some people with dementia referred to using practical aids to support their memory. ○ Finding 1: One man with dementia talked about using the date function on his television remote control to orient himself in time; however, he did worry that using such an aid would increase his dependency: "Yeah, well that was one way to get 'round it, but you think, 'Am I doing the right thing by doing this? I'm not remembering anything if I keep relying on stuff like this.'" ○ Finding 2: A carer said: "She prepares all the ingredients first and puts them in a little pots in a row so she has something to refer to. She can counts the numbers, counts the items so she knows, and then she knows whether everything's in or not and if anything's missing it's there so." • Theme 8: What was most pertinent to carers was the diminished ability of the person living with dementia to complete daily tasks. ○ Finding 1: A carer said: "Well, he can't really do any jobs now. You know, like the washer on the… Well, my son came a couple of weeks ago and I had my sons and err he [person living with dementia] needed a washer on a tap. But I couldn't ask Karl [person living with dementia] to do it 'cos he wouldn't have known – known what to do." • Theme 9: The approach of normalising difficulties was evident in many interviews. ○ Finding 1: A carer said: "Erm, 'cos you know when they talk about people with memory problems and things like that, well it isn't true. They, they do have a difficulty with memories, but we've all got it. It's not a problem; you get by." • Theme 10: A sense of stoicism, often expressed when respondents gave their ideas about self-management, was evident in many interviews, and this seemed to be a form of psychological management. Some respondents also spoke of this form of self-management as "determination," and a related sentiment was the need to adopt a positive attitude. Caregivers also talked about being patient, whereas people living with dementia talked more about not dwelling "on the downside of it," and instead finding "some humour." This way of self-managing was evident in several interviews and the investigators heard laughter in many interview recordings. ○ Finding 1: A carer said: "Just, you've just got to get on with the thing," ○ Finding 2: A person living with dementia said: "You've got to keep, as you can, to keep, keep up with what you've normally done." ○ Finding 3: A carer said: "It, it, it's helpful to have erm, a good outlook, to be positive. That's, that's the word." • Theme 11: Some people with dementia discussed losing confidence, and it was additionally evident in the interviews that people with dementia often expressed themselves hesitantly and requested reassurance. It was implied that this loss of confidence could diminish

Full citation	**Toms Gill R, Quinn Catherine, Anderson Daniel E, and Clare Linda (2015) Help yourself: Perspectives on self-management from people with dementia and their caregivers. Qualitative Health Research 25(1), 87-98**
	people's belief that they could self-manage. In some cases, this loss of confidence seemed to relate to uncertainty about the future and how the illness would progress. ○ Finding 1: A person living with dementia said: "Well you start thinking, 'Well, have I got a future?' You think your memory's gone; well what else is gonna go? You see people sitting like a row of cabbages and you think, 'No. Am I going to sit like that?' I'd rather snuff it than sit like that all day."
Author's comments	Respondents thought of self-management as "coping" and "looking after" themselves, and they identified that they did try to do these things despite tensions in managing personal relationships and developing relationships with professional services. Participants described various things that facilitated self-management, including keeping their mind working and adopting a positive, stoic attitude. They also gained support from others experiencing similar situations. The primary self-management techniques described by respondents included emotional stoicism, humour, and, for some respondents, a tendency to normalize the difficulties they were facing. In terms of social cognitive theory, which often forms the basis for self-management approaches, the main perceived barriers to better management were the dementia symptoms and a dearth of support. Respondents' goals focused on keeping busy, trying to maintain cognitive abilities, and remaining stoic. Maintaining a positive attitude could include taking steps such as ensuring that there were positive things to look forward to and staying active. Other similar self-management strategies involved cultivating self-confidence and a resolve not to worry about the future. A few respondents, mainly caregivers, also made plans to prevent future worries, such as arranging finances. Only one respondent, a caregiver, talked about making power of attorney arrangements as per recommendations. However, respondents sometimes implied that it was previous life experience and personality style that determined whether such psychological self-management strategies could be employed. For some, the ability to cope was an intrinsic part of who they were, and one person with dementia commented that they were "born that way". Some respondents also indicated that they were managing other conditions related to health, mobility, and age. These could also interfere with self-management of dementia. For instance, one respondent who had dementia talked about stopping daily activities because of her arthritis rather than her memory problems. Two caregivers also implied that age or health impacted their daily functioning.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes. The investigators thought that data saturation was being approached. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes

Full citation	**Toms Gill R, Quinn Catherine, Anderson Daniel E, and Clare Linda (2015) Help yourself: Perspectives on self-management from people with dementia and their caregivers. Qualitative Health Research 25(1), 87-98**
	• Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: High

Full citation	**Willis Rosalind, Chan Jenifer, Scriven Issy, Lawrence Vanessa, Matthews David, Murray Joanna, and Banerjee Sube (2011) The Croydon Memory Service: Using generic working to create efficiency, job satisfaction and satisfied customers. In: Mental health and later life: Delivering an holistic model for practice. New York, NY: Routledge/Taylor & Francis Group; US, p125-136**
Study details	Country/ies where the study was carried out: UK Study type: semi-structured interviews Aim of the study: to explore the effect of the memory service on staff, referrers, people living with dementia and family carers. Study dates: March to August 2014 Source of funding: not mentioned
Participants	• Sample size: 16 people living with dementia and 15 carers • Inclusion criteria: Purposive sampling was used to identify a group of people living with dementia and carers with a mix of demographic characteristics and differing views about the memory service. • Exclusion criteria: none • Sample characteristics: not provided
Methods	The following description of the Croydon Memory Service was taken from Banerjee 2007: The Croydon Memory Service has two main aims: • Early identification and engagement with people with dementia and their carers. • Provision of a comprehensive early assessment, diagnostic and treatment service for people with dementia and their carers. This involved the introduction into the existing local system of care of an additional low-cost, high-throughput, generic service to enable early identification and intervention in dementia. The model was one of modest extra investment (£230,000 to establish a full-time team of five members for a borough with 46,000 65+) with system redesign to deliver new functions increasing the capacity to diagnose and manage dementia. The model has at its core generic team working. This removes the rate-limiting step which is imposed when all referrals need to be seen by a particular individual or professional group. In the CMSM, the team training is paramount so that any individual, no matter what their clinical background, can complete the initial assessment. The diagnosis is made and the management plan formulated by the multidisciplinary team as a whole. Following this, profession-specific skills can be deployed as needed. Assessment and care is provided in the patients' own homes. The model was designed to maximise efficiency and acceptability and to be easily transferable to and replicable in other areas.

Full citation	**Willis Rosalind, Chan Jenifer, Scriven Issy, Lawrence Vanessa, Matthews David, Murray Joanna, and Banerjee Sube (2011) The Croydon Memory Service: Using generic working to create efficiency, job satisfaction and satisfied customers. In: Mental health and later life: Delivering an holistic model for practice. New York, NY: Routledge/Taylor & Francis Group; US, p125-136**
	The team involves nursing, psychiatry, social work and psychology. The team leader is a clinical psychologist. The treatments offered to those with mild to moderate dementia include the anti-dementia drugs (the acetylcholinesterase inhibitors), social interventions, and individual and group psychological therapies.

Thematic analysis	• Theme 1: People living with dementia and their carers valued the continuity of having a key worker from initial assessment throughout the treatment and management.
	  ○ Finding 1: A person living with dementia said: “It’s reassuring. You can’t, don’t have to explain every time what you think, what’s going on and so on.”
	• Theme 2: People living with dementia and their carers recognised the one stop shop aspect of the memory service. Ten participants described the memory service as a central point of access to all necessary services.
	  ○ Finding 1: A carer said: “It’s the whole lot in one place rather than different groups in different places. It’s like you get all, everybody you need in one place, so that’s very helpful.”

Author’s comments	The efficiency of the team was noted by people living with dementia and their carers. People living with dementia and their carers were satisfied by the care provided. The consistency of having a key worker from the point of assessment onward was valued by people living with dementia and their carers. They described the benefits of not having to explain their situation anew each time they had contact with the service. The continuity was seen as reassurance, especially important for people coping with a distressing illness. This appears to be a marker of improved quality care.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Unclear. Although saturation of themes was mentioned, there were only two quotes from people living with dementia and their carers. • Was the research design appropriate to address the aims of the research? Yes. However, we are only interested in outcomes regarding people living with dementia and their carers. The emphasis of the study was on the opinions of staff. • Was the recruitment strategy appropriate to the aims of the research? Yes. Saturation of themes was mentioned. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Unclear. Although saturation of themes was mentioned, there were only two quotes from people living with dementia and their carers. • Is there a clear statement of findings? Yes • How valuable is the research? Valuable

Full citation	**Willis Rosalind, Chan Jenifer, Scriven Issy, Lawrence Vanessa, Matthews David, Murray Joanna, and Banerjee Sube (2011) The Croydon Memory Service: Using generic working to create efficiency, job satisfaction and satisfied customers. In: Mental health and later life: Delivering an holistic model for practice. New York, NY: Routledge/Taylor & Francis Group; US, p125-136**
	Overall quality: Moderate. There were only two quotes from people living with dementia and their carers. The emphasis of the study appears to be on the opinions of staff.

E.3.1.2 Quantitative evidence

Bibliographic reference	**Bass D M, Judge K S, Maslow K, Wilson N L, Morgan R O, McCarthy C A, Looman W J, Snow A L, and Kunik M E (2015) Impact of the care coordination program "partners in Dementia Care" on veterans' hospital admissions and emergency department visits. Alzheimer's and Dementia: Translational Research and Clinical Interventions 1(1), 13-22**
Study type	RCT
Participants	Inclusion criteria: Eligible veterans received primary healthcare from the Veterans' Association (VA), resided outside a residential care facility at enrolment, lived within a partnering Alzheimer's Association Chapter's, service area; were 60 and above; and had at least one International Classification of Diseases, 9th Revision dementia diagnostic code in the medical record. Exclusion criteria: None
Sample characteristics	N= 328 people living with dementia and their carers. n= 206 experimental intervention: 'Partners in Dementia Care' Baseline cognitive symptoms (SD) = 6.77/14 (3.78), baseline behavioural symptoms (SD) = 2.60 (2.56) Caregiver age (SD) = 68.56 (12.64) n= 122 comparator: usual care Baseline cognitive symptoms (SD) = 6.77/14 (3.65), baseline behavioural symptoms (SD) = 2.49 (2.32) Caregiver age (SD) = 71.77 (10.39)
Intervention	Partners in Dementia Care (PDC) was a coaching model driven by the preferences of veterans and caregivers. Coordinators offered guidance in finding solutions to the concerns that were priorities of veterans and caregivers. PDC had a standardized protocol, with a minimum of one contact between coordinators and veteran/caregiver dyads per month, with more frequent contacts as needed. Two half-time care coordinators delivered PDC; one from the VA medical centre and one from the partnering Alzheimer's Association Chapter. The two coordinators worked as a team, sharing the electronic Care Consultation Information System. Coordinators had bachelors or master's degrees in social work, nursing, or other helping professions.

Bibliographic reference	**Bass D M, Judge K S, Maslow K, Wilson N L, Morgan R O, McCarthy C A, Looman W J, Snow A L, and Kunik M E (2015) Impact of the care coordination program "partners in Dementia Care" on veterans' hospital admissions and emergency department visits. Alzheimer's and Dementia: Translational Research and Clinical Interventions 1(1), 13-22**
	VA coordinators had primary responsibility for veterans' medical-related concerns (e.g., medications, disease management, VA services and benefits); Alzheimer's Association coordinators had primary responsibility for caregivers' nonmedical concerns (e.g., care-related strain, community service use). PDC was low-cost because it was delivered by telephone, mail, and e-mail. Two partnering half-time coordinators (1 full time equivalent) maintained caseloads of 100 to 125 families. Although economies of scale came from larger caseloads and exact program costs depended on salaries and benefits of care consultants, all expenses to deliver PDC typically (i.e., salaries, benefits, equipment, supplies, training, software, licensing, supervision, overhead) were $60 to $80 per month per family. PDC's main components were: (1) initial assessment, (2) action plan, and (3) ongoing monitoring and reassessment.
Comparison	Usual care
Outcome measures	Percentage of participants with any hospital admissions Mean number of hospital admissions Percentage of participants with any emergency department visits Mean number of emergency department visits Utilisation records were extracted electronically for 1-year post each participant's baseline interview. Data on non-VA hospital and ED use (including urgent care) came from the structured caregiver research interviews. The following were measured at 6 months: **Cognitive symptoms** Cognitive symptoms were the sum of seven items, scored from (0) to (2) ("no," "some," or "a great deal" of difficulty), that asked caregivers about the amount of difficulty veterans had with: tracking current events; knowing the day of the week; repeating things; paying attention; and remembering addresses, people, and appointments. **Behavioural symptoms** Behavioural symptoms represented one part of the broad category of neuropsychiatric symptoms that can be particularly stressful for caregivers. It was the sum of four items, scored from (0) to (3) ("none of the time" to "most or all the time"), that asked about the frequency of veterans: complaining or criticizing, interfering with family members, yelling or swearing, and being agitated.
Study dates	Not provided. This study was published in 2015
Study location	USA

Bibliographic reference	**Bass D M, Judge K S, Maslow K, Wilson N L, Morgan R O, McCarthy C A, Looman W J, Snow A L, and Kunik M E (2015) Impact of the care coordination program "partners in Dementia Care" on veterans' hospital admissions and emergency department visits. Alzheimer's and Dementia: Translational Research and Clinical Interventions 1(1), 13-22**
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The details of centre randomisation were not given. • Were clinicians and investigators blinded? No. However, this is not likely to be relevant because the outcome measures are not subjective. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? No. There was a very large dropout rate for unknown reasons: 31.1% in the intervention group and 34.7% in the usual care group. • Can the results be applied to the local population? Unclear. The system in the USA may differ from the UK system. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R O, Maslow K, Randazzo R, Moye J A, Odenheimer G L, Archambault E, Elbein R, Pirraglia P, Teasdale T A, McCarthy C A, Looman W J, and Kunik M E (2014) A controlled trial of Partners in Dementia Care: veteran outcomes after six and twelve months. Alzheimer's Research & Therapy 6(1), 9**
Study type	RCT
Participants	Inclusion criteria: Eligibility requirements for veterans included receiving primary healthcare from the Veterans' Association (VA), residing outside a residential care facility at the time of enrolment, living within a partnering chapter's service area, being 60+ years of age and having a dementia diagnostic code from the International Classification of Diseases, Ninth Revision recorded in the VA medical record. VA primary care physicians confirmed veterans' diagnoses and eligibility prior to sample selection. Exclusion criteria: None
Sample characteristics	N= 194 people living with dementia and their carers.

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R O, Maslow K, Randazzo R, Moye J A, Odenheimer G L, Archambault E, Elbein R, Pirraglia P, Teasdale T A, McCarthy C A, Looman W J, and Kunik M E (2014) A controlled trial of Partners in Dementia Care: veteran outcomes after six and twelve months. Alzheimer's Research & Therapy 6(1), 9**
	n= 122 experimental intervention: Partners in Dementia Care Mean age (SD)= 78.72 years (8.64); mean cognitive impairment score (SD) = 11.54/28 (6.28) n= 72 comparator: usual care Mean age (SD)= 80.32 years (6.54); mean cognitive impairment score (SD) = 10.77/28 (5.37)
Intervention	Two half-time care coordinators, with part-time administrative assistant support, delivered PDC at each intervention site. One care coordinator worked in the local VA medical centre (healthcare organization) and the other worked in the partnering Alzheimer's Association chapter (community service organization). Although from different organisations, the two care coordinators worked as a team, with one shared electronic Care Coordination Information System (CCIS) and regularly scheduled planning and case-conference meetings. Care coordinators had bachelor's or master's degrees in social work, nursing or other helping professions. The care coordinator from the VA medical centres had primary responsibility for assisting veterans with medically related concerns (for example, medications, accessing medical services, disease management) while the care coordinator from the Alzheimer's Association chapter had primary responsibility for assisting caregivers with nonmedical concerns (for example, care-related strain, accessing family support and information services). The VA care coordinator also focused on helping families access VA services and benefits, whereas the Alzheimer's Association care coordinator focused on helping families use community services, including those offered by the Alzheimer's Association. This division of labour between care coordinators capitalized on the complementary strengths of each partner organization and represented a bridge between health care and community services. Training for care coordinators consisted of a 1.5-day initial session on the PDC philosophy, service-delivery protocol and the CCIS that guides service delivery. Additionally, one- to two-hour biweekly refresher trainings were completed throughout the study period. These sessions focused on case reviews to monitor fidelity to the intervention protocol, strategies for working with a partner organization, using the CCIS and handling difficult cases. Continuing education also was provided on special topics, such as differences among illnesses that cause dementia, helping families respond to emergencies and respite for caregivers. PDC is a coaching model driven by consumer choice, with care coordinators helping find solutions to concerns that are the priorities of veterans and caregivers. PDC followed a set, standardized protocol that required a minimum of at least one contact between care coordinators and consumers per month; more-frequent contacts occurred as needed. The protocol required care coordinators to discuss with veterans and/or caregivers a broad range of medical and nonmedical concerns, although the specific content was customized to consumers' preferences and needs.

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R O, Maslow K, Randazzo R, Moye J A, Odenheimer G L, Archambault E, Elbein R, Pirraglia P, Teasdale T A, McCarthy C A, Looman W J, and Kunik M E (2014) A controlled trial of Partners in Dementia Care: veteran outcomes after six and twelve months. Alzheimer's Research & Therapy 6(1), 9**
	PDC is a low-cost service delivered by telephone, mail and e-mail, with in-person contacts rarely needed. The two half-time care coordinators from the partnering organisations (one full-time equivalent (FTE)) maintained caseloads of 75 to 125 families. All expenses to deliver PDC (that is, salaries, benefits, equipment, supplies, training, software, licensing, supervision, administrative overhead) can be recovered by charging a fee of $60 to $80 per month per family. PDC gives equal attention to preferences and needs of veterans and caregivers. Veterans with dementia are engaged in the program whenever possible, despite their impairments. Veterans without caregivers are able to use PDC, so long as they can communicate by telephone. If veterans are too impaired to communicate by telephone, their caregivers can be the sole participant in the program. PDC has three main components: 1) initial assessment, 2) action plan, and 3) ongoing monitoring and reassessment. **Initial assessment** The initial assessment is completed gradually during the first four weeks of enrolment. It is designed to be brief, with the action plan to address assessed concerns implemented simultaneously with or prior to completion of the entire initial assessment. The initial assessment covers a broad range of domains or potential problem areas: 23 for veterans (for example, coordinating and accessing VA services, medication management, getting and understanding the diagnosis) and 16 for caregivers (for example, finding and accessing community services, care-related strains and depression). The required initial assessment consists of a single-item trigger question for each domain; trigger questions can be formally asked or covered informally during conversations. More extensive detailed assessment questions are available for each domain as optional tools, if additional probing is necessary to clarify a problem. **Action plan** The action plan is the core of PDC. It comprises simple behavioural tasks called action steps that, if accomplished, move veterans and caregivers toward solutions to concerns they identified as important. Action steps should be easy to complete and include, for example, calling an organization to inquire about the availability of a service, reading an educational resource on a topic of concern or contacting another family member to ask whether he or she is willing to help with a caregiving task. With coaching and guidance from care coordinators, veterans and caregivers determine the content of action steps, who will complete the action steps and the projected dates of completion. New action steps are continuously added and build upon prior action steps. Multiple action steps, spread over a period of weeks or months, often are needed to find solutions to specific problems. As action steps are completed, veterans and caregivers move toward solutions and gain confidence in their self-management

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R O, Maslow K, Randazzo R, Moye J A, Odenheimer G L, Archambault E, Elbein R, Pirraglia P, Teasdale T A, McCarthy C A, Looman W J, and Kunik M E (2014) A controlled trial of Partners in Dementia Care: veteran outcomes after six and twelve months. Alzheimer's Research & Therapy 6(1), 9**
	abilities. Copies of action plans are mailed to veterans and caregivers and summarized in the larger medical record. On average, each veteran and his or her caregiver had more than seven action steps. The most common pertained to accessing and coordinating services and benefits available from the VA, Alzheimer's Association or other community agencies. Specifically, 78% of veterans and caregivers had action steps related to accessing VA services or benefits, 59% to accessing Alzheimer's Association services and 76% to accessing other community organizations. Other common action steps focused on improving care from the informal network (57%), managing symptoms (40%), improving communication with healthcare providers (33%) and home safety (29%). **Ongoing monitoring and reassessment** The hallmark of PDC is a long-term relationship to provide continuous support to veterans and caregivers. Ideally, care coordinators become knowledgeable and familiar experts who are trusted by families. On average, families had over 14 contacts with coordinators during the twelve-month study period, which focused on completing the required initial assessment and reassessments, adding new action steps and checking the disposition of pending action steps, and completing required routine checking. Reassessments involved re-administering trigger questions used in the initial assessment. They were required at least every six months. More frequent reassessments for selected domains are recommended for persistent or ongoing problems. Reassessment helps care coordinators and consumers gauge progress in finding solutions to problems. Consistent with the design of PDC, the most contacts between care coordinators and veterans or caregivers were by telephone (80%) and regular mail and e-mail (16%), with a small number in person (4%). The number of contacts was evenly split between care coordinators from the VA and the Alzheimer's Association, which reflected PDC's team-based delivery model. Care coordinators initiated approximately 90% of contacts; veterans or caregivers initiated 10%. (For a more detailed description of PDC, see Judge et al).
Comparison	Usual care
Outcome measures	Outcomes were measured at 12 months via a telephone interview. **Unmet needs** Developed for this study, this outcome was based on 24 dichotomous questions that were summed to measure veterans' perceptions of unmet need across eight domains: 1) understanding dementia, 2) daily living tasks, 3) accessing VA and other services, 4) legal and financial issues, 5) organizing family care, 6) alternative living arrangements, 7) emotional support and 8) medications. **Embarrassment about memory problems**

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R O, Maslow K, Randazzo R, Moye J A, Odenheimer G L, Archambault E, Elbein R, Pirraglia P, Teasdale T A, McCarthy C A, Looman W J, and Kunik M E (2014) A controlled trial of Partners in Dementia Care: veteran outcomes after six and twelve months. Alzheimer's Research & Therapy 6(1), 9**
	This was the sum of three dichotomous items that asked whether veterans felt embarrassed about memory problems, uncomfortable telling others about memory problems and uncomfortable accepting help for memory problems. **Isolation** This included four dichotomous items and asked veterans whether their health problems and need for assistance made them feel isolated from other people, less able to participate in group activities, less able to participate in church or religious activities, and less able to visit with family and friends. **Relationship strain** This was the sum of four dichotomous items focused on veterans' perceptions of the quality of the relationship with their caregivers. Questions asked whether, because of their health problems and need for assistance, veterans felt that their caregiver tried to manipulate them, felt that the relationship with the caregiver was strained, felt resentful toward the caregiver or felt angry toward the caregiver. **Depression** Veteran depression was measured by the 11-item Center for Epidemiologic Studies Depression Scale.
Study dates	2007 to 2009
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of site randomisation is not given. • Were clinicians and investigators blinded? Unclear. Blinding was not mentioned. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare US and UK systems. • Were all clinically relevant outcomes reported? No. Some twelve month outcome results were reported as "not significant" but the data was not published. In addition, the 'embarrassment' outcome was reported as two subgroups. One of these subgroups had 'significant' results and the other's result was 'no change'. This introduces the risk of data mining and finding 'significant' results that may not be in reality significant. Overall risk of bias: High

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R, Looman W J, McCarthy C A, Maslow K, Moye J A, Randazzo R, Garcia-Maldonado M, Elbein R, Odenheimer G, and Kunik M E (2013) Caregiver outcomes of partners in dementia care: effect of a care coordination program for veterans with dementia and their family members and friends. Journal of the American Geriatrics Society 61(8), 1377-86**
Study type	RCT
Participants	Inclusion criteria: Veterans aged 50 and older who had at least one dementia diagnosis recorded in the VA medical record during the past 14 years (International Classification of Diseases, Ninth Revision), received primary care from the VA, and resided in the service areas of partner Alzheimer's Association chapters were eligible. Exclusion criteria: None
Sample characteristics	N= 486 people living with dementia and their carers. n= 299 experimental intervention: Partners in Dementia Care Caregiver mean age (SD)= 68 years (12.6); Veterans' mean cognitive impairment (SD)= 7/14 (3.7) n= 187 comparator: usual care Caregiver mean age (SD)= 70.8 years (11.4); Veterans' mean cognitive impairment (SD)= 7/14 (3.7)
Intervention	Two half-time care coordinators and two part-time care coordinator assistants delivered the Partners in Dementia Care (PDC) at each intervention site. One care coordinator and an assistant worked in the local VAMC (healthcare organization), and the other worked in the partnering Alzheimer's Association chapter (community service organization). Although from different organizations, the two care coordinators and assistants worked as a team, with one shared electronic Care Coordination Information System and regularly scheduled planning and case-conference meetings. The two coordinators often worked with veterans, caregivers, or both in tandem on the same issues, although the care coordinator from the VAMC had primary responsibility for assisting veterans with medical-related concerns (e.g., medications, accessing medical services, disease management), whereas the care coordinator from the Alzheimer's Association chapter had primary responsibility for assisting caregivers with nonmedical concerns (e.g., care-related strain, accessing family support and information services). The VA care coordinator also focused on helping families use VA services and benefits effectively, whereas the Alzheimer's Association care coordinator focused on helping families use community services effectively, including those that the Alzheimer's Association offered. This general division of labour capitalized on the complementary strengths of each partner organization and reinforced the collaboration of the two coordinators, who represented a bridge between healthcare and community services. Partners in Dementia Care is a coaching model driven by consumer choice, with care coordinators helping find

Bibliographic reference	Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R, Looman W J, McCarthy C A, Maslow K, Moye J A, Randazzo R, Garcia-Maldonado M, Elbein R, Odenheimer G, and Kunik M E (2013) Caregiver outcomes of partners in dementia care: effect of a care coordination program for veterans with dementia and their family members and friends. Journal of the American Geriatrics Society 61(8), 1377-86
	solutions to concerns that are the priorities of veterans and caregivers. PDC followed a set, standardized protocol that required a minimum of one contact between care coordinators and consumers per month; more-frequent contacts occurred as needed. The protocol also required care coordinators to discuss with veterans or caregivers a broad range of medical and nonmedical concerns, although the specific content of assistance was customized for consumers' preferences and needs. Partners in Dementia Care is a low-cost service delivered by telephone, mail, and e-mail, with two half-time care coordinators and two part-time assistants maintaining caseloads of between 100 and 125 families at any one time. All expenses to deliver PDC (e.g., salaries, benefits, equipment, supplies, training, software, licensing, supervision, administrative overhead) can be recovered by charging a fee of $60 to $80 per month per family. Partners in Dementia Care gives equal attention to preferences and needs of veterans and caregivers, rather than focusing on one or the other member of the caregiving dyad, including engaging veterans with dementia in the program whenever possible, despite their impairments. When veterans were too impaired, caregivers were the main target of the intervention, but PDC also served a number of veterans who did not have informal caregivers. Partners in Dementia Care has three main components: initial assessment, action plan, and ongoing monitoring and reassessment. **Initial Assessment** The initial assessment is completed gradually during the first 4 weeks of enrolment. It is designed to be brief, with an action plan to address assessed concerns implemented simultaneously with the assessment process. The initial assessment covers a broad range of potential problem areas or domains; 23 for veterans (e.g., coordinating and accessing VA services, medication management, getting and understanding the diagnosis) and 16 for caregivers (e.g., finding and accessing community services, care-related strains and depression). The required initial assessment consists of a single-item trigger question for each domain. Care coordinators can formally ask trigger questions, or they can be covered informally during naturally occurring discussions. The brevity of using simple trigger questions allows the initial assessment to be quick, which facilitates formation of the action plan, within which solutions to problems begin. The PDC protocol provides more-extensive detailed assessment questions as optional tools if more-structured probing is needed to clarify a problem. **Action Plan** The action plan is the core of PDC. It comprises simple behavioural tasks called action steps that move veterans and caregivers toward solutions to concerns identified in the initial assessment and reassessments. Veterans and caregivers determine the content of action steps with coaching and guidance from care coordinators. New action steps are continuously added and build upon prior action steps. Multiple action steps, spread over a period of weeks

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R, Looman W J, McCarthy C A, Maslow K, Moye J A, Randazzo R, Garcia-Maldonado M, Elbein R, Odenheimer G, and Kunik M E (2013) Caregiver outcomes of partners in dementia care: effect of a care coordination program for veterans with dementia and their family members and friends. Journal of the American Geriatrics Society 61(8), 1377-86**
	or months, are often needed to find solutions. As action steps are completed, veterans and caregivers build confidence in their self-management abilities. Updated copies of action plans are continuously mailed to veterans and caregivers and are incorporated into the larger medical record. On average, each veteran and his or her caregiver had more than seven action steps. The most common pertained to accessing and coordinating services and benefits available from the VA, partner agencies, and other community agencies. Specifically, 78% of veterans and caregivers had action steps related to coordination of VA services or benefits, 59% related to coordination of Alzheimer's Association services, and 76% related to coordination of services from other community organizations. Other common action steps focused on improving care from the informal network (57%), managing symptoms (40%), improving communication with healthcare providers (33%), and home safety (29%). **Ongoing Monitoring and Reassessment** The hallmark of PDC is establishing a long-term relationship that provides continuous support to veterans and caregivers. Care coordinators are knowledgeable experts who become familiar with and trusted by families. They are an easily accessible resource to help with changes in the dynamic caregiving situation. The critical facilitator of ongoing monitoring is frequent contact with the veterans and their caregivers. The average number of contacts is more than 20 during a 12-month period. Follow-up contacts are used to determine the disposition of pending action steps, add new action steps, complete the required reassessment, and conduct routine check-ins, even when the situation is stable. Reassessment of all domains included in the initial assessment by re-administering trigger questions is required at least every 6 months. More-frequent reassessments for selected domains are recommended for persistent or ongoing problems. Reassessment helps care coordinators and consumers gauge progress in finding solutions to problems. Throughout the study period, the vast majority of contacts between care coordinators and veterans or caregivers were by telephone (80%), followed by mail (11%) and e-mail (9%). The number of contacts was evenly split between care coordinators from the VA and the Alzheimer's Association, which reflected PDC's team-based delivery model. Care coordinators initiated approximately 90% of contacts, and veterans or caregivers initiated 10%.
Comparison	Usual care
Outcome measures	**Unmet Needs** Thirty-nine yes-or-no questions developed for this study measured caregiver perceptions of unmet needs in eight domains: understanding dementia, care tasks, accessing VA and other services, legal and financial issues,

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R, Looman W J, McCarthy C A, Maslow K, Moye J A, Randazzo R, Garcia-Maldonado M, Elbein R, Odenheimer G, and Kunik M E (2013) Caregiver outcomes of partners in dementia care: effect of a care coordination program for veterans with dementia and their family members and friends. Journal of the American Geriatrics Society 61(8), 1377-86**
	organizing family care, alternative living arrangements, emotional support, and medications and medical follow-up. **Caregiver Strains** Three established measures represented strains or negative caregiving effects: role captivity, physical health strain, and relationship strain. Individual items were scored from 0 (strongly disagree) to 3 (strongly agree). Role captivity consisted of three items asking whether caregivers wished they could run away from the caregiving situation, wished they were free to live their own life without caregiving, and felt trapped by caregiving. Physical health strain consisted of three items asking whether, because of caregiving, their physical health was worse, they got sick more often, and they were bothered more by aches and pains. Relationship strain focused on the quality of caregivers' relationships with veterans. It had six items that asked whether, because of caregiving, they felt closer to the veteran, felt appreciated, got pleasure out of helping, felt the relationship was strained, felt angry, and felt the veteran was manipulative. **Depression** Caregiver depression, the indicator of general well-being, was measured using the 11-item Center for Epidemiologic Studies Depression Scale. **Support Resources** Two resources that help caregivers cope with caregiving were used as outcomes: number of informal helpers (family members, friends, neighbours) who assisted veterans and caregivers, and use of caregiver support services (respite and emotional support services).
Study dates	Not provided. Study was published in 2013.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of centre randomisation is not given. • Were clinicians and investigators blinded? Yes. Data was collected by blinded interviewers. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare US and UK systems.

Bibliographic reference	**Bass D M, Judge K S, Snow A L, Wilson N L, Morgan R, Looman W J, McCarthy C A, Maslow K, Moye J A, Randazzo R, Garcia-Maldonado M, Elbein R, Odenheimer G, and Kunik M E (2013) Caregiver outcomes of partners in dementia care: effect of a care coordination program for veterans with dementia and their family members and friends. Journal of the American Geriatrics Society 61(8), 1377-86**
	• Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Bass D M, Clark P A, Looman W J, McCarthy C A, and Eckert S (2003) The Cleveland Alzheimer's managed care demonstration: outcomes after 12 months of implementation. Gerontologist 43(1), 73-85**
Study type	RCT
Participants	Inclusion criteria: The sample was drawn from those whose medical records indicated they had either a specific diagnosis of dementia or a symptom code indicating memory loss. In addition, eligible participants had to be 55 years or older; reside outside of a nursing home at the start of the demonstration. Exclusion criteria:
Sample characteristics	N= 157 people living with dementia and their carers n= 92? (60% in intervention group) experimental intervention: managed care Baseline characteristics are not provided n= 65? (40% in control group) comparator: usual care Baseline characteristics are not provided
Intervention	Care consultation is a flexible, multicomponent intervention that builds on more than 10 years of research on interventions for family caregivers (Biegel & Schulz, 1999; Bourgeois, Schulz, & Burgio, 1996; Kennet, Burgio, & Schulz, 2000). It is a telephone intervention based on an empowerment conceptual framework (Guttierrez, GlenMaye, & DeLois, 1995). This framework assumes that patients and families have the capacity to make their own decisions if given sufficient information and coaching. Care consultants work with families in a collegial fashion to help identify personal strengths, as well as resources within the family system, health plan, and community. The goal is to provide tools to enhance patients' and caregivers' competence and self-efficacy. Care consultants also provide information about available community services, facilitate decisions about how to best utilize and apply for these services, and may contact service agencies on behalf of patients and caregivers. Care consultants initiate the first contacts with patients and family caregivers. This strategy is intended to overcome delays in support and information service use or the use of these services only in times of crisis (Bass, McCarthy, Eckert, & Bichler, 1994; Costa et al., 1996). Care consultation is delivered by one of three Association staff

Bibliographic reference	**Bass D M, Clark P A, Looman W J, McCarthy C A, and Eckert S (2003) The Cleveland Alzheimer's managed care demonstration: outcomes after 12 months of implementation. Gerontologist 43(1), 73-85**
	members, two of whom are master's prepared licensed social workers. Care consultants follow a standardized protocol for service delivery that includes conducting a structured initial assessment, identifying problems or challenges, and developing strategies for using personal, family, and community resources. Care consultants collaborate with patients and family caregivers to create an individualized plan of care. The care plan outlines specific tasks to be completed; assigns patients, family members, or Association staff/volunteers to work on these tasks; and gives a time frame for task completion and reassessment. Tasks often include using other Association services, such as education and training programs, support groups, a respite reimbursement program, and a nationwide program to return wanderers safely home. Regularly scheduled follow-ups monitor progress and add new tasks to the care plan as needed. Follow-ups are initially done biweekly, decreasing to 1-month and 3-month intervals unless needs dictate more frequent contacts. In difficult periods, daily contact with care consultants may be necessary. Alternatively, if care consultants, patients, and caregivers agree and there are no problems that have not been addressed or discussed, trained volunteers make follow-up contacts, with care consultants on call. Although all persons in the intervention group are offered care consultation, there is variation in the extent to which patients and families accept services. On average, care consultants have 12 direct communication contacts with patients and caregivers per year. Control group patients and caregivers are able to contact the Association independently and use any of its services other than care consultation. Use of Association services other than care consultation by both the intervention and control groups is incorporated into the analysis. All Association services are free-of-charge.
Comparison	Usual care
Outcome measures	**Utilization outcomes**, including patients' use of hospital, emergency department, and physicians; patients' use of community services; and patients' and caregivers' use of non-Association information and support services. **Caregiver satisfaction** with managed care services, including satisfaction with types and quality of services provided; and information about memory problems. **Caregiver depression** and care-related strain, including perceived health deterioration, role captivity, and relationship strain.
Study dates	Not provided. This study was published in 2003.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation is not given. • Were clinicians and investigators blinded? Unclear. Blinding is not mentioned.

Bibliographic reference	**Bass D M, Clark P A, Looman W J, McCarthy C A, and Eckert S (2003) The Cleveland Alzheimer's managed care demonstration: outcomes after 12 months of implementation. Gerontologist 43(1), 73-85**
	• Were the groups similar at the start of the trial? Unclear. Baseline data is not provided. • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare US and UK systems. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Very high

Bibliographic reference	**Callahan C M, Boustani M A, Unverzagt F W, Austrom M G, Damush T M, Perkins A J, Fultz B A, Hui S L, Counsell S R, and Hendrie H C (2006) Effectiveness of collaborative care for older adults with Alzheimer disease in primary care: a randomized controlled trial. JAMA 295(18), 2148-57**
Study type	RCT
Participants	Inclusion criteria: A diagnosis of dementia. Exclusion criteria: Residence in a nursing home, unable to understand English, no access to a telephone, or no caregiver willing to consent to participate in the study.
Sample characteristics	N= 114 people living with dementia and their carers n= 65 experimental intervention: care management 95.7%=female; 4.3%=male; mean age (SD)= 77.7 years (5.7); mean MMSE (SD)= 17.5 (5.2) n= 49 comparator: usual care 83.3%=female; 16.7%=male; mean age (SD)= 77.4 years (5.9); mean MMSE (SD)= 18.6 (5.9)
Intervention	Primary care physicians of augmented usual care patients could pursue any evaluation or treatment they deemed appropriate. Intervention patients and their caregivers received collaborative care management for a maximum of 12 months by a team led by their primary care physician and a geriatric nurse practitioner who served as the care manager. All intervention patients were recommended for treatment with cholinesterase inhibitors (or memantine) unless contraindicated. The minimum intervention that all treatment group caregivers and patients received included education on communication skills; caregiver coping skills; legal and financial advice; patient exercise guidelines with a guidebook and videotape; and a caregiver guide provided by the local chapter of the Alzheimer's Association. All of the components of this minimum intervention as well as the behavioural interventions described below were provided by a geriatric nurse practitioner, who served as the care manager.

Bibliographic reference	**Callahan C M, Boustani M A, Unverzagt F W, Austrom M G, Damush T M, Perkins A J, Fultz B A, Hui S L, Counsell S R, and Hendrie H C (2006) Effectiveness of collaborative care for older adults with Alzheimer disease in primary care: a randomized controlled trial. JAMA 295(18), 2148-57**
	There were 2 care managers, each of whom was an advanced practice nurse, with 1 based at each of the 2 large primary care practices. Caregivers and patients were seen by the care manager in the primary care clinic bimonthly initially and then contacts were lengthened to monthly for a period of 1 year. At each contact with the care manager, caregivers completed the Memory and Behaviour Problems Checklist to assess current symptoms and stressors. Based on the caregiver's responses, individualized recommendations were made regarding how to manage a patient's behavioural symptoms. Items checked on a subscale of the Memory and Behaviour Problems Checklist activated a specific behavioural intervention protocol that had been developed for this study. These 8 protocols included personal care, repetitive behaviour, mobility, sleep disturbances, depression, agitation or aggression, delusions or hallucinations, and the caregiver's physical health. Each of these protocols focused first on nonpharmacological interventions. A description of these nonpharmacological interventions has been previously published and the protocols are available at http://iucar.iu.edu/research/behavioralprotocols.html. If the nonpharmacological approach failed, the care manager then collaborated with the primary care physician to institute drug therapy for depression, agitation, sleep disturbance, or delusions. The primary care physician and the care manager were supported through 2 additional mechanisms. First, the care manager had weekly meetings with a support team comprised of a geriatrician, geriatric psychiatrist, and a psychologist who reviewed the care of new and active patients and monitored adherence to the standard protocols. Second, the care manager was supported by a Web-based longitudinal tracking system that managed the schedule for patient contacts, tracked the patient's progress and current treatments, and provided an instrument for communicating the patient's and caregiver's current clinical status to the entire care team. All intervention patients and their caregivers also were invited to participate in voluntary group sessions. During these sessions, caregivers were taken to a support session led by a social psychologist that focused on caregiver stress. Patients were taken to a nearby room for a group chair-based exercise class led by a health psychologist and the care manager. The study protocol did not mandate additional visits to the primary care physician.
Comparison	Usual care
Outcome measures	The caregivers of patients in both treatment groups completed a baseline assessment by telephone with interviewers who were blinded to the patient's randomisation status. This telephone interview was repeated at 18 months. The interview included 3 standardized instruments developed by the Alzheimer's Disease Cooperative Study investigators: the Neuropsychiatric Inventory (NPI), activities of daily living, and health care resource use. Caregivers also provided the data to complete the Cornell Scale for Depression in Dementia for the patient. Caregivers completed the caregiver portion of the NPI and the Patient Health Questionnaire to assess the caregiver's mood. Caregiver's satisfaction with the patient's care was assessed with the question: "Over the last 3

Bibliographic reference	**Callahan C M, Boustani M A, Unverzagt F W, Austrom M G, Damush T M, Perkins A J, Fultz B A, Hui S L, Counsell S R, and Hendrie H C (2006) Effectiveness of collaborative care for older adults with Alzheimer disease in primary care: a randomized controlled trial. JAMA 295(18), 2148-57**
	months, how would you rate the quality of care [the patient] has received overall from the primary care clinic?". At each follow-up interview, caregivers completed the Alzheimer's Disease Cooperative Study health resource use questionnaire. Specific questions included "In the last 6 months, how many times was [the patient] examined by a doctor or nurse? In the last 6 months, how many times was she [or he] admitted to the hospital and how many nights for each hospital stay?" The caregiver also provided information on whether the patient had been placed in a nursing home for long-term care.
Study dates	2002 to 2004
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes. Interviewers were blinded. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare US and UK systems. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Chien W T, and Lee Y M (2008) A disease management program for families of persons in Hong Kong with dementia. Psychiatric Services 59(4), 433-6**
Study type	RCT
Participants	Inclusion criteria: The inclusion criteria for family caregivers included being 18 years or older and living with and caring for a relative who was diagnosed as having a type of dementia caused by Alzheimer's disease, according to DSM-IV criteria. Exclusion criteria: Caregivers who had mental illness themselves or who had cared for their family member for less than three months were excluded.
Sample characteristics	N= 85 people living with dementia and their carers

Bibliographic reference	Chien W T, and Lee Y M (2008) A disease management program for families of persons in Hong Kong with dementia. Psychiatric Services 59(4), 433-6
	n= 42 experimental intervention: dementia care management n= 43 comparator: usual care Baseline characteristics were not provided. However, the researchers wrote that they could not detect any significant difference between groups at a 5% significance level.
Intervention	The dementia care management program is an education and support group for family members that lasted for six months. A multidisciplinary committee—including a psychiatrist, a social worker, a case manager (nurse) from each centre, and the researchers selected 25 intervention objectives from the recommended dementia guidelines established in the United States and designed an information and psychological support system linking case managers and dementia care services, health professionals, and referrals. One key component was the case managers who received 32 hours of formal training by the researchers and coordinated all levels of family care according to the results of a structured needs assessment. Each family was assigned one case manager who together with another nurse in the centre, summarised the assessment data and, in collaboration with the caregivers, prioritized problem areas and formulated a multidisciplinary education program for each family on effective dementia care— for example, cognitive stimulation. The program consisted of 12 sessions that were held every other week and lasted two hours each. It consisted of five phases—orientation to dementia care (one session), educational workshop about dementia care (three sessions), family role and strength rebuilding (six sessions), community support resources (one session), and review of program and evaluation (one session)—that were based on the family programs by Belle and colleagues and Fung and Chien. The program content was selected on the basis of the results of the family needs assessments. For example, two families who found dementia caregiving very difficult were helped in multiple ways: they were provided information, problem solving skills training, and stress management techniques. The program also used a culturally sensitive family intervention model, and many of the Chinese cultural tenets (for example, valuing collectivism over individualism and emphasizing filial obligation and family and kinship ties) were considered in respect to family relationships and value orientation during the program. The case managers also conducted home visits and brief education about dementia care every other week and family health assessment once per month. Both centres provided both groups with routine dementia care, such as pharmacotherapy and social and recreational activities for the patients and written educational materials about dementia care for the caregivers.
Comparison	Usual care. In order to conceal the intervention of interest for family caregivers, six monthly education sessions on dementia care were provided to the usual care group.
Outcome measures	The following were recorded by a blinded researcher at baseline and at 12 months: • The Family Caregiving Burden Inventory (FCBI) is a 24-item scale developed by Novak and Guest (1989), which

Bibliographic reference	Chien W T, and Lee Y M (2008) A disease management program for families of persons in Hong Kong with dementia. Psychiatric Services 59(4), 433-6
	measures the impact of the burden on caregivers of elderly clients with dementia. Items are rated on a 5-point Likert scale from 0 (totally disagree) to 4 (totally agree). A respondent's total burden score ranges from 0 to 96, a higher score indicating a higher burden. • The World Health Organisation Quality of Life Measure-Brief Version (WHOQoL-BREF) was modified from the WHOQoL-100 by the World Health Organisation (1995). Items are structured in four domains: physical health, psychological, social relationship, and environment (i.e. seven items for each subscale). They are rated on a 5-point Likert scale with a high score indicating a better quality of life (total score range 28–144). • A Six-item Social Support Questionnaire (SSQ6) developed by Sarason et al. (1987) measures satisfaction with social support available in their immediate social environment. Higher total scores (0–30) indicating more satisfaction with the available social support. • Mini-Mental State Examination. • 12-item Neuro-psychiatric Inventory. • Institutionalization over the past 6 months (number of times and duration). • The Family Support Services Index (FSSI) (Heller & Factor 1991) is a checklist to measure formal support services needed and their usage by psychiatric clients and their families. The revised index contained 16 items related to family support services, and each item was rated for whether the family was in need of it (Yes/No) and whether they were receiving it (Yes/No). The responses to this scale indicate the number and types of services that families were in need of and receiving.
Study dates	2005 to 2006
Study location	Hong Kong
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation is not given. • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare Hong Kong and UK systems and cultures. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Chien W T, and Lee I Y (2011) Randomized controlled trial of a dementia care programme for families of home-resided older people with dementia. Journal of Advanced Nursing 67(4), 774-87**
Study type	RCT
Participants	Inclusion criteria: The participants in this study were family members caring for a relative with dementia at home, and they were recruited from the two largest dementia resources centres, which had about 1500 clients primarily diagnosed with dementia, representing 8% of this client population in Hong Kong. Participants were eligible for inclusion if: • They were aged at least 18 years and could speak and read Chinese; • They lived with a relative who was diagnosed as having the Alzheimer's type of dementia (mild or moderate illness stage) according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (American Psychiatric Association 1994), and they provided care for at least 4 hours per day. Exclusion criteria: If the person living with dementia had a co-morbidity of another mental illness. If the carer had a mental illness or cognitive impairment. If the carer had been the primary carer for <3 months.
Sample characteristics	N= 90 people living with dementia and their carers n= 45 experimental intervention: Dementia Family Care Programme (DFCP) 41.3%=female; 58.7%=male; mean age (SD)= 68.1 years (7.1); mean MMSE (SD)= 17.5 (4.7) n= 45 comparator: usual care 45.7%=female; 54.3%=male; mean age (SD)= 67.2 years (6.5); mean MMSE (SD)= 17.3 (3.9)
Intervention	For the Dementia Family Care Programme (DFCP), a multi-disciplinary committee including a psychiatrist, a social worker, a case nurse manager from each centre, and the researchers, selected 25 intervention goals and objectives from the recommended dementia guidelines established in the United States. The committee designed an information and psychological support system linking case managers and dementia care services, health professionals and referrals. One of the main components of the DFCP was the case managers, who received formal training by the research team and coordinated all levels of family care of clients with dementia. Each of the family participants (n = 46) was assigned one case manager, who conducted weekly home visits, family health and educational needs assessment using the Educational Needs Questionnaire, and education about dementia care. The case manager, together with another nurse in the centre, then summarized the needs assessment data to generate important problem areas in dementia caregiving. In collaboration with the caregivers, the case managers prioritized the problems and formulated an individualized education and support programme for effective dementia care for each family. This preparatory phase lasted about 1 month. After 1 month's needs assessment and preparation, the DFCP was conducted for individual families, lasting about 5

Bibliographic reference	Chien W T, and Lee I Y (2011) Randomized controlled trial of a dementia care programme for families of home-resided older people with dementia. Journal of Advanced Nursing 67(4), 774-87
	months. The family and the case manager met bi-weekly, for a total of 10 two-hour sessions. All family care sessions consisted of education, sharing and discussion, psychological support and problem-solving, in accordance with the common elements found effective in previous studies for caregivers. A protocol was specifically designed for this study, based on evidence from other family intervention studies in dementia. Seven major themes of family supportive care programmes identified from the literature were used in the DFCP along with the results of a needs assessment, including (1) information about the client's illness condition, prognosis, and current treatment and care; (2) the development of social relationships with close relatives and friends, and thus a satisfactory extended social support network; (3) sharing and adaptation of the emotional impact of caregiving; (4) learning about self-care and motivation; (5) improvement of interpersonal relationships between family members and the client; (6) establishing support from community groups and healthcare resources; and (7) improvement of home care and finance skills. To strengthen the problem solving skills within the families, one or two experienced family caregivers were invited to share their personal caregiving problems with the families during the third and fourth sessions. Under the guidance of the case manager, these problems were worked on by each family using a six-step model suggested by Zarit et al. (1985). The six steps included defining the problem, generation of alternatives, examining and evaluating each alternative, cognitive rehearsal of action plan, execution of the plan as homework, and evaluation of outcomes.
Comparison	The routine care group participants received the usual family services provided by the dementia resources centres. These services included (1) medical consultation of client and advice to family on client's illness condition, treatment plan and effects of medications provided weekly by a visiting psychiatrist; (2) advice and referrals for financial aid and social welfare services provided by a social worker in-charge of the centre; (3) education talks in dementia care conducted monthly by a registered psychiatric nurse; and (4) social and recreational activities organized weekly by staff at the centre.
Outcome measures	The family caregivers were asked to complete the Chinese versions of five scales for pre- and post-testing to assess the effects of the intervention. The questionnaires at below required about 40 minutes for completion. **Family Caregiving Burden Inventory** The Family Caregiving Burden Inventory (FCBI) is a 24-item scale developed by Novak and Guest (1989), which measures the impact of the burden on caregivers of elderly clients with dementia. Items are rated on a 5-point Likert scale from 0 (totally disagree) to 4 (totally agree). A respondent's total burden score ranges from 0 to 96, a higher score indicating a higher burden. **World Health Organisation Quality of Life Measure-Brief Version** The World Health Organisation Quality of Life Measure-Brief Version (WHOQoL-BREF) was modified from the WHOQoL-100 by the World Health Organisation (1995). Items are structured in four domains: physical health,

Bibliographic reference	Chien W T, and Lee I Y (2011) Randomized controlled trial of a dementia care programme for families of home-resided older people with dementia. Journal of Advanced Nursing 67(4), 774-87
	psychological, social relationship, and environment (i.e. seven items for each subscale). They are rated on a 5-point Likert scale with a high score indicating a better quality of life (total score range 28–144). **Six-item Social Support Questionnaire** A Six-item Social Support Questionnaire (SSQ6) developed by Sarason et al. (1987) measures satisfaction with social support available in their immediate social environment. The items are rated on a 6-point Likert scale, with higher total scores (0–30) indicating more satisfaction with the available social support. **Family Support Services Index** The Family Support Services Index (FSSI) (Heller & Factor 1991) is a checklist to measure formal support services needed and their usage by psychiatric clients and their families. The revised index contained 16 items related to family support services, and each item was rated for whether the family was in need of it (Yes/No) and whether they were receiving it (Yes/No). The responses to this scale indicate the number and types of services that families were in need of and receiving. **Neuropsychiatric Inventory Questionnaire** The Neuropsychiatric Inventory Questionnaire (NPI) is a rapidly administered instrument that provides a reliable assessment of behaviours commonly observed in clients with dementia (Cummings 1998, Kaufer et al. 2000). This is a 12-item scale and each item (symptom) is rated for frequency, severity and degree of caregiver distress produced. The total score for each domain is calculated by multiplying the frequency by the severity and a total score (range 12–144) is calculated by adding all the item scores together, representing the overall level of caregiver distress. The rates of clients' institutionalization (number and days/month of residential placement) in the previous 6 months were also measured at pre- and post-tests. **Mini Mental State Examination test** The Mini Mental State Examination test (MMSE) developed by Folstein et al. (1975) is a brief test for cognitive mental status, including an assessment in five domains: orientation to time and place, registration of three words/objects, attention and calculation, recall of objects, and language. As there is a high level of illiteracy among the Hong Kong elderly with cognitive impairment, a cut-off point of 18 is recommended for elderly people who are illiterate, 20 for those with 1–2 years of schooling, and 22 for those with more than 2 years of education (Chiu et al. 1994).
Study dates	2007 to 2009
Study location	Hong Kong
Comments	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	**Chien W T, and Lee I Y (2011) Randomized controlled trial of a dementia care programme for families of home-resided older people with dementia. Journal of Advanced Nursing 67(4), 774-87**
Risk of bias	• Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare Hong Kong and UK systems and cultures. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Chodosh J, Colaiaco B A, Connor K I, Cope D W, Liu H, Ganz D A, Richman M J, Cherry D L, Blank J M, Carbone Rdel, P , Wolf S M, and Vickrey B G (2015) Dementia Care Management in an Underserved Community: The Comparative Effectiveness of Two Different Approaches. Journal of Aging & Health 27(5), 864-93**
Study type	RCT
Participants	Inclusion criteria: Caregivers had to be at least 21 years old and either live with the care recipient (person with dementia) or be the identified primary support; the relationship must have been present for the prior 6 months. Care recipients had to have a prior dementia diagnosis and had to live in the community other than in a nursing facility. All caregivers were required to have telephone access, the ability to communicate in Spanish or English, and consent capacity. Exclusion criteria: No other exclusion criteria.
Sample characteristics	N= 43 people living with dementia and their carers n= 23 experimental intervention 1: Telephone care management 64.79%=female; 35.21%=male; mean age (SD)= 75.32 years (11.23); mean dementia severity (SD)= 10.65/17 (1.98) n= 20 experimental intervention 2: In-person care management 60.27%=female; 39.73%=male; mean age (SD)= 70.82 years (14.44); mean dementia severity (SD)= 10.82/17 (2.1)
Intervention	For the purposes of this review, the ‘intervention’ is care coordination by telephone.

Bibliographic reference	Chodosh J, Colaiaco B A, Connor K I, Cope D W, Liu H, Ganz D A, Richman M J, Cherry D L, Blank J M, Carbone Rdel, P , Wolf S M, and Vickrey B G (2015) Dementia Care Management in an Underserved Community: The Comparative Effectiveness of Two Different Approaches. Journal of Aging & Health 27(5), 864-93
	All care managers were social workers with previous experience with either bachelor's- or master's-level degrees. All care managers (both phone and in-person/community arms) attended community health fairs and visited local community agencies including day centres and other support services. Both care management strategies involved a common care management protocol, based on the ACCESS study, conducted over a 12-month period. This protocol included a structured initial assessment to generate a problem list and to guide care management activities tailored to the participant's problems. Care managers utilized pen-and-paper forms as well as an electronic database into which the structured initial assessment was programmed. Prevalent problems that could be identified included (a) unmet need for assistance; (b) lack of social support; (c) educational needs; (d) difficulty with managing dementia-related behavioural issues and safety concerns; (e) need for respite; (f) establishing advance care planning; (f) depression of the person with dementia as well as the caregiver; (g) management of other chronic medical issues—most notably medication management; and (h) need for diagnostic information and assistance with acute medical issues. Care managers worked collaboratively with caregivers to achieve problem prioritization and subsequent counselling, education, referrals as needed, and follow-up to achieve problem resolution. Protocols included counselling, education, self (caregiver)-management skills, referrals for community services and medical care (when needed), and proactive, ongoing follow-up. Care managers used a previously developed care manual (Vickrey et al., 2006) and added local, community-specific resources for connecting caregivers and care recipients to dementia-related services, including resources provided by the Alzheimer's Association and other agencies. Self-management of caregiver stress and problem solving are integral components of counselling and support that are facilitated by a review of common strategies, role-playing and regularly scheduled follow-up. Identification of certain issues including acute behaviour changes, untreated depression, or the need for clarification and assistance with medication management required physician referral. Care managers coached caregivers on how to have productive visits with physicians and provided them with assessment information to facilitate care. A complete re-assessment was planned at 6-months to capture new problems that were likely to develop in the dynamic process of caregiving for a condition that often fluctuates and progresses. Care managers were instructed to send a summary of their initial assessment to the primary care provider of the person with dementia recognizing that in this setting, a relationship with a primary care provider is often not established. Thus, the care managers anticipated needing to help some patients establish care with a network primary care provider. The minimum contact frequency was similar for the in person and telephone-only protocols, intended at every month for the first 3 months followed by at least quarterly contacts thereafter.

Bibliographic reference	Chodosh J, Colaiaco B A, Connor K I, Cope D W, Liu H, Ganz D A, Richman M J, Cherry D L, Blank J M, Carbone Rdel, P , Wolf S M, and Vickrey B G (2015) Dementia Care Management in an Underserved Community: The Comparative Effectiveness of Two Different Approaches. Journal of Aging & Health 27(5), 864-93
	We made some modifications to the intervention over time, to adapt to this setting. For example, although all caregivers had to have telephone access to be enrolled, we discovered that some caregivers did not respond to care managers because of limited minutes on their phone plan. We purchased cell phones and unlimited minutes for eight caregivers in which this need was identified, so that paying for phone time was not a barrier to communication with the care manager in either arm. The protocol was also modified to allow care managers to begin care management activities even if the initial assessment had not been completed. The two care management strategies differed in mode and intensity of care management delivery. The community-centred care management strategy included a care manager from a health care organization and a care manager from the local Alzheimer's Association; these individuals collaborated in providing the care management protocol through home visits and in-person interactions at local community facilities, in addition to telephone contacts but only in so far as sharing resources and consultation. The community centred care management arm was structured to provide the additional benefit of in-home visits supplemented by telephone whereas the telephone-only arm was intended to be as described—care management only by telephone. In-home visits were expected to provide unique assessment information (observation) that cannot be obtained by telephone and may build stronger relationships and trust. In the comparison strategy, a single care manager at OVMC delivered the care management protocol for the same number of study participants, but without face-to-face interaction. The community centred intervention was structured to include a minimum of seven contacts, primarily in-person but also by phone or mail, whereas the telephone-only approach included a minimum of this same number of contacts but solely by telephone or mail. Because of the anticipated increased workload in the community centred intervention due to time spent on travel for home visits, two care managers staffed this arm whereas the telephone-only arm utilized just one care manager, with randomisation of caregivers into each arm in a 1:1 ratio. The in-person (community-centred) care managers had greater opportunity to utilize the resources of the dementia- and caregiver-advocacy pre-established partner groups through the Los Angeles chapters of the Alzheimer's Association where one of the two in-person care managers was located. Thus, because the Alzheimer's Association local chapter used one care manager from the community-based arm, that community organization had direct involvement in care management. The in-person care managers also had the opportunity to work collaboratively, sharing information when necessary, and delegating responsibilities to one another based on the needs of the dyad, but each dyad had only one care manager. Although care management protocols did not differ from those of the telephone-only care manager, the in-person care managers had additional opportunities to identify potential psychosocial supports during home visits, as well as to visualize and assess clinically important issues and contexts such as medication management and environmental impacts/precursors of problem behaviour crises (Vickrey et al., 2006). The in-

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	person care managers were also able to directly supervise caregivers and educate them using modelling, repeat demonstration, and direct observation, potentially having a greater impact on caregiver mastery in caring for persons with dementia. Study staff provided approximately 24 hours of in-person training to care managers supplemented with detailed assessment protocols and intervention materials. Further training occurred during weekly 1-hr telephone meetings attended by all care managers at which time they presented and discussed individual cases ("clinical huddles"). Throughout the intervention period, during weekly meetings, care management procedures and individual cases were reviewed and discussed in a case conference format. The study care management trainer, a nurse-scientist with more than 15 years of dementia care experience, and a study geriatrician with dementia expertise and similar care management experience, attended the majority of these phone meetings, which addressed difficult management issues and ongoing education for care managers. At these weekly meetings, the study team leadership also reviewed one-by-one with each care manager all contact procedures, numbers of complete and incomplete contacts, efforts to achieve meetings with dyads, and strategies used to address identified dementia-related problems as guided by established study protocols. We found that clinical huddles utilized in training were useful, and we continued this weekly activity throughout the course of the intervention.
Comparison	For the purposes of this review, the 'comparison' or 'control' is care coordination in-person.
Outcome measures	The two primary outcome measures were caregiver burden measured by the Zarit Burden Interview (ZBI; Zarit, Reever, & Bach-Peterson, 1980), and care-recipient memory and problem behaviours measured by the Revised Memory and Behaviour Problem Checklist (RMBPC; Teri et al., 1992). These constructs have been identified as important mediators of nursing home placement (Mittelman, Haley, Clay, & Roth, 2006) and key drivers of caregiver and care-recipient quality of life. Declines in these outcome measures account for a substantial proportion of nursing home placement rates (Yaffe et al., 2002). **Caregiver burden**. The ZBI is a widely used, 22-item measure to assess stressors experienced by caregivers of persons with dementia and can be administered by telephone (Zarit et al., 1980). Items use a 5-point scale, ranging from "0" (never) to "4" (nearly always). Example questions are, "Do you feel you do not have enough time for yourself?" and "Do you feel your health has suffered because of your relative?" The ZBI taps health, psychological well-being, finances, social life, and relationship with the impaired person, and yields an overall summary score. **Problem behaviours of care recipients**. The RMBPC (Teri et al., 1992) includes three domains of care receiver problems (behaviour, memory, and depression) and caregiver's reaction to each of these problems. The three domain subscales and the summary score each have a corresponding subscale for caregiver reaction. The RMBPC also assesses whether the behaviour changed or is new in the last 4 weeks, and it accounts for different reactions

Bibliographic reference	**Chodosh J, Colaiaco B A, Connor K I, Cope D W, Liu H, Ganz D A, Richman M J, Cherry D L, Blank J M, Carbone Rdel, P , Wolf S M, and Vickrey B G (2015) Dementia Care Management in an Underserved Community: The Comparative Effectiveness of Two Different Approaches. Journal of Aging & Health 27(5), 864-93**
	to certain types of behaviour problems by eliciting how much the behaviour is bothersome to the caregiver. **Caregiver depression**. The Patient Health Questionnaire-9 items (PHQ-9; Kroenke, Spitzer, & Williams, 2001) is a 9-item self-report measure of depressive symptoms over the previous 2 weeks and is the depression module of the PRIME-MD diagnostic instrument for common mental disorders (Spitzer, Kroenke, & Williams, 1999). It covers each of the nine Diagnostic and Statistical Manual of Mental Disorders (4th ed.; DSM-IV; American Psychiatric Association, 1994) depression criteria scoring them as “0” (not at all) to “3” (nearly every day). **Caregiver quality of life**. The Caregiver Quality of Life instrument (CGQOL; Vickrey et al., 2009) was developed and tested for dementia caregivers and is applicable to caregivers of diverse ethnic backgrounds, with demonstrated feasibility as a phone-based instrument in both English and Spanish (Vickrey et al., 2009). This 80-item instrument covers 10 dimensions of quality of life and incorporates non-health-related issues as well as positive aspects of caregiving. The researchers selected two CG-QOL scales (11 items total) for their study: “Spirituality and faith,” and “Benefits of caregiving.” Care-recipient quality of life was assessed by proxy (caregiver) assessment using the Health Utilities Index (HUI; Horsman, Furlong, Feeny, & Torrance, 2003; Torrance et al., 1996), a generic health state classification system with preference-based utility weights derived from the general population (Torrance et al., 1996; Vickrey et al., 2009). The HUI is widely used, including previous studies of elderly with dementia and their family caregivers. Caregivers can provide proxy ratings for the individual with dementia. **Other measures**. A range of process measures of dementia care quality were assessed by caregiver survey (Vickrey et al., 2006). They also measured aspects of the care recipient’s health care utilization by caregiver survey, including emergency room visits, hospital admissions, and nursing home placement (distinct from respite care use). The survey included the Blessed Roth Dementia Scale to measure dementia severity (Blessed, Tomlinson, & Roth, 1988) and the Bi-Dimensional Acculturation Scale (BAS) for Hispanics (Marin & Gamba, 1996), which measures years in United States, primary language, connection to Hispanic heritage, and family traditions.
Study dates	Not provided. This study was published in 2015.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes. The people conducting the telephone surveys were blinded. • Were the groups similar at the start of the trial? Unclear. The ages of participants in the telephone group were approximately 5 years older. However, their mean dementia severities were similar.

Bibliographic reference	**Chodosh J, Colaiaco B A, Connor K I, Cope D W, Liu H, Ganz D A, Richman M J, Cherry D L, Blank J M, Carbone Rdel, P , Wolf S M, and Vickrey B G (2015) Dementia Care Management in an Underserved Community: The Comparative Effectiveness of Two Different Approaches. Journal of Aging & Health 27(5), 864-93**
	• Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? No: 28% of participants became “unreachable” as time progressed. • Can the results be applied to the local population? Unclear. It is difficult to compare US and UK systems. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Chu P, Edwards J, Levin R, and Thomson J (2000) The use of clinical case management for early stage Alzheimer's patients and their families. American-Journal-of-Alzheimer's-Disease 15(5), 284-90**
Study type	RCT
Participants	Inclusion criteria: Eligibility criteria for the person with dementia were: 1) had a possible diagnosis of early stage AD; 2) did not have a serious concomitant illness; 3) was not at imminent risk of placement to a long term facility; 4) lived in the city; and 5) was not in the regular home care program and not eligible for the program. Criteria for caregivers included: 1) identified himself or herself as the principle informal caregiver for the client; 2) did not have a serious illness; and 3) lived with the client or in the city. Exclusion criteria: No other exclusion criteria.
Sample characteristics	N= 69 people living with dementia and their carers n= 33 experimental intervention: case management Mean MMSE (SD)= 22.7 (3.8) n= 36 comparator: usual care Mean MMSE (SD)= 22.8 (4.2) The researchers write that there were no significant demographic differences between the two groups.
Intervention	The Early Home Care Program provided case management, occupational therapy, physical therapy, social work, nursing, respiratory therapy, in home respite, and out-of-home respite, homemaking, personal care assistance, volunteer service and psychiatric consultation. The objectives of the program were to assist the clients and family to: 1) initiate long term planning early related to issues such as housing, finance, legal matters and caregiving support; 2) increase the early use of home care and other community services; 3) improve the coping strategies related to

Bibliographic reference	Chu P, Edwards J, Levin R, and Thomson J (2000) The use of clinical case management for early stage Alzheimer's patients and their families. American-Journal-of-Alzheimer's-Disease 15(5), 284-90
	psychosocial issues which often hinder long term planning and service utilization; and 4) improve caregiving strategies related to functional and behavioural difficulties of the individuals with AD. The goal was to prepare clients and families for the crises that occur along the course of the disease. When clients and families were admitted to the Early Home Care Program, initial interventions consisted primarily of education, referrals to community resources, ongoing monitoring, supportive counselling and caregiving skill training. The case manager made monthly contact by phone or home visit. The frequency of contacts increased as needed and professionals such as occupational therapist, nurse and social worker were involved as appropriate. As the client's cognitive and functional status declined, the case manager promoted and facilitated the use of homemaking, personal care assistance, and in-home, as well as out-of-home, respite services. The case manager provided most of the education regarding the disease process, community services, legal and housing issues, and long term planning, as well as referrals. It was found that information often needed to be repeated during several home visits before the client and family would, or could, internalize it. In those instances, subjects seemed unprepared emotionally to accept information concerning the dementia progression, particularly when the diagnosis had just been made. Also, referrals often required several home visits to complete because the family needed emotional support, encouragement, and facilitation in order to follow through. The case manager continuously monitored the progress of the education and referral as well as the psychosocial and functional status of the client and family. As time progressed, the case manager encouraged the early use of homemaking service. It seemed the client and caregiver perceived the homemaking service as less intrusive and were generally more willing to try it. In this way, the clients and caregivers were familiarized with using in-home services and paid care providers. Also, the case manager strongly promoted the use of the day program. The case manager provided supportive counselling to the client and family regarding psychosocial issues such as grief, guilt and family conflicts. These issues frequently hindered the family's ability to make long term plans, to attempt alternative caregiving strategies, or to use services. The case manager also provided skills training related to strategies for compensating for functional and behavioural decline in the person with AD drawing on other disciplines as required.
Comparison	Usual care
Outcome measures	Data was collected at baseline and at 18 months. The Mini-Mental State Examination (MMSE) was used to measure the cognitive status of the person with AD. The Geriatric Depression Scale-Short Form (GDS) was applied to measure the level of depressive symptoms. Alberta Assessment and Placement Instrument (AAPI) was used to measure functional performance of the persons with AD. The Burden Interview was applied to measure the burden experienced by caregivers. Memory and Behaviour Checklist was used to measure the frequency of occurrence of the disturbing behaviours

Bibliographic reference	**Chu P, Edwards J, Levin R, and Thomson J (2000) The use of clinical case management for early stage Alzheimer's patients and their families. American-Journal-of-Alzheimer's-Disease 15(5), 284-90**
	exhibited by the persons with AD and the caregivers' reaction. The Centre for Epidemiological Studies-Depression Scale (CES-D) was used to measure the level of depressive symptoms of the caregivers.
Study dates	Not provided. This study was published in 2000.
Study location	Canada
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation is not given. • Were clinicians and investigators blinded? Unclear. Blinding is not mentioned. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare the Canadian and UK systems. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Dias A, Dewey M E, D'Souza J, Dhume R, Motghare D D, Shaji K S, Menon R, Prince M, and Patel V (2008) The effectiveness of a home care program for supporting caregivers of persons with dementia in developing countries: a randomised controlled trial from Goa, India. PLoS ONE [Electronic Resource] 3(6), e2333**
Study type	RCT
Participants	Inclusion criteria: Mild and moderate dementia. Exclusion criteria: Severe dementia or severe co-morbid physical health conditions.
Sample characteristics	N= 59 people living with dementia and their carers. n= 33 experimental intervention: Home care intervention. Mean age (SD) = 79.4 years (8) n= 26 comparator: usual care

Bibliographic reference	**Dias A, Dewey M E, D'Souza J, Dhume R, Motghare D D, Shaji K S, Menon R, Prince M, and Patel V (2008) The effectiveness of a home care program for supporting caregivers of persons with dementia in developing countries: a randomised controlled trial from Goa, India. PLoS ONE [Electronic Resource] 3(6), e2333**
	Mean age (SD) = 77.3 years (8)
Intervention	The principles of the intervention were that, first, it had to utilise locally available health and human resources so that there was a good probability that it might be affordable for scaling up; and second, that it needed to be community and homebased, since many people with dementia and their families had difficulties accessing public health services. The intervention was a flexible, stepped-care model primarily aimed to improve the awareness and knowledge of family caregivers regarding dementia, to provide emotional support to caregivers, to maximise their caregiving resources and to improve their caregiving skills. The intervention was delivered by a Community Team, one for each taluka. Each team comprised two full-time Home Care Advisors (HCA), and a part-time local psychiatrist from the public health services, and a part-time lay counsellor (who was shared by both teams). The minimum requirements for being a HCA were knowledge of the local language, being literate, preferably passed higher secondary school, and motivated to be involved in the community care of older people. They received intensive training for a week through role play and interactive training methods. The HCA were trained in key skills including listening and counselling skills, bereavement counselling, stress management and health advice for common health problems. The specific components of the intervention carried out by the HCA were: • Basic education about dementia (what is the disease, its course, its features etc). • Education about common behaviour problems and how they can be managed. • Support to the caregiver, for example for an elderly caregiver living alone with the patient, in activities of daily living. • Referral to psychiatrists or the family doctor when behaviour problems are severe and warrant medication intervention. • Networking of families to enable the formation of support groups. • Advice regarding existing government schemes for elders. The HCA applied a flexible home-care program tailored to the needs of the individual and the family. The baseline information collected by the researchers was made available to the HCA before they initiated the intervention. The minimum frequency of visits was at least once a fortnight for six months. The maximum was based on the needs as assessed by the HCA. Thus, the visits could be more frequent depending on the need of that particular family. The HCA were supported, and supervised, by the two part-time specialists: two psychiatrists (one supporting each team) and one counsellor (supporting both teams). Each person with dementia was seen at least once by a local psychiatrist who advised regarding use of medication for behaviour and other common medical problems based on

Bibliographic reference	**Dias A, Dewey M E, D'Souza J, Dhume R, Motghare D D, Shaji K S, Menon R, Prince M, and Patel V (2008) The effectiveness of a home care program for supporting caregivers of persons with dementia in developing countries: a randomised controlled trial from Goa, India. PLoS ONE [Electronic Resource] 3(6), e2333**
	an agreed protocol. The caregiver and the person with dementia were encouraged to visit the psychiatrist in the clinic so that, if medication or clinical investigations were needed, these could be availed of at no cost from the public health service, and because the time required for travel for the psychiatrist for home visits was considered to be a precious resource. A home visit was arranged if a clinic visit was not possible. HCA would meet the psychiatrist twice a month and update them on the progress of the person with dementia, particularly those who were receiving medication. The other specialist was a lay counsellor who had herself been a caregiver for a parent with dementia. The HCA from both talukas met with the counsellor once a fortnight to share experiences, support one another, and problem solve difficult situations.
Comparison	The control arm dyads received only education and information regarding dementia and were then placed in a waiting list to receive the intervention after 6 months. They were free to utilize the existing health services during this time.
Outcome measures	Measurements were taken at baseline and at 6 months: • Caregiver mental health (GHQ score). • Caregiver burden (Zarit Burden score), • Distress due to problem behaviours (NPI-D) • Severity of the behavioural problems in the person with dementia (NPI-S) • Functional ability of the subject (EASI).
Study dates	Not provided. The study was submitted for publication in 2007.
Study location	Goa, India
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Unclear. The intervention group had less mean income per month: 1209 rupees (SD 100-5000) vs 1768 rupees (SD 200-13333). • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare India to the UK.

Bibliographic reference	**Dias A, Dewey M E, D'Souza J, Dhume R, Motghare D D, Shaji K S, Menon R, Prince M, and Patel V (2008) The effectiveness of a home care program for supporting caregivers of persons with dementia in developing countries: a randomised controlled trial from Goa, India. PLoS ONE [Electronic Resource] 3(6), e2333**
	• Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Eloniemi-Sulkava U, Notkola I L, Hentinen M, Kivela S L, Sivenius J, and Sulkava R (2001) Effects of supporting community-living demented patients and their caregivers: a randomized trial. Journal of the American Geriatrics Society 49(10), 1282-7**
Study type	RCT
Participants	Inclusion criteria: Age 65 and older and entitled to payments from the Social Insurance Institution for community care because of a dementing disease. Exclusion criteria: Other severe diseases (e.g., severe stroke, cancer) that might lead to institutionalisation in the near future. They excluded people living with dementia if they and their caregivers were not able to participate in annual training courses.
Sample characteristics	N= 100 people living with dementia and their carers n= 53 experimental intervention: Care coordination 49%=female; 51%=male; mean age (range)= 78.8 years (65-97); mean MMSE (SD)= 14.4 (6.2) n= 47 comparator: usual care 57%=female; 43%=male; mean age (range)= 80.1 years (67-91); mean MMSE (SD)= 15.3 (5.5)
Intervention	Patients in the intervention group and their caregivers were enrolled in a 2-year support program. The program, based on nurse case management, involved systematic and comprehensive support for the patients and their caregivers by the dementia family care coordinator, who had access to the physician. The coordinator was a registered nurse with a public health background. They worked at the Department of Public Health and General Practice in the University of Kuopio. At the beginning and throughout the study, the coordinator received extensive training, support, and advice in dementia care from dementia specialists. The coordinator, as a nurse case manager, coordinated the care, services, and support of the families. The coordinator provided: • Advocacy for patients and their caregivers. • Comprehensive support for the patients and their caregivers. • Continuous and systematic counselling.

Bibliographic reference	Eloniemi-Sulkava U, Notkola I L, Hentinen M, Kivela S L, Sivenius J, and Sulkava R (2001) Effects of supporting community-living demented patients and their caregivers: a randomized trial. Journal of the American Geriatrics Society 49(10), 1282-7
	• Annual training courses for patients and their caregivers. • Follow-up calls. • In-home visits. • Assistance with arrangements for social and healthcare services. • 24-hour-per-day availability by mobile telephone. During the study, the frequency of contacts varied from once a month to five times a day depending on the situation of the patients and their caregivers. Problematic situations at home accounted for the great variability in the number of contacts. In such problematic situations and crises, which threatened the continuity of community care, the coordinator was persistent in trying to find solutions. When needed, the coordinator contacted the physician in the study for consultation and medical care. The caregivers contacted the coordinator only 10 times outside working hours in the 2 years. Because the coordinator had no extra money to buy services for the patients, only those services within the financial means of the patients were used. The coordinator documented the services that were planned and arranged and her contacts with the patients, their caregivers, and the social and healthcare system. The coordinator also documented the problematic situations and the intervention measures delivered in solving the problems. Annual training courses (eight to 10 patients with their caregivers in each course) provided the educational part of the intervention program. The patients and their caregivers were admitted to the Brain Research and Rehabilitation Center “Neuron” for the courses. The first course was conducted at the beginning of the study and lasted 10 days. The following two courses were conducted 1 year and 2 years later and lasted 5 days. The purpose of the courses was to support the functional abilities and adaptation of both the patients and their caregivers. They included a medical check-up and psychological assessment of the patients and various kinds of physical, mental, and social activities for both patients and caregivers. There were lectures on dementia, dementia care, and support systems for the caregivers. Separate group meetings for patients and caregivers were provided, allowing participants to share their feelings and experiences with others in similar situations. During each course, a service plan was made for each family, and the dementia family care coordinator then arranged the planned services, with the caregiver’s permission and at the patient’s expense.
Comparison	Based on the patients’ needs and wishes, the control group received the usual services provided for geriatric patients in community care by the municipal social and healthcare system or the private sector.
Outcome measures	Measurements were taken at baseline and at two years.

Bibliographic reference	**Eloniemi-Sulkava U, Notkola I L, Hentinen M, Kivela S L, Sivenius J, and Sulkava R (2001) Effects of supporting community-living demented patients and their caregivers: a randomized trial. Journal of the American Geriatrics Society 49(10), 1282-7**
Study dates	1993 to 1995
Study location	Finland
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes. Clinicians who advised on institutionalisation were blinded to the study. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare systems in Finland to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Eloniemi-Sulkava U, Saarenheimo M, Laakkonen M L, Pietila M, Savikko N, Kautiainen H, Tilvis R S, and Pitkala K H (2009) Family care as collaboration: effectiveness of a multicomponent support program for elderly couples with dementia. Randomized controlled intervention study. Journal of the American Geriatrics Society 57(12), 2200-8**
Study type	RCT
Participants	Inclusion criteria: Couples were eligible for the study if one spouse was caring for a partner with dementia at home and they were living in Helsinki. All participants with dementia had to have an etiological diagnosis of dementia based on a specialist's examinations, including brain computed tomography or magnetic resonance scans. Other inclusion criteria for participants with dementia were a minimum score of 1.0 on the Clinical Dementia Rating Scale (CDR) and a maximum score of 23 on the Mini-Mental State Examination (MMSE). Exclusion criteria: Couples in which one spouse had another severe disease (e.g., cancer) with a prognosis of an estimated life span of less than 6 months were excluded.
Sample characteristics	N= 125 people living with dementia and their carers

Bibliographic reference	**Eloniemi-Sulkava U, Saarenheimo M, Laakkonen M L, Pietila M, Savikko N, Kautiainen H, Tilvis R S, and Pitkala K H (2009) Family care as collaboration: effectiveness of a multicomponent support program for elderly couples with dementia. Randomized controlled intervention study. Journal of the American Geriatrics Society 57(12), 2200-8**
	n= 63 experimental intervention: multicomponent support programme 42.9%=female; 57.1%=male; mean age (SD)= 78 years (7.2); mean MMSE (SD)= 13.4 (6.2) n= 62 comparator: usual care 32.3%=female; 67.7%=male; mean age (SD)= 77 years (6.4); mean MMSE (SD)= 14.2 (6.6)
Intervention	The intervention couples were enrolled in a support program for the maximum of 24 months, but the length of time varied because of the phased recruitment and the attrition of the participants. The end of the intervention was the end of the follow-up period or the long-term institutionalisation or death of the spouse with dementia. Several elements of the intervention were based on a previous intervention. The core elements of the intervention consisted of a family care coordinator's (FCC's) actions, a geriatrician's medical investigations and treatments, goal-oriented support group meetings for spouse caregivers, and individualized services. Well-established working principles influenced by awareness of problems in current service systems that have been identified in many previous studies guided the intervention. Client-centeredness was emphasised. All of the coordinated services were planned in collaboration with the families, respecting the autonomy and enhancing empowerment of the couples. The couples' needs to maintain their customary way of life was appreciated. In addition, the flexibility and immediacy of support actions were emphasised. A home visit from the FCC initiated the intervention. During the visit, the initial support plan was created in cooperation with the couples. The geriatrician's appointments and comprehensive geriatric assessments and treatment for the patients with dementia and, by request, also for the caregivers followed the visit. The intervention couples continued their own physician's visits in the primary care system or the private sector, although the FCC and the geriatrician cooperated closely with them and also made sure that the intervention was properly implemented using municipal services or purchased from the intervention budget (as described below). The FCC was a trained public health registered nurse with advanced practice education (3.5 years) and special education in dementia care (1 year). The FCC was responsible for providing the versatile, individually tailored, need-based support activities. The services were primarily arranged through the municipal social and healthcare system, although if required services were not available in the municipal service system, the FCC was able, through an intervention budget, to tailor services for the couples using private sector or non-profit organizations. The FCC operated in partnership with the geriatrician, whose medical expertise the intervention couples had at their disposal. The FCC and the geriatrician had broad expertise in dementia care and good knowledge of the public service system. The FCC and the geriatrician worked in the Central Union for the Welfare of the Aged in Helsinki. A

Bibliographic reference	**Eloniemi-Sulkava U, Saarenheimo M, Laakkonen M L, Pietila M, Savikko N, Kautiainen H, Tilvis R S, and Pitkala K H (2009) Family care as collaboration: effectiveness of a multicomponent support program for elderly couples with dementia. Randomized controlled intervention study. Journal of the American Geriatrics Society 57(12), 2200-8**
	dementia expert trained them for their work and tutored them throughout the intervention. The caregivers participated in five goal-oriented peer support group meetings during the first follow-up year (7–10 participants in 7 groups). Each group meeting had a different theme relevant to family caregiving. Together, the participants were able to share and compare their experiences. The group leaders were specially trained to lead the groups. In addition, the group meetings were tape recorded and the group leaders tutored to ensure the fidelity of this element of intervention. Rehabilitation groups were arranged simultaneously for the spouses with dementia in the same setting to enable the spousal caregiver to attend the meetings. Some elements of the intervention were initiated by and developed in cooperation with the caregiving couples. Three 2-hour dementia information sessions were arranged for the caregivers and their interested family members. A large proportion of patients with dementia received home-based exercise training according to individual assessment. During the first year of the intervention, five group meetings were arranged to support addressing challenging caregiving situations (e.g., BPSDs) at home.
Comparison	Couples in the control group continued in usual community care and received care and services from the municipal social and healthcare system, the private sector, or both, depending on their own initiative. The Finnish municipal service system includes a large variety of services, and families with members with dementia have the right to access these services. Furthermore, the control families were provided with information and referrals to community resources, written educational materials, and opportunities to share experiences and feelings with the study nurse in baseline assessments and 6- and 12-month study follow-up visits.
Outcome measures	Percentage of people living with dementia who had been admitted to long-term institutional care by the end of the study (2 years).
Study dates	2004 to 2006
Study location	Finland
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Yes

Bibliographic reference	**Eloniemi-Sulkava U, Saarenheimo M, Laakkonen M L, Pietila M, Savikko N, Kautiainen H, Tilvis R S, and Pitkala K H (2009) Family care as collaboration: effectiveness of a multicomponent support program for elderly couples with dementia. Randomized controlled intervention study. Journal of the American Geriatrics Society 57(12), 2200-8**
	• Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Unclear. Drop-out rates are not mentioned. • Can the results be applied to the local population? Unclear. It is difficult to compare Finland to the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Fortinsky R H, Kulldorff M, Kleppinger A, and Kenyon-Pesce L (2009) Dementia care consultation for family caregivers: collaborative model linking an Alzheimer's association chapter with primary care physicians. Aging & Mental Health 13(2), 162-70**
Study type	RCT
Participants	Inclusion criteria: Patients were eligible for this study if they had a physician's diagnosis of any type of irreversible dementia; resided in a home setting outside of a nursing home or assisted living facility; ambulated without constant human assistance; used the referring physician as their regular source of medical care; and had at least one identifiable family caregiver. Caregivers were eligible if they were related to eligible patients; had primary or shared responsibility for patients' health-related needs, and were known by the referring physician's office staff. These criteria were intended to include community-dwelling, ambulatory dementia patients seen by a primary care physician, and cared for by a family member who is familiar to the physician. Exclusion criteria: none other
Sample characteristics	N= 84 people living with dementia and their carers. However, 11% dropped out and the numbers who dropped out for each group is not given. n= 54 experimental intervention: care management program that involves monthly meetings 61%=female; 39%=male; mean age (SD)= 81.8 years (8.8); mean cognitive status score (SD)= 11.0 (7.2) n= 30 comparator: usual care 70%=female; 30%=male; mean age (SD)= 81.7 years (7.6); mean cognitive status score (SD)= 11.7 (5.7)
Intervention	The over-riding principle of the dementia care consultation intervention was that family caregivers, with proper guidance and reinforcement, would learn about dementia symptom management and available services to help them care for their relatives in a home setting. A successful intervention would increase family caregivers' self-

Bibliographic reference	Fortinsky R H, Kulldorff M, Kleppinger A, and Kenyon-Pesce L (2009) Dementia care consultation for family caregivers: collaborative model linking an Alzheimer's association chapter with primary care physicians. Aging & Mental Health 13(2), 162-70
	efficacy in the behavioural domains of symptom management and service access, leading to a lower rate of nursing home admission among patients related to intervention group family caregivers. Self-efficacy refers to the amount of confidence individuals have that they can achieve specific behaviours or actions. Maximizing family caregivers' self-efficacy is especially important when their relatives have dementia, because as the disease progresses, caregivers are increasingly responsible for specific care decisions and behaviours. Self-efficacy among family caregivers of people with dementia also has an influence on psychological health, as low levels of self-efficacy and confidence have been associated with higher levels of depression and burden among family caregivers of persons with dementia. The dementia care consultant training protocol mandated the use of a standardized assessment tool and process. The intervention protocol called for the care consultant to have monthly contact for 12 months with each family caregiver. Responsibilities at each contact were to determine which aspects of dementia symptoms and care responsibilities caused caregiver concerns, discuss action steps to address caregiver concerns, and compose a written care plan. Each monthly care plan was organized according to problems or concerns expressed by the family caregiver, whether related directly to their relative (e.g., agitation, wandering), or to the caregiver (e.g., emotional distress), along with action steps that caregivers should take to address each concern. The minimum care plan for all family caregivers included the action steps that family caregivers should take to learn more about or use; key information about the clinical course of the disease process; legal and financial planning issues; family support groups; dementia educational programs offered by the chapter and other organisations; adult day care services; and respite care services. The care consultant's initial and final meetings with family caregivers occurred in the home of the family caregiver and/or patient. The care consultant also was trained to fax each written care plan to the patient's physician, with the expectation that the physician would review the care plan(s) with the family caregiver and patient during subsequent office visits, inquire if action steps had been taken, and reinforce the importance of carrying out the care plan. The care consultant also offered to provide physicians and/or their office personnel with explanations and further detail regarding any aspect of the care plan.
Comparison	Usual care
Outcome measures	The primary outcome, nursing home admission, was measured as whether or not patients were admitted to a long-stay nursing home within 12 months after the baseline interview. Nursing home admission was determined in two ways. First, family caregivers were asked at the 12-month interview where their relative lived at that time. If they mentioned a nursing home for permanent residence, the subject was coded as a nursing home admission. Second, the care consultant notified the research team when any people with dementia cared by intervention group subjects were admitted for long-term nursing home stays. These reported events were verified with family

Bibliographic reference	**Fortinsky R H, Kulldorff M, Kleppinger A, and Kenyon-Pesce L (2009) Dementia care consultation for family caregivers: collaborative model linking an Alzheimer's association chapter with primary care physicians. Aging & Mental Health 13(2), 162-70**
	caregivers at the 12-month interview. The remaining dependent variables were assessed during baseline and 12-month interviews. Two measures of self-efficacy for managing dementia were used to determine the impact of the intervention on caregiver self-efficacy. These measures determined how certain family caregivers were that they could manage their relatives' dementia symptoms, and access community support services when needed. All items began with the phrase: "How certain are you right now that you can . . .?". Responses ranged from 1 (not at all certain) to 10 (very certain), and caregivers were asked to place themselves on the 10-point response scale. Five items comprised the symptom management self-efficacy measure, and four items comprised the community support service use self-efficacy measure. Caregiver burden was measured using the 22-item Revised Caregiver Burden Scale. Caregivers' depressive symptoms were measured using the 20-item Center for Epidemiological Studies Depression inventory. Caregivers' physical health symptoms were measured using 12 items expressing physical signs and symptoms from the Hopkins Symptoms Checklist.
Study dates	Not provided. This study was submitted for publication in 2008.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of site randomisation was not explained. • Were clinicians and investigators blinded? No. Follow-up interviewers were not blinded. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? No. 11% dropped out and it was not explained why. • Can the results be applied to the local population? Unclear. It is difficult to compare US and UK systems. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Jansen A P, van Hout , H P, Nijpels G, Rijmen F, Droes R M, Pot A M, Schellevis F G, Stalman W A, van Marwijk , and H W (2011) Effectiveness of case management among older adults with early symptoms of dementia and their primary informal caregivers: a randomized clinical trial. International Journal of Nursing Studies 48(8), 933-43**
Study type	RCT
Participants	Inclusion criteria: Persons were eligible for trial entry if they had scores on the MMSE below 24 or a risk of dementia of 50% or more according to the 7MS and if a primary caregiver was present. The primary caregiver was defined as the caregiver who spent most hours on the caring process and/or who coordinated the caring process. Exclusion criteria: Assistance by an outpatient geriatric or psychiatric team for cognitive problems, terminal illness, insufficient command of the Dutch language, participation in other research projects, and institutionalization. Exclusion criteria for caregivers were terminal illness, providing less than 1 h of care a week, and insufficient command of the Dutch language.
Sample characteristics	N= 81 people living with dementia and their carers n= 43 experimental intervention: case management by district nurses 70%=female; 30%=male; mean age (SD)= 82.1 years (5.7); mean MMSE (SD)= 22.0 (4.2) n= 38 comparator: usual care 58%=female; 42%=male; mean age (SD)= 81.0 years (6.5); mean MMSE (SD)= 22.7 (3.8)
Intervention	During one year, three district nurses who were specialized in geriatric care, acted as case managers. The nurses had mainly a coordinating function consisting of assessment, giving advice and information, planning, coordinating, organizing collaboration, and monitoring of care. The nurses started the intervention with a home-visit in which they administered the Resident Assessment Instrument Home Care (RAI-HC). The RAI-HC is a computerized multidimensional instrument that consists of a Minimum Data Set, which assesses the general functioning of the patient, and Client Assessment Protocols, providing protocols for the management of 30 potential and actual problem areas. Together with the participants, the nurses ordered the problems identified into a hierarchy of importance, and they formulated a care plan. Subsequently, they left behind a form to register care and the agreements made with health care professionals. In the second home-visit, the nurses explored the caregiver's situation with a capacity and burden questionnaire to formulate a care plan. They handed a guide holding available social and welfare services. After these two visits, the nurses and participants decided how to proceed. When more visits were not considered necessary, the nurses contacted the participants at least every 3 months by telephone to monitor their situation. In addition, the nurses were available for consultation by telephone. The nurses visited the PCPs to inform them about the participants' situation. Apart from these standard activities, the intervention held some tailor-made activities. For instance, the nurses

Bibliographic reference	**Jansen A P, van Hout , H P, Nijpels G, Rijmen F, Droes R M, Pot A M, Schellevis F G, Stalman W A, van Marwijk , and H W (2011) Effectiveness of case management among older adults with early symptoms of dementia and their primary informal caregivers: a randomized clinical trial. International Journal of Nursing Studies 48(8), 933-43**
	referred patients and caregivers to other health care professionals, including diagnostic services, and they monitored the anticipated effect. In addition, the nurses organized family-meetings aimed at educating relatives, improving social support and relieving the primary caregiver. The nurses were trained in working with RAI-HC and in organising family-meetings. They also attended seminars on how to deal with dementia patients and their caregivers. They met monthly to discuss innovations and geriatric cases while supervised by a staff member of their home care organisation.
Comparison	Usual care in the Netherlands comprehends a diversity of health care and welfare services. Participating pairs received care depending on their own initiative. They had no access to family meetings, nor were they offered an assessment with the RAI-HC, because these supportive activities are not offered regularly in the Netherlands.
Outcome measures	Outcomes were assessed by means of interviews and caregiver-completed questionnaires at baseline and after 12 months. Primary outcome was caregiver's sense of competence measured with the three subscales of the Sense of Competence Questionnaire (SCQ; with higher scores indicating better sense of competence): consequences of involvement in care for the personal life of the caregiver (scores ranging from 8 to 40), satisfaction with one's own performance as a caregiver (12–60) and satisfaction with the care recipient (7–35). Secondary outcomes were caregiver's quality of life, measured with the Caregiver's (SF-36), caregiver's depressive symptoms determined with the Center for Epidemiologic Studies Depression Scale (CES-D) (0–60), burden measured with the Self-Perceived Pressure by Informal Care (SPPIC) (0–9) (Pot et al., 1995), patient's quality of life measured with the subscales self-esteem, positive affect, negative affect, feelings of belonging, sense of aesthetics, and overall perception on quality of life of the Dementia Quality of Life Instrument (DQOL) (1–5). Apart from these outcomes, they assessed the following variables of the caregiver at baseline: socio-demographic characteristics (age, gender, educational level, relation with the care recipient, (not) living together with the care recipient), months spent on caring, hours spent on caring a week, help from other persons, functioning in activities of daily living (ADL) and instrumental activities of daily living (IADL) measured with the Groningen Activity Restriction Scale (GARS) (18–72), presence of chronic diseases, mastery over one's life measured with the Mastery Scale (7–35), caregiver's distress due to patient's behavioural problems measured with the distress-subscale of the Neuropsychiatric Inventory (NPI-Q) (0–60), and social support measured with the social support list (SSL-I, subscale positive interactions) (34–136). On patient level at baseline we assessed sociodemographic characteristics (age, gender, last job level), presence of chronic diseases, patient's initiative to perform self-care (0–36) and patient's actual performance of self-care (0–44) measured with the Interview for Deterioration in Daily living activities in Dementia (IDDD), behavioural problems measured with the Neuropsychiatric Inventory (NPI-Q) (0–36), and

Bibliographic reference	**Jansen A P, van Hout , H P, Nijpels G, Rijmen F, Droes R M, Pot A M, Schellevis F G, Stalman W A, van Marwijk , and H W (2011) Effectiveness of case management among older adults with early symptoms of dementia and their primary informal caregivers: a randomized clinical trial. International Journal of Nursing Studies 48(8), 933-43**
	urinary incontinence. Health care utilization of pairs was measured continuously by means of caregivers' self-reports.
Study dates	Not provided. This study was received for publication during 2009.
Study location	The Netherlands
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare the system in the Netherlands to that in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Kwak J, Montgomery R J, Kosloski K, and Lang J (2011) The impact of TCARE on service recommendation, use, and caregiver well-being. Gerontologist 51(5), 704-13**
Study type	RCT
Participants	Inclusion criteria: A short standardised screening tool was used to identify caregivers whose score on one or more of the five major outcome areas (caregiver identity discrepancy, objective burden, relationship burden, stress burden, or depression) was above a pre-set cutoff or they indicated that they "probably would" or "definitely would" place their care receivers in a nursing home in the near future. Exclusion criteria: None other
Sample characteristics	N= 74. The results section says: "Over 70% of care receivers were diagnosed with probable Alzheimer's disease." n= 41 (assuming equal numbers dropped out of both arms) experimental intervention: Tailored Caregiver Assessment and Referral (TCARE®) protocol, a care management process designed to help family caregivers, on

Bibliographic reference	Kwak J, Montgomery R J, Kosloski K, and Lang J (2011) The impact of TCARE on service recommendation, use, and caregiver well-being. Gerontologist 51(5), 704-13
	care planning and caregiver outcomes. Caregiver characteristics: 90.6%=female; 9.4%=male; mean age (SD)= 62.81 years (13.4) n= 32 (assuming equal numbers dropped out of both arms) comparator: usual care Caregiver characteristics: 77.3%=female; 22.7%=male; mean age (SD)= 63.43 years (11.2) Baseline data for the people living with dementia was not given.
Intervention	The Tailored Caregiver Assessment and Referral (TCARE®) protocol is a manualised care management process designed to help practitioners efficiently triage resources and services available within a community to effectively address caregivers' needs. The protocol is grounded in the caregiver identity theory. **TCARE® as a Triaging Mechanism** The TCARE® protocol empowers family caregivers by providing them with critical information to make informed decisions. In this regard, the protocol is similar to caregiver coaching protocols such as that implemented by Bass and colleagues (2003) and the care management protocol designed by Gitlin and colleagues (2006). The TCARE® protocol differs, however, from these approaches in two major aspects. First, the TCARE® protocol does not assume that caregivers always know which services will be helpful and which will not. Indeed, the persistent finding that many caregivers discontinue service use after a short trial period raises serious questions about this assumption (Montgomery, 2002). Second, the TCARE® protocol expands upon the work of Gitlin and colleagues by first focusing on strategies for helping caregivers achieve intervention goals, rather than a specific set of services options. Indeed, the protocol identifies more than 90 different types of resources or services that could benefit caregivers and are consistent with one or more of the four main support strategies of the protocol. **Description of TCARE® Protocol** The six-step process includes two meetings with caregivers and a structured process for tailoring a care plan to the needs and preferences of the caregiver. A central feature of the TCARE® protocol is a decision algorithm that helps care managers integrate extensive information about the caregiver and care context. The 44 pathways through the decision algorithm reflect various combinations of caregivers' scores on measures of three types of burden, intentions to place, depression, identity discrepancy, uplifts, and the care manager's professional judgment regarding the capacity of the caregiver to provide necessary care in a safe manner. The algorithm leads to the identification of (a) an appropriate intervention goal, (b) strategies for reaching that goal, and (c) a generic list of services that is consistent with the identified strategies. Reflecting the core assumptions of the caregiver identity theory, one of the three intervention goals is selected to minimize identity discrepancy. The three possible goals for a caregiver are to (a) continue in his or her current identity as a caregiver by "stretching" that identity to include current caregiving activities, (b) reduce the caregiving aspects of his or her identity to bring his or her identity into line with what he or she is actually doing, or (c) further

Bibliographic reference	Kwak J, Montgomery R J, Kosloski K, and Lang J (2011) The impact of TCARE on service recommendation, use, and caregiver well-being. Gerontologist 51(5), 704-13
	embrace an identity as a caregiver to bring his or her identity into line with what he or she is actually doing. For many caregivers, the algorithm also identifies enhancing the caregiver's health as a secondary goal. The four possible strategies for achieving the selected goal include (a) changing the caregiver's personal norms or rules pertaining to care responsibilities and interactions with the care recipient, (b) reducing the work load, (c) enhancing positive self-appraisal, and (d) reducing emotional stress. The initial list of generic service types is drawn from the TCARE® Guide for Selecting Services which is a catalogue of more than 90 types of resources, grouped into 15 major categories that have been identified as potentially useful for supporting caregivers. The guide links each type of resource with the strategies that it could support. Starting with the initial list of generic services and using a directory or database of local resources, care managers follow a structured process to tailor the list of services to reflect preferences and circumstances of the caregiver and the availability of resources within the local community. All of this information is recorded on the Care Consultation Worksheet. During a consultation session, the care manager interprets the caregiver's scores on key measures and uses the worksheet to discuss the recommended goals and strategies and explains the potential benefits of each recommended service. Decisions regarding a care plan are then jointly made with the caregiver and later recorded on the Care Plan Form and sent to the caregiver. An essential aspect of the TCARE® protocol is a scheduled follow-up, which took place at three-month intervals for the duration of this study.
Comparison	Usual care
Outcome measures	Service Recommendation, Compliance, and Use: The variety of services included on a care plan was measured by counting the number of different types of services listed on the care plan. A dichotomous variable reflecting use (1) or non-use (0) was created for each of the 22 service types for which data were obtained. Similarly, a dichotomous variable reflecting compliance (1) or noncompliance (0) was created for each service listed on an individual's care plan. Identity Discrepancy: Caregiver identity discrepancy is defined as the affective psychological state that accrues when there is a disparity between the care activities in which a caregiver is engaging and those activities that would be consistent with his or her identity standard. Identity discrepancy was measured using a 6-point six-item scale with scores ranging 6–36. Caregiver Burden: Caregiver burden was measured using the modified Montgomery Borgatta Caregiver Burden scale. Objective burden is defined as a negative psychological state that results from the perception that caregiving activities and responsibilities are infringing on other aspects of the caregiver's life, including time and energy to address other family obligations, leisure activities, and personal needs. It was measured using a 5-point six-item scale with scores ranging 6–30. Relationship burden, measured using a 5-point five-item scale with scores ranging 5–25, is defined as demands for care and attention over and above the level that the caregiver perceives is warranted by the care receiver's condition. Stress burden is defined as a generalized form of negative affect that

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	results from caregiving and was measured using a 5-point five-item scale with scores ranging 5–25. Depressive Symptoms: Depressive symptoms were measured using a 4-point 10-item short version of the Center for Epidemiological Studies Depressive Symptoms scale. Scores ranged 0–30.
Study dates	Not provided. This study was published in 2011.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? No. Over 70% of care recipients were diagnosed with probable Alzheimer's disease. • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Unclear. Baseline data for the people living with dementia was not provided. • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare US and UK systems. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Very high

Bibliographic reference	**Lam L C, Lee J S, Chung J C, Lau A, Woo J, and Kwok T C (2010) A randomized controlled trial to examine the effectiveness of case management model for community dwelling older persons with mild dementia in Hong Kong. International Journal of Geriatric Psychiatry 25(4), 395-402**
Study type	RCT
Participants	Inclusion criteria: Community dwelling people aged 65 years old or above, diagnosed to have mild dementia, with Chinese Mini-Mental State Examination (CMMSE) scored 15 or above, and/or a Clinical Dementia Rating of 1 (Hughes et al., 1982) were recruited from psychogeriatric outpatient and memory clinics of Prince of Wales Hospital, a teaching hospital in Hong Kong. Exclusion criteria: (1) no family caregiver, defined as a family member who visited the person at least once a month; (2) refused home visits by case manager, (3) subjects with significant concomitant diseases with more than one hospital admission in the previous 12 months. The last criterion was introduced in order to obtain a more

Bibliographic reference	**Lam L C, Lee J S, Chung J C, Lau A, Woo J, and Kwok T C (2010) A randomized controlled trial to examine the effectiveness of case management model for community dwelling older persons with mild dementia in Hong Kong. International Journal of Geriatric Psychiatry 25(4), 395-402**
	homogenous sample of people with dementia with relatively stable physical condition.
Sample characteristics	N= 92 people living with dementia and their carers n= 53 experimental intervention: a case management (CM) model for people with mild dementia 59%=female; 41%=male; mean age (SD)= 78.6 years (6.4); mean MMSE (SD)= 17.6 (5.2) n= 39 comparator: usual care 56%=female; 44%=male; mean age (SD)= 78.2 years (5.4); mean MMSE (SD)= 18.0 (5.1)
Intervention	The subjects were assigned to a case manager (CM) who was a trained occupational therapist. The intervention period lasted for 4 months. During the intervention period, regular home visits were carried out. The median numbers of follow-ups of the CM group subjects by the case manager by home visit, telephone, and at hospital clinic were three, eight, and two, respectively. The CM offered interventions in the following areas: 1. Assessment and advice: CM evaluated the activities of daily living and neuropsychiatric symptoms of the demented subjects, and caregiver distress in care duties. CM also advised caregivers and demented subjects on the following areas: safe performance in basic self-care activities with environmental modification to promote safe home living, behavioural management, and communication techniques. 2. Home-based program on cognitive stimulation: Subjects with family caregivers received training on home-based cognitive stimulation strategies which included reading newspapers together, reminiscence by old-time photos and continued engagement in usual household tasks and leisure activities. The cognitive stimulating program was reinforced by home visits and telephone calls were appropriate for 16 weeks. Afterward, family caregivers were encouraged to continue with the activities. 3. Case management: CM provided support to both caregivers and subjects by home visits initially, and later by telephone calls, and follow-up at hospital clinic visits. CM encouraged the subjects to be registered with local social centres so that the family could tap into the locally available social services. CM liaised with the staff in the social centres involved to ensure smooth integration of the subjects into the activity schedule. The CM was accessible by a telephone hotline during working hours from Monday to Saturday. The CM liaised closely with the psychogeriatricians or geriatricians in the clinics. An early review would be arranged if necessary. In order to standardize the quality of medical care, both group subjects were followed up at three monthly intervals in the psychogeriatric or memory clinics. Subjects from both CM and control groups received standard medical treatment as clinically indicated.
Comparison	One home visit for home safety was performed by the same occupational therapist with the control subjects at the beginning of the trial, but the subjects did not have access to case management.

Bibliographic reference	**Lam L C, Lee J S, Chung J C, Lau A, Woo J, and Kwok T C (2010) A randomized controlled trial to examine the effectiveness of case management model for community dwelling older persons with mild dementia in Hong Kong. International Journal of Geriatric Psychiatry 25(4), 395-402**
Outcome measures	Assessments of outcome variables were conducted at the baseline and were repeated at the fourth and twelfth month after recruitment. **Assessment of family caregivers** Zarit Carer Burden Interview (ZBI) has 22 items measuring caregiver stress. Areas assessed include the perceived health and psychological well-being of the caregiver, financial impact, social life, and relationship between the caregiver and the person with impairments. General Health Questionnaire. This is a commonly used tool to measure psychological health. Its Chinese version has been validated in Hong Kong. Higher scores indicate psychological distress. The Personal Well-Being Index for adults (PWIAs). This is a generic and cross-cultural instrument which was adopted to measure subjective QOL, and has been translated and validated for use in Hong Kong. The instrument contains seven items which asks how people are satisfied with seven life domains. A 0–10 rating scale on satisfaction is used. The PWI is accompanied by ‘‘gold standard’’ normative values, which range between 60 and 70 on a 0–100 scale distribution for Asian Chinese populations. Use of social care support: Data on the use of day care, home help, part time or full time domestic helper, and respite care in the care of the people with dementia were collected by a questionnaire at each follow-up visit. **Assessment of persons with dementia** The Chinese version of Mini Mental State Examination (CMMSE) was assessed at the baseline and subsequent follow-up. The Cornell Scale for Depression in Dementia (CSDD) is a 19-item clinician-rated scale that measures depression after interviews with the patient and the caregiver. It was administered at psychogeriatric or memory clinics by doctors who were blinded to the group assignment. A cut-off score of 6/7 has been shown to be sensitive in identifying significant depressive symptoms in persons with mild dementia in the Chinese population. The Neuropsychiatric Inventory (NPI) was used to measure the profile of psychiatric symptoms and behavioural disturbances. Ten major groups of neuropsychiatric symptoms with vegetative symptoms of sleep and appetite disturbances were evaluated with a semi-structured interview by a caregiver. The present study adopted the Chinese version validated for community dwelling Chinese persons in Hong Kong. The Personal Well-Being Index-Intellectual Disability (PWI-ID): This is a parallel form of the original adult PWI designed for use with people who have cognitive impairment PWI-ID. A main unique feature of the ID version is the incorporation of a standardised pre-test for determining the ability of the respondent to cope with testing demands of the PWI. The PWI-ID demonstrates satisfactory psychometric performance in validation studies conducted with a wide range of cognitively impaired populations including dementia.

Bibliographic reference	**Lam L C, Lee J S, Chung J C, Lau A, Woo J, and Kwok T C (2010) A randomized controlled trial to examine the effectiveness of case management model for community dwelling older persons with mild dementia in Hong Kong. International Journal of Geriatric Psychiatry 25(4), 395-402**
Study dates	2005 to 2008
Study location	Hong Kong
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare the cultures and systems of Hong Kong to those of the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Meeuwsen E J, Melis R J, Van Der Aa , G C, Goluke-Willemse G A, De Leest , B J, Van Raak , F H, Scholzel-Dorenbos C J, Verheijen D C, Verhey F R, Visser M C, Wolfs C A, Adang E M, Olde Rikkert, and M G (2012) Effectiveness of dementia follow-up care by memory clinics or general practitioners: randomised controlled trial. BMJ 344, e3086**
Study type	RCT
Participants	Inclusion criteria: Patients had to be newly diagnosed as having dementia meeting the criteria of the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV), with a clinical dementia rating of 0.5, 1, or 2.22 Each patient had an informal caregiver, Exclusion criteria: Patient-caregiver pairs were excluded when the patient lived in a nursing home, had a life expectancy of less than a year, or needed specific memory clinic care (for example, in the case of Creutzfeldt-Jakob disease) that could not be given by general practitioners.
Sample characteristics	N= 153 people living with dementia and their carers n= 78 experimental intervention: memory clinic follow-up 62%=female; 38%=male; mean age (SD)= 78.2 years (6.2); mean MMSE (SD)= 22.7 (3.6)

Bibliographic reference	**Meeuwsen E J, Melis R J, Van Der Aa , G C, Goluke-Willemse G A, De Leest , B J, Van Raak , F H, Scholzel-Dorenbos C J, Verheijen D C, Verhey F R, Visser M C, Wolfs C A, Adang E M, Olde Rikkert, and M G (2012) Effectiveness of dementia follow-up care by memory clinics or general practitioners: randomised controlled trial. BMJ 344, e3086**
	n= 75 comparator: GP follow-up 59%=female; 41%=male; mean age (SD)= 77.9 years (5.2); mean MMSE (SD)= 22.7 (4.2)
Intervention	The interventions in this study consisted of usual care by either the memory clinic or the general practitioner. The memory clinic provided treatment and care coordination based on the specialist Dutch dementia guideline of the Dutch Institute for Healthcare Improvement. The main content of the intervention of the memory clinic was prescribing and guidance of anti-dementia drugs (cholinesterase inhibitors and memantine). Furthermore, they provided non-drug interventions—for example, occupational therapy, providing day structure, or referral to a nurse specialist, day care, or home care. Using the guidelines mentioned, both drug prescription/guidance and the non-drug interventions were delivered on a tailored basis.
Comparison	Patient-caregiver pairs assigned to the general practitioner received post-diagnosis treatment and care provided by the general practitioner based on the Dutch general practice and homecare dementia guidelines. As usual, the general practitioner received a discharge letter with advice about treatment after diagnostic investigation by the memory clinic. Contrary to the Dutch specialist guideline on dementia treatment, the general practice guideline states that the use of cholinesterase inhibitors is not recommended; however, several general practitioners did prescribe dementia drugs as part of the intervention. Most non-drug interventions available in memory clinic care are also available in general practitioner care and were also delivered on a tailored basis.
Outcome measures	Measurements were taken at baseline and at 12 months. Primary outcome measures to establish effectiveness were the quality of life of the patient as rated by the caregiver, using the quality of life in Alzheimer's disease instrument (range 13-52; higher scores indicate a better quality of life), and self-perceived caregiving burden of the informal caregiver, as measured by the sense of competence questionnaire (range 27-135; higher score reflects a greater sense of competence). Several secondary outcome measures in both patients and caregivers were assessed. To measure patients' depression, we used the geriatric depression scale, a short questionnaire validated in mild to moderate dementia. We measured behavioural disturbance by using the neuropsychiatric inventory in questionnaire format and the patient's functional performance by using the interview for deterioration in daily living activities in dementia scale. Secondary outcome measures related to the caregiver were mood measured with the Centre for Epidemiologic Studies depression scale and anxiety measured with the state-trait anxiety inventory. We also used the Eysenck personality questionnaire to evaluate caregivers' personality and the Pearlin mastery scale to determine the amount of mastery (the extent to which life chances are seen as being under a person's own control in contrast to being

Bibliographic reference	**Meeuwsen E J, Melis R J, Van Der Aa , G C, Goluke-Willemse G A, De Leest , B J, Van Raak , F H, Scholzel-Dorenbos C J, Verheijen D C, Verhey F R, Visser M C, Wolfs C A, Adang E M, Olde Rikkert, and M G (2012) Effectiveness of dementia follow-up care by memory clinics or general practitioners: randomised controlled trial. BMJ 344, e3086**
	fatalistically ruled). We measured emotional problems of the caregiver concerning the behaviour of the patient with the neuropsychiatric inventory in questionnaire format. To measure social support, we used the inventory for measuring social involvement.
Study dates	2007 to 2009
Study location	The Netherlands
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare systems in the Netherlands compared to the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Miller R, Newcomer R, and Fox P (1999) Effects of the Medicare Alzheimer's Disease Demonstration on nursing home entry. Health Services Research 34(3), 691-714**
Study type	RCT
Participants	Inclusion criteria: The demonstration enrolled participants who met four criteria: (1) diagnosis of irreversible dementia, (2) enrolment in the Medicare program, (3) residence in a demonstration site's catchment area, and (4) living in the community at the time of their application to the program. Exclusion criteria: All but one site chose to exclude Medicaid recipients. During the first month, 97 participants died, 160 entered a nursing home, and 35 dropped out. These cases were excluded under the assumption that the program did not have a sufficient opportunity to affect the needs of the caregivers during such a short interval.
Sample characteristics	N= 8095 people living with dementia and their carers

Bibliographic reference	Miller R, Newcomer R, and Fox P (1999) Effects of the Medicare Alzheimer's Disease Demonstration on nursing home entry. Health Services Research 34(3), 691-714
	n= 4005* experimental intervention: the Medicare Alzheimer's Disease Demonstration4005 n= 3798* comparator: usual care *Assuming that equal numbers dropped out of both groups, which is what the authors have written. A summary of the baseline characteristics was not provided. However, the descriptive statistics table shows that both groups were similar.
Intervention	(The following studies have the same intervention with the same wording: Miller 1999, Newcomer 1999, Shelton 2001. The details were taken from Yordi 1997 and Shelton 2001 because together they had the most detailed explanations). Following randomization into the treatment group, both AD clients and their caregivers received comprehensive in-home, clinical assessments conducted by nurse case managers. The clinical assessment domains, completed on the AD client and caregiver, included physical health conditions and status, cognitive functioning, psychosocial and financial needs, environmental problems, prior healthcare and community service utilization, and formal and informal caregiving arrangements. After the initial assessment, which was updated every 6 months, nurse case managers identified client and caregiver medical and psychosocial problems and service needs and developed a plan of care to serve as the basis for future interventions. Care plans were developed in agreement with caregiver and client. The plan outlined specific interventions to be performed by the case manager, the caregiver, healthcare providers, and informal resources. Care plans were shared with the client and the caregiver's primary care physician and all healthcare providers involved in the delivery of community-based services. Nurse case managers had a caseload of approximately 100 AD clients and their caregivers and were responsible for the authorization and monitoring of all services provided by the demonstration under a monthly cap for each AD client. Services included: • Adult day care • Skilled and rehabilitation nursing • Therapies (i.e., speech, occupational, physical) • Home health aide • Homemaker/personal care • Housekeeping • General chore (i.e., heavy cleaning) • Home repairs and maintenance • Companion (i.e., friendly visiting, shopping and errands, telephone reassurance, and caretaker while caregiver

Bibliographic reference	Miller R, Newcomer R, and Fox P (1999) Effects of the Medicare Alzheimer's Disease Demonstration on nursing home entry. Health Services Research 34(3), 691-714
	attends educational and/or support groups) • Home-delivered meals • Non-emergency transportation for client • Adaptive and assistive equipment • Medical supplies in conjunction with skilled and unskilled home care • Consumable care goods • Safety modifications to the home Among these support services are caregiver education and training, caregiver support groups, and caregiver transportation to education and support groups. These services did not have co-payment and were reimbursed by HCFA as part of each demonstration site's administrative overhead. Details of the average number of follow-up frequencies were not given.
Comparison	Usual care
Outcome measures	Hazard ratio for entry into residential care. Data was collected over a three year period.
Study dates	Enrolment started in 1991. The study was published in 1999.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Unclear. The description of the intervention lacks detail compared to other studies. For example, follow-up frequencies. • Was the assignment of patients to treatment randomised? Unclear. Details of the randomisation method were not given. • Were clinicians and investigators blinded? Unclear. There is no mention of blinding. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare the US system to the UK system. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Newcomer R, Yordi C, DuNah R, Fox P, and Wilkinson A (1999) Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. Health Services Research 34(3), 669-89**
Study type	RCT
Participants	Inclusion criteria: The demonstration enrolled participants who met four criteria: (1) diagnosis of irreversible dementia, (2) enrolment in the Medicare program, (3) residence in a demonstration site's catchment area, and (4) living in the community at the time of their application to the program. Exclusion criteria: No informal caregiver at baseline.
Sample characteristics	N= 1906 people living with dementia and their carers n= 986 experimental intervention: the Medicare Alzheimer's Disease Demonstration 72%=female; 28%=male; mean age (SD)= 78.0 years (8.06); mean MMSE (SD)= 14.9 (8.63) n= 920 comparator: usual care 74%=female; 26%=male; mean age (SD)= 78.0 years (8.35); mean MMSE (SD)= 15.2 (8.57)
Intervention	(The following studies have the same intervention with the same wording: Miller 1999, Newcomer 1999, Shelton 2001. The details were taken from Yordi 1997 and Shelton 2001 because together they had the most detailed explanations). Following randomization into the treatment group, both AD clients and their caregivers received comprehensive in-home, clinical assessments conducted by nurse case managers. The clinical assessment domains, completed on the AD client and caregiver, included physical health conditions and status, cognitive functioning, psychosocial and financial needs, environmental problems, prior healthcare and community service utilization, and formal and informal caregiving arrangements. After the initial assessment, which was updated every 6 months, nurse case managers identified client and caregiver medical and psychosocial problems and service needs and developed a plan of care to serve as the basis for future interventions. Care plans were developed in agreement with caregiver and client. The plan outlined specific interventions to be performed by the case manager, the caregiver, healthcare providers, and informal resources. Care plans were shared with the client and the caregiver's primary care physician and all healthcare providers involved in the delivery of community-based services. Nurse case managers had a caseload of approximately 100 AD clients and their caregivers and were responsible for the authorization and monitoring of all services provided by the demonstration under a monthly cap for each AD client. Services included: • Adult day care • Skilled and rehabilitation nursing • Therapies (i.e., speech, occupational, physical)

Bibliographic reference	Newcomer R, Yordi C, DuNah R, Fox P, and Wilkinson A (1999) Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. Health Services Research 34(3), 669-89
	• Home health aide • Homemaker/personal care • Housekeeping • General chore (i.e., heavy cleaning) • Home repairs and maintenance • Companion (i.e., friendly visiting, shopping and errands, telephone reassurance, and caretaker while caregiver attends educational and/or support groups) • Home-delivered meals • Non-emergency transportation for client • Adaptive and assistive equipment • Medical supplies in conjunction with skilled and unskilled home care • Consumable care goods • Safety modifications to the home Among these support services are caregiver education and training, caregiver support groups, and caregiver transportation to education and support groups. These services did not have co-payment and were reimbursed by HCFA as part of each demonstration site's administrative overhead. Details of the average number of follow-up frequencies were not given.
Comparison	Usual care
Outcome measures	The final re-assessment was at 36 months. Caregiver burden was measured using an adaptation of a scale developed by Zarit, Reever, and Bach-Peterson. The scale, in which eight items were summed with responses ranging from 0 (never) to 4 (always), included items that asked caregivers whether they felt stressed between caring for the client and meeting other family responsibilities and between caring for the client and having enough time for themselves; whether they felt angry around the client; whether they felt tense or anxious due to their involvement in caregiving; whether they felt that their health had suffered due to caregiving; whether their social life had suffered; whether they felt that they had lost control of their life since the client's illness; and the extent of burden they felt in caring for the client. Caregiver depression was measured using the short-form Geriatric Depression Scale (Yesavage et al). The scale sums affirmative responses to 15 items that asked caregivers whether they were basically satisfied with their life, had dropped many of their activities and interests, felt that their life was empty, were often bored, were in good spirits most of the time, felt helpless, preferred to stay home or to go out and do new things, felt that they had more problems with memory than most people, thought it was wonderful to be alive, felt worthless, were full of energy, felt

Bibliographic reference	**Newcomer R, Yordi C, DuNah R, Fox P, and Wilkinson A (1999) Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. Health Services Research 34(3), 669-89**
	that their situation was hopeless, and thought that most people were better off than they were.
Study dates	1989 to 1994
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Unclear. The description of the intervention lacks detail compared to other studies. For example, follow-up frequencies. • Was the assignment of patients to treatment randomised? Unclear. Details of the randomisation method were not given. • Were clinicians and investigators blinded? Unclear. There is no mention of blinding. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? No. 2642 cases were excluded because they only had a baseline assessment. This represents a dropout rate for unknown reasons of 32%. • Can the results be applied to the local population? Unclear. It is difficult to compare the US system to the UK system. • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Very high

Bibliographic reference	**Samus Q M, Johnston D, Black B S, Hess E, Lyman C, Vavilikolanu A, Pollutra J, Leoutsakos J M, Gitlin L N, Rabins P V, and Lyketsos C G (2014) A multidimensional home-based care coordination intervention for elders with memory disorders: the maximizing independence at home (MIND) pilot randomized trial. American Journal of Geriatric Psychiatry 22(4), 398-414**
Study type	RCT
Participants	Inclusion criteria: Eligible participants were age 70+ years, English-speaking, community-residing in the northwest Baltimore area, had a reliable study partner available who was willing to participate in all study visits, met diagnostic criteria for dementia or Cognitive Disorder Not Otherwise Specified, and had 1 or more unmet care needs on the Johns Hopkins Dementia Care Needs Assessment (JHDCNA). Exclusion criteria: Individuals in a crisis situation (i.e., signs of abuse, neglect, risk of danger to self or others) were excluded.

Bibliographic reference	**Samus Q M, Johnston D, Black B S, Hess E, Lyman C, Vavilikolanu A, Pollutra J, Leoutsakos J M, Gitlin L N, Rabins P V, and Lyketsos C G (2014) A multidimensional home-based care coordination intervention for elders with memory disorders: the maximizing independence at home (MIND) pilot randomized trial. American Journal of Geriatric Psychiatry 22(4), 398-414**
Sample characteristics	N= 188 people living with dementia and their carers. n= 74 experimental intervention: care coordination 66.4%=female; 33.6%=male; mean age (SD)= 84.0 years (5.8); mean MMSE (SD)= 19.0 (7.9) n= 114 comparator: augmented usual care 62.2%=female; 37.8%=male; mean age (SD)= 83.9 years (5.9); mean MMSE (SD)= 19.2 (7.7)
Intervention	Intervention participants, their study partners, and their PCP received the written JHDCNA results and 18 months of care coordination by an interdisciplinary care team comprising non-clinical community workers (Coordinators) linked to a registered nurse and a geriatric psychiatrist. The manualised care coordination protocol consisted of four key components: • Identification of needs and individualised care planning based on the JHDCNA to address unmet needs and to match the priorities and preferences of the patient and family. • Provision of dementia education and skill building strategies. • Coordination, referral, and linkage to services. • Care monitoring. Care components are individually tailored to current unmet needs and updated based on emergent needs of participants and CGs. After randomisation, coordinators reviewed the JHDCNA assessment, conducted an in-home visit with the participant and study partner to review and prioritise needs, and developed the care plan. The study partner and/or participant, when appropriate, then implemented the plan with guidance from the coordinator. A menu of care options/strategies was available for each unmet need item and consisted of referral and linkage to resources/services; CG memory disorder education and skill building; and informal counselling and problem-solving. All recommended resource referrals were selected from those available locally. The protocol pre-specified two in-home visits (initial visit and 18-month visit), and monthly contacts to maintain engagement with the care team. Otherwise, the type and frequency of coordinator involvement with the participant and family was individualized over the 18 months and driven by need level, care plan, and family preference. (In fact, on the results tables, the mean number of conversations by telephone and in-person was 1.7 per month. The mean number of all contacts, including emails, letters, faxes and left messages was 2.6 per month.) Needs were monitored over time and new strategies were implemented when necessary. Emergent needs were identified by the coordinators and incorporated into care plans. When appropriate, coordinators took a direct role to ensure follow-through with recommended strategies/care options (e.g., reminders of appointments, attending

Bibliographic reference	**Samus Q M, Johnston D, Black B S, Hess E, Lyman C, Vavilikolanu A, Pollutra J, Leoutsakos J M, Gitlin L N, Rabins P V, and Lyketsos C G (2014) A multidimensional home-based care coordination intervention for elders with memory disorders: the maximizing independence at home (MIND) pilot randomized trial. American Journal of Geriatric Psychiatry 22(4), 398-414**
	outpatient visits or nursing home rehabilitation meetings, pricing medical equipment or services, assisting with service program applications, providing educational material, and modelling management techniques). The three coordinators (2 full-time equivalent bachelors-prepared with Marketing or Psychology degrees, and 0.5 full-time equivalent with Social Work Master's degree) were employees of two community-based social service agencies hired explicitly for the study and located at the agencies based on *a priori* design. None had prior formal training or certifications in geriatric case management or dementia care. Coordinators were trained over a 1-month period. This structured training was provided by the study's clinical investigators and colleagues from a range of disciplines (e.g., geriatric psychiatry, geriatric medicine, nursing, social work) affiliated with the Bayview Memory Center. It included didactic and interactive sessions on dementia care and management, community resource identification, family engagement, rapport, and CG skill building, the JHDCNA, the Dementia Care Management System (DCMS) clinical tracking software, human subjects research principles, and HIPAA; JHDCNA home-visit needs assessment observations; clinical care observations (i.e., inpatient, outpatient, and long-term care); and proficiency assessments. The geriatric psychiatrist and registered nurse provided direct support and clinical guidance to coordinators, led weekly in-person 2-hour meetings to review recommendations, cases, and protocol adherence, and were accessible by cell phone and e-mail. Coordinators used a customised Web-based application, the DCMS, specifically designed for MIND. The DCMS provided decision support and secure information sharing across the care team. It was used to track care plans, clinical progress, service and provider referrals, and service use. Built-in query and reporting capabilities enabled tracking of protocol fidelity and self-monitoring of the implementation process. Fidelity was ensured through: 1) The initial coordinator training. 2) Observation of the coordinators by the registered nurse or geriatric psychiatrist during the first several independent field visits. 3) Weekly in-person care team meetings. 4) Monitoring of the Coordinators' use and data entries into the DCMS clinical tracking software.
Comparison	Augmented usual care (control) participants, study partners, and primary care physicians (PCPs) received the written results of the JHDCNA following the baseline visit, including recommendations for each identified unmet need. They also received a brief resource guide developed for the study that provided program and contact information for 11 local and national aging service organisations.
Outcome measures	Time to Transfer Out of the Home: Time to transfer out of the home was collected through study partner report by masked evaluators at 4.5 (telephone), 9 (in-home), 14.5 (telephone), and 18 months (in-home). In cases of

Bibliographic reference	**Samus Q M, Johnston D, Black B S, Hess E, Lyman C, Vavilikolanu A, Pollutra J, Leoutsakos J M, Gitlin L N, Rabins P V, and Lyketsos C G (2014) A multidimensional home-based care coordination intervention for elders with memory disorders: the maximizing independence at home (MIND) pilot randomized trial. American Journal of Geriatric Psychiatry 22(4), 398-414**
	permanent transfer from home, the date, destination, and primary reason for relocation were recorded. For temporary transfers (e.g., in-patient hospital, rehabilitation facility), the location was recorded and evaluators followed up at the next scheduled interval to determine the participant's location. For death of the participant, the date, location, and cause of death were recorded. If death occurred outside of the home, evaluators recorded the date the participant left the home, the destination(s) and duration of stay in each destination prior to death. Extended surveillance by unmasked evaluators was conducted at 4.5-month intervals post-intervention for all participants until December 1, 2011. Time was expressed in days from enrolment to time censor or event (i.e., all-cause permanent transfer or death). Unmet Care Needs: The JHDCNA is a multidimensional, manualized tool used to identify 19 common care need categories for participants (71 items) and CGs (15 items). JHDCNA was developed by a multidisciplinary group of clinical dementia experts through an iterative process based on best practices, suggesting face and content validity, and our prior studies have suggested convergent and discriminant validity. Need items have standardized descriptions and definitions, listings of indicators of needs, and a linked menu of potential care strategies/options to address each need. Evaluators document needs and assess each as being either "fully met" or "unmet". Total percent of unmet care needs based on the JHDCNA ([no. of unmet need items/no. need items assessed] x 100), was determined at the initial in-home screening visit and at 18 months. The proportion of unmet items in six pre-specified need categories (Evaluation and Treatment of Memory Symptoms; Neuropsychiatric Symptom Management; Home and Personal Safety; General, Specialist, and Allied Health Care; Daily and Meaningful Activities; Legal Issues/Advanced Care Planning) was also evaluated for treatment group differences. An unmasked RN rated the JHDCNA at the 18-month visit. Secondary Outcome Measures. Secondary outcome measures were assessed at baseline and 18 months by masked evaluators. These included the Quality of Life in AD, which was administered to participants (QOL-AD-participant) and study partners (QOL-AD-proxy); the Alzheimer's Disease Rated Quality of Life-40 item (ADRQL-40) scale, an informant rated disease-specific QOL instrument; the Neuropsychiatric Inventory-Q (NPI-Q), an informant rated questionnaire for NPS; and the Cornell Scale for Depression in Dementia (CSDD), a depression inventory for persons with dementia.
Study dates	Study dates were not provided. The study was published in 2014.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes

Bibliographic reference	**Samus Q M, Johnston D, Black B S, Hess E, Lyman C, Vavilikolanu A, Pollutra J, Leoutsakos J M, Gitlin L N, Rabins P V, and Lyketsos C G (2014) A multidimensional home-based care coordination intervention for elders with memory disorders: the maximizing independence at home (MIND) pilot randomized trial. American Journal of Geriatric Psychiatry 22(4), 398-414**
	• Were clinicians and investigators blinded? No: the 18-month unmet need data (JHDCNA) was collected by a non-blinded nurse. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to compare systems in the US to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low. Moderate for the 18-month unmet need data.

Bibliographic reference	**Schoenmakers Birgitte, Buntinx Frank, and DeLepeleire Jan (2010) Supporting the dementia family caregiver. Aging & Mental Health 14(1),**
Study type	RCT
Participants	Inclusion criteria: cognitive impairment. Patients had to be accompanied by a family carer. Exclusion criteria: All patients were tested with a Mini Mental State Examinations and those scoring above 22 were excluded. A severe or terminally ill patient, a definitive institutionalization planned on a short term, no available carer, or an impaired carer.
Sample characteristics	N= 46 people with an MMSE of 22 or below. n= 23 experimental intervention: care coordination n= 23 comparator: usual care Baseline characteristics of the people living with an MMSE of 22 or below are not given separately for each group.
Intervention	The care counsellor was a primary care professional with a bachelor degree and was selected on excellence in social and communicative skills and because of her experience in dementia home care. An extra training included a theoretic guidance through local community services addressing dementia home care provided by a skilled general practitioner. Beside, the care counsellor was introduced to the home nursing organization, a local service centre for the elder and the local general practitioners network. During the ongoing of the study and in particular with each new intervention, the care counsellor was supervised

Bibliographic reference	Schoenmakers Birgitte, Buntinx Frank, and DeLepeleire Jan (2010) Supporting the dementia family caregiver. Aging & Mental Health 14(1),
	and given feedback by a skilled general practitioner. The care counsellor was asked to write down an unstructured report on every provided and extra contact with the carer. The care counsellor was at the exclusive disposal of the intervention group. Over a course of 12 months, the care counsellor guided the family carer in organizing home care. At a first visit, the counsellor assisted the family carer in exploring any problematic home care situations. Additionally, the care counsellor arranged a monthly phone call with the family carer and a three monthly visit. During the intervention period twelve phone calls and four home visits were scheduled. Additionally, the care counsellor was within permanent reach for advice by phone, for adjusting home care or for an extra visit. No structured or hierarchical care plan was provided but drawn out following the needs of the family carer and patient. General practitioners were informed about each change in formal or informal home care of their patients.
Comparison	Usual care. Subjects in the control group were not guided or visited by the care counsellor but were passively directed to the usual care systems.
Outcome measures	Measurements were taken at baseline and at 6 months. Primary outcome measure was defined as depression in the family carer and measured by the Beck Depression Inventory with a score of 10 or more implying mild to moderate depression (according to Beck 1972). Secondary outcome measures were coping behaviour, anxiety, and burden in the family carer. Burden was measured with the 14 item Zarit Burden inventory. This shortened version of the original Burden Inventory has proved its validity in family caregiving topics. Coping behaviour was quantified by the Ways of Coping Checklist. Anxiety was determined by the Trait subscale of the Stai-instrument. This subscale points out if subjects are prone to anxiety rather than it does reflect a state of mind during a limited period. The patient's status was measured with the aid of Frail, the Activities and Instrumental Activities of Daily Living, the Mini Mental State Examination for cognitive status, and the Neuro psychiatric Inventory for behaviour. The symptoms described in this instrument were grouped into four categories: psychotic symptoms, disturbing behaviour, mood swings and neuro-vegetative alterations (sleeping and eating problems, fears). Additionally, an extensive quantitative assessment of formal and informal care support was made. Finally, for each newly installed care support, the general practitioner was contacted.
Study dates	2005 to 2006
Study location	Belgium
Comments	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	**Schoenmakers Birgitte, Buntinx Frank, and DeLepeleire Jan (2010) Supporting the dementia family caregiver. Aging & Mental Health 14(1),**
Risk of bias	• Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Unclear. Baseline characteristics of the people living with an MMSE of 22 or below are not given separately for each group. However, the baseline characteristics of the carers in each group is similar. • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare systems in Belgium to those in the UK. • Were all clinically relevant outcomes reported? No. The number of events in either group are not reported. Therefore, only the relative difference is reported, not the absolute difference. Overall risk of bias: Very high

Bibliographic reference	**Shelton P, Schraeder C, Dworak D, Fraser C, and Sager M A (2001) Caregivers' utilization of health services: results from the Medicare Alzheimer's Disease Demonstration, Illinois site. Journal of the American Geriatrics Society 49(12), 1600-5**
Study type	RCT
Participants	Inclusion criteria: The demonstration enrolled participants who met four criteria: (1) diagnosis of irreversible dementia, (2) enrolment in the Medicare program, (3) residence in a demonstration site's catchment area, and (4) living in the community at the time of their application to the program. Exclusion criteria: No informal caregiver at baseline.
Sample characteristics	N= 412 people living with dementia and their carers n= 210 experimental intervention: the Medicare Alzheimer's Disease Demonstration 66%=female; 34%=male; mean age (SD)= 74.9 years (7.2) n= 202 comparator: usual care 63%=female; 37%=male; mean age (SD)= 74.9 years (6.8)
Intervention	(The following studies have the same intervention with the same wording: Miller 1999, Newcomer 1999, Shelton 2001. The details were taken from Yordi 1997 and Shelton 2001 because together they had the most detailed explanations).

Bibliographic reference	Shelton P, Schraeder C, Dworak D, Fraser C, and Sager M A (2001) Caregivers' utilization of health services: results from the Medicare Alzheimer's Disease Demonstration, Illinois site. Journal of the American Geriatrics Society 49(12), 1600-5
	Following randomization into the treatment group, both AD clients and their caregivers received comprehensive in-home, clinical assessments conducted by nurse case managers. The clinical assessment domains, completed on the AD client and caregiver, included physical health conditions and status, cognitive functioning, psychosocial and financial needs, environmental problems, prior healthcare and community service utilization, and formal and informal caregiving arrangements. After the initial assessment, which was updated every 6 months, nurse case managers identified client and caregiver medical and psychosocial problems and service needs and developed a plan of care to serve as the basis for future interventions. Care plans were developed in agreement with caregiver and client. The plan outlined specific interventions to be performed by the case manager, the caregiver, healthcare providers, and informal resources. Care plans were shared with the client and the caregiver's primary care physician and all healthcare providers involved in the delivery of community-based services. Nurse case managers had a caseload of approximately 100 AD clients and their caregivers and were responsible for the authorization and monitoring of all services provided by the demonstration under a monthly cap for each AD client. Services included: • Adult day care • Skilled and rehabilitation nursing • Therapies (i.e., speech, occupational, physical) • Home health aide • Homemaker/personal care • Housekeeping • General chore (i.e., heavy cleaning) • Home repairs and maintenance • Companion (i.e., friendly visiting, shopping and errands, telephone reassurance, and caretaker while caregiver attends educational and/or support groups) • Home-delivered meals • Non-emergency transportation for client • Adaptive and assistive equipment • Medical supplies in conjunction with skilled and unskilled home care • Consumable care goods • Safety modifications to the home

Bibliographic reference	**Shelton P, Schraeder C, Dworak D, Fraser C, and Sager M A (2001) Caregivers' utilization of health services: results from the Medicare Alzheimer's Disease Demonstration, Illinois site. Journal of the American Geriatrics Society 49(12), 1600-5**
	Among these support services are caregiver education and training, caregiver support groups, and caregiver transportation to education and support groups. These services did not have co-payment and were reimbursed by HCFA as part of each demonstration site's administrative overhead. Details of the average number of follow-up frequencies were not given.
Comparison	Usual care
Outcome measures	Likelihood of hospitalisation. Likelihood of emergency department usage.
Study dates	1989 to 1994
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. Details of the method of randomisation were not given. • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. It is difficult to compare US and UK systems. • Were all clinically relevant outcomes reported? No. The number of events in either group are not reported. Therefore, only the relative difference is reported, not the absolute difference. • Overall risk of bias: High

Bibliographic reference	**Tanner J A, Black B S, Johnston D, Hess E, Leoutsakos J M, Gitlin L N, Rabins P V, Lyketsos C G, and Samus Q M (2015) A randomized controlled trial of a community-based dementia care coordination intervention: effects of MIND at Home on caregiver outcomes. American Journal of Geriatric Psychiatry 23(4), 391-402**
Study type	RCT (This study is the same as Samus 2014 except that it has different outcomes and slightly different participant numbers)

Bibliographic reference	**Tanner J A, Black B S, Johnston D, Hess E, Leoutsakos J M, Gitlin L N, Rabins P V, Lyketsos C G, and Samus Q M (2015) A randomized controlled trial of a community-based dementia care coordination intervention: effects of MIND at Home on caregiver outcomes. American Journal of Geriatric Psychiatry 23(4), 391-402**
Participants	Inclusion criteria: Eligible participants were age 70+ years, English-speaking, community-residing in the northwest Baltimore area, had a reliable study partner available who was willing to participate in all study visits, met diagnostic criteria for dementia or Cognitive Disorder Not Otherwise Specified, and had 1 or more unmet care needs on the Johns Hopkins Dementia Care Needs Assessment (JHDCNA). Exclusion criteria: Individuals in a crisis situation (i.e., signs of abuse, neglect, risk of danger to self or others) were excluded.
Sample characteristics	N= 171 people living with dementia and their carers n= 67 experimental intervention: care coordination Baseline characteristics of caregivers: 75%=female; 25%=male; mean age (SD)= 66.3 years (14.1) n= 104 comparator: augmented usual care Baseline characteristics of caregivers: 74%=female; 26%=male; mean age (SD)= 67.5 years (13.0)
Intervention	Intervention participants, their study partners, and their PCP received the written JHDCNA results and 18 months of care coordination by an interdisciplinary care team comprising non-clinical community workers (Coordinators) linked to a registered nurse and a geriatric psychiatrist. The manualised care coordination protocol consisted of four key components: • Identification of needs and individualised care planning based on the JHDCNA to address unmet needs and to match the priorities and preferences of the patient and family. • Provision of dementia education and skill building strategies. • Coordination, referral, and linkage to services. • Care monitoring. Care components are individually tailored to current unmet needs and updated based on emergent needs of participants and CGs. After randomisation, coordinators reviewed the JHDCNA assessment, conducted an in-home visit with the participant and study partner to review and prioritise needs, and developed the care plan. The study partner and/or participant, when appropriate, then implemented the plan with guidance from the coordinator. A menu of care options/strategies was available for each unmet need item and consisted of referral and linkage to resources/services; CG memory disorder education and skill building; and informal counselling and problem-solving. All recommended resource referrals were selected from those available locally. The protocol pre-specified two in-home visits (initial visit and 18-month visit), and monthly contacts to maintain engagement with the care team. Otherwise, the type and frequency of coordinator involvement with the participant and family was individualized over

Bibliographic reference	Tanner J A, Black B S, Johnston D, Hess E, Leoutsakos J M, Gitlin L N, Rabins P V, Lyketsos C G, and Samus Q M (2015) A randomized controlled trial of a community-based dementia care coordination intervention: effects of MIND at Home on caregiver outcomes. American Journal of Geriatric Psychiatry 23(4), 391-402
	the 18 months and driven by need level, care plan, and family preference. (In fact, on the results tables, the mean number of conversations by telephone and in-person was 1.7 per month. The mean number of all contacts, including emails, letters, faxes and left messages was 2.6 per month.) Needs were monitored over time and new strategies were implemented when necessary. Emergent needs were identified by the coordinators and incorporated into care plans. When appropriate, coordinators took a direct role to ensure follow-through with recommended strategies/care options (e.g., reminders of appointments, attending outpatient visits or nursing home rehabilitation meetings, pricing medical equipment or services, assisting with service program applications, providing educational material, and modelling management techniques). The three coordinators (2 full-time equivalent bachelors-prepared with Marketing or Psychology degrees, and 0.5 full-time equivalent with Social Work Master's degree) were employees of two community-based social service agencies hired explicitly for the study and located at the agencies based on a priori design. None had prior formal training or certifications in geriatric case management or dementia care. Coordinators were trained over a 1-month period. This structured training was provided by the study's clinical investigators and colleagues from a range of disciplines (e.g., geriatric psychiatry, geriatric medicine, nursing, social work) affiliated with the Bayview Memory Center. It included didactic and interactive sessions on dementia care and management, community resource identification, family engagement, rapport, and CG skill building, the JHDCNA, the Dementia Care Management System (DCMS) clinical tracking software, human subjects research principles, and HIPAA; JHDCNA home-visit needs assessment observations; clinical care observations (i.e., inpatient, outpatient, and long-term care); and proficiency assessments. The geriatric psychiatrist and registered nurse provided direct support and clinical guidance to coordinators, led weekly in-person 2-hour meetings to review recommendations, cases, and protocol adherence, and were accessible by cell phone and e-mail. Coordinators used a customised Web-based application, the DCMS, specifically designed for MIND. The DCMS provided decision support and secure information sharing across the care team. It was used to track care plans, clinical progress, service and provider referrals, and service use. Built-in query and reporting capabilities enabled tracking of protocol fidelity and self-monitoring of the implementation process. Fidelity was ensured through: 1) The initial coordinator training. 2) Observation of the coordinators by the registered nurse or geriatric psychiatrist during the first several independent field visits. 3) Weekly in-person care team meetings. 4) Monitoring of the Coordinators' use and data entries into the DCMS clinical tracking software.

Bibliographic reference	**Tanner J A, Black B S, Johnston D, Hess E, Leoutsakos J M, Gitlin L N, Rabins P V, Lyketsos C G, and Samus Q M (2015) A randomized controlled trial of a community-based dementia care coordination intervention: effects of MIND at Home on caregiver outcomes. American Journal of Geriatric Psychiatry 23(4), 391-402**
Comparison	Augmented usual care (control) participants, study partners, and primary care physicians (PCPs) received the written results of the JHDCNA following the baseline visit, including recommendations for each identified unmet need. They also received a brief resource guide developed for the study that provided program and contact information for 11 local and national aging service organisations.
Outcome measures	Caregiver Unmet Needs: The Johns Hopkins Dementia Care Needs Assessment (JHDCNA) is a multidimensional instrument for trained community evaluators to identify caregiver and care recipient (CR) dementia-related needs. It is formatted as a checklist to evaluate 15 CR need domains (71 items) and 4 caregiver domains (15 items). The evaluator determines if the need is unmet, partially met or fully met based on criteria specified in the intervention manual. Total percent of unmet caregiver needs on the JHDCNA was calculated using the 15 items assessing caregiver needs. The percent of unmet needs in 4 need domains (caregiver education, resource referral, mental health, medical health) were also evaluated for treatment group differences. A registered nurse, unmasked to group placement, rated the JHDCNA at baseline and 18-month visits. Secondary outcome measures: Aspects of caregiver burden (objective and subjective), depression, and QOL were assessed by masked evaluators at baseline, 9 months, and 18 months. Objective caregiver burden was operationalized with 3 items that asked caregivers to estimate their time expenditures: • “How many hours in the past week did you spend with the CR?” • “How many hours in the past week did you spend doing things for the CR (e.g., paying bills, picking up supplies)?” • (For those currently employed) “How many hours in the past month did you miss from work due to your caregiver responsibilities for the CR?” Subjective caregiver burden was measured by the 12-item Zarit Burden Interview (ZBI) on which scores range from 0 to 44 with higher scores being worse. Depression was measured by the 15-item Geriatric Depression Scale (GDS), with scores ranging from 0 to 15 and scores above 5 suggestive of depression. QOL was measured by the SF-12, which consists of physical and mental health components ranging from 0 to 100, with a lower score being worse. Additionally, single-item Likert burden ratings recorded perceived day-to-day difficulty caring for the CR (1 least difficult, 5 most difficult), self-rated overall health (1 poor health, 5 excellent health), and self-rated stress (1 not stressed, 5 extremely stressed).
Study dates	Study dates were not provided. The study was published in 2015.
Study location	USA
Comments	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	**Tanner J A, Black B S, Johnston D, Hess E, Leoutsakos J M, Gitlin L N, Rabins P V, Lyketsos C G, and Samus Q M (2015) A randomized controlled trial of a community-based dementia care coordination intervention: effects of MIND at Home on caregiver outcomes. American Journal of Geriatric Psychiatry 23(4), 391-402**
Risk of bias	• Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes and no: Caregiver unmet needs was not blinded. Other measurements were. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Difficult to compare systems in the US to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low. Moderate for caregiver unmet needs.

Bibliographic reference	**Van Mierlo , L D, Meiland F J, Van de Ven , P M, Van Hout , H P, and Droes R M (2015) Evaluation of DEM-DISC, customized e-advice on health and social support services for informal carers and case managers of people with dementia; a cluster randomized trial. International Psychogeriatrics 27(8), 1365-78**
Study type	RCT
Participants	Inclusion criteria: informal caregivers of people with dementia living at home who (i.e. the caregiver) have a computer with internet possibility and knows how to use it. Exclusion criteria: the caregiver is not able to understand or read Dutch, and anticipated nursing home admission of the person with dementia within six months.
Sample characteristics	N= 49 people living with dementia and their carers n= 30 experimental intervention: DEM-DISC 78.0%=female; 22%=male; mean age (SD)= 82.1 years (7.3); mean MMSE (SD)= 18.2 (6.7) n= 19 comparator: No DEM-DISC 65.6%=female; 34.4%=male; mean age (SD)= 79.5 years (7.9); mean MMSE (SD)= 17.5 (5.8)
Intervention	Case managers from the experimental group had access to DEM-DISC. They could use it to assist them advise their clients on care and welfare services that were relevant for them. Their clients (informal caregivers of people with dementia) had unrestricted access to DEM-DISC at home for a period of one year.

Bibliographic reference	**Van Mierlo , L D, Meiland F J, Van de Ven , P M, Van Hout , H P, and Droes R M (2015) Evaluation of DEM-DISC, customized e-advice on health and social support services for informal carers and case managers of people with dementia; a cluster randomized trial. International Psychogeriatrics 27(8), 1365-78**
	During an introduction meeting, case managers received information about DEM-DISC and instructions on how to introduce the DEM-DISC study to their clients (informal caregivers). When informal caregivers agreed to participate (and had signed an informed consent form), they were given a username and password, with which they could log in to DEM-DISC at home. Both informal caregivers and case managers received an instruction manual on DEM-DISC and a telephone number of a helpdesk that they could call during the intervention period with any questions or problems regarding the use of DEM-DISC. Instruction on how to use DEM-DISC at home was available to informal caregivers if they wanted it. During the whole intervention period, the usage of the DEM-DISC was logged. The participants were interviewed at home. The data collected through the interviews and questionnaires at pre-test and 12 months follow-up were used for the DEM-DISC study. Furthermore, informal caregivers filled in a questionnaire they received via email to evaluate the DEM-DISC. This questionnaire incidentally was conducted by telephone. The case managers were interviewed by telephone after six months. Stakeholders were interviewed on the implementation of the DEMDISC using semi-structured interviews.
Comparison	Usual care. Participants in the control group did not have access to DEM-DISC. They had access to the regular information channels (e.g. via the GP, brochures etc.) and were advised by case managers who did not have access to DEM-DISC.
Outcome measures	The primary outcome measure of this study was needs of people with dementia as reported by informal caregivers, measured by the Dutch version of the Camberwell Assessment of Needs for the Elderly. The CANE consists of 24 domains of daily living and assesses if respondents have needs and, if so, whether these needs are met or unmet. Three scores can be derived from the CANE, one for total needs, met needs and unmet needs. For people with dementia, secondary outcome measures were: quality of life (QoI-AD) and neuropsychiatric symptoms as measured by the Neuropsychiatric Inventory (NPI). For informal caregivers, secondary outcome measures were feelings of competence as measured by the Short Sense of Competence Questionnaire (SSCQ), quality of life (EQ5D+c) and the stress caused by neuropsychiatric symptoms in people with dementia (NPI). Furthermore, the user-friendliness, usability and satisfaction with DEM-DISC were assessed with the USE Questionnaire in both the informal carers and case managers, and some additional questions were emailed to informal caregivers only. The USE questionnaire contains four components: “usefulness,” “ease of use,” “ease of learning,” and “satisfaction.” Questions are scored on a five-point scale (range 1–5, lower scores indicate a more positive outcome).
Study dates	Not provided. This study was published in 2015.
Study location	The Netherlands

Bibliographic reference	**Van Mierlo , L D, Meiland F J, Van de Ven , P M, Van Hout , H P, and Droes R M (2015) Evaluation of DEM-DISC, customized e-advice on health and social support services for informal carers and case managers of people with dementia; a cluster randomized trial. International Psychogeriatrics 27(8), 1365-78**
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Unclear. Blinding is not mentioned. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? No. 32% of the original participants were lost to follow-up without explanation. In addition, of those who did participate in the intervention arm, there were 5 out of 41 who did not log in to use DEM-DISC. Furthermore, only the primary outcomes were reported in evidence tables. Data that was published as odds ratios so it is not easy to compare baseline values. • Can the results be applied to the local population? Unclear. It is difficult to compare systems in the Netherlands and the UK. • Were all clinically relevant outcomes reported? No. The number of events in either group are not reported. Therefore, only the relative difference is reported, not the absolute difference. • Overall risk of bias: Very high

Bibliographic reference	**Vickrey B G, Mittman B S, Connor K I, Pearson M L, Della Penna, R D, Ganiats T G, Demonte R W, Jr , Chodosh J, Cui X, Vassar S, Duan N, and Lee M (2006) The effect of a disease management intervention on quality and outcomes of dementia care: a randomized, controlled trial.[Summary for patients in Ann Intern Med. 2006 Nov 21;145(10):I31; PMID: 17116913]. Annals of Internal Medicine 145(10), 713-26**
Study type	RCT
Participants	Inclusion criteria: People living with dementia who were age 65 years or older and receiving Medicare were identified by querying health care organisation administrative databases for occurrence during the previous year of a dementia diagnosis code at an outpatient visit or hospitalization or a cholinesterase inhibitor prescription. Participants had to have an informal caregiver (age ≥18 years). Exclusion criteria: None other
Sample characteristics	N= 290 people living with dementia and their carers. n= 166 experimental intervention: care management system 54.2%=female; 45.8%=male; mean age (SD)= 80.10 years (6.5); mean dementia severity score (SD)= 5.7 (3.4)

Bibliographic reference	**Vickrey B G, Mittman B S, Connor K I, Pearson M L, Della Penna, R D, Ganiats T G, Demonte R W, Jr , Chodosh J, Cui X, Vassar S, Duan N, and Lee M (2006) The effect of a disease management intervention on quality and outcomes of dementia care: a randomized, controlled trial.[Summary for patients in Ann Intern Med. 2006 Nov 21;145(10):I31; PMID: 17116913]. Annals of Internal Medicine 145(10), 713-26**
	n= 124 comparator: usual care 55.9%=female; 44.1%=male; mean age (SD)= 80.11 years (6.8); mean dementia severity score (SD)= 6.3 (4.2)
Intervention	A steering committee that included a physician from each health care organisation, a leader from each community agency, a community caregiver, and investigators used a formal method to identify 23 existing dementia guideline recommendations as care goals. They also designed a structured assessment, algorithms linking specific care management actions to assessment results, and inter-organisation care coordination and referral protocols. A key intervention element was health care organisation and community agency-based dementia care managers (primarily social workers) who received formal training and used an Internet-based care management software system for care planning and coordination. Every enrolled patient and caregiver dyad in the intervention group was assigned 1 health care organisation care manager, who contacted them to schedule a structured home assessment. Assessment responses were entered into the software system, generating a preliminary problem list and guides to care-plan actions. The care manager collaborated with the caregiver to prioritise problem areas; teach problem-solving skills; initiate care plan actions; and send an assessment summary, a problem list, and selected recommendations to the patient's primary care physician and other designated providers. A menu of potential care plan actions (for example, referral for respite care services) was documented in a comprehensive care management manual. The care management protocol included ongoing follow-up, usually by telephone, with frequency based on need and a formal in-home reassessment every 6 months to assess the need for major care-plan revisions. The software system had a feature to enable efficient tracking of multiple cases and tasks. Referrals to a particular community agency were guided by flagged problem areas. With patient and caregiver consent, referrals were communicated through the software system to that agency, whose designated care manager subsequently received system access to the assessment, problem list, and care plan. Each dyad could have 1 or more community agency care managers. Care managers from the health care organisations and community agencies received the same formal education and training program, which was conducted jointly, and met monthly to refine care coordination procedures. Care management began within a month after enrolment of the first dyads and was active throughout the study follow-up unless a case was closed, for example, because a patient moved out of the study area and no longer was enrolled in the health care organisation. At each intervention clinic, more than 90 minutes of standardized, interactive seminars (in up to 5 sessions) on relevant care issues, including evaluation of acute behavioural changes, depression management, and determination of decision-making capacity, were offered to primary care providers. Selected intervention tools and documents with more detailed descriptions can be accessed at http://www.adc.ucla.edu/access/access.swf.

Bibliographic reference	**Vickrey B G, Mittman B S, Connor K I, Pearson M L, Della Penna, R D, Ganiats T G, Demonte R W, Jr , Chodosh J, Cui X, Vassar S, Duan N, and Lee M (2006) The effect of a disease management intervention on quality and outcomes of dementia care: a randomized, controlled trial.[Summary for patients in Ann Intern Med. 2006 Nov 21;145(10):I31; PMID: 17116913]. Annals of Internal Medicine 145(10), 713-26**
	Patients, caregivers, and providers in the usual care group were not offered study interventions. The follow-up frequency by telephone was approximately monthly. In addition, there was a home visit and re-assessment at 6 months.
Comparison	Usual care
Outcome measures	Patient health-related quality of life (assessed by using the Health Utilities Index Mark 3 [HUI3], a generic health state classification system). Caregiver ratings of the patient's overall health care quality (by using a range of 0 to 10, anchored at "worst" and "best" possible health care over the previous 6 or 12 months). Caregiver confidence and mastery of caregiving. Caregiver ratings of his or her health-related quality of life; caregiver social support; and unmet need for assistance in behaviour problem management. Caregiver health-related quality of life was measured by using the EuroQol-5D, a 5-item generic preference measure, and changes in caregiver health and in social functioning attributable to caregiving demands over the previous 6 or 12 months.
Study dates	2003 to 2004
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Unclear. Blinding was not mentioned. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes. By the end of the trial, some participants had either withdrawn or not completed the survey. However this was only 53 of them (13% of those who started). This is below the arbitrary 20% cut-off point. • Can the results be applied to the local population? Unclear. It is difficult to compare systems in the US to those in the UK. • Were all clinically relevant outcomes reported? Yes

Bibliographic reference	**Vickrey B G, Mittman B S, Connor K I, Pearson M L, Della Penna, R D, Ganiats T G, Demonte R W, Jr , Chodosh J, Cui X, Vassar S, Duan N, and Lee M (2006) The effect of a disease management intervention on quality and outcomes of dementia care: a randomized, controlled trial.[Summary for patients in Ann Intern Med. 2006 Nov 21;145(10):I31; PMID: 17116913]. Annals of Internal Medicine 145(10), 713-26**
	Overall risk of bias: Low

Bibliographic reference	**Xiao L D, De Bellis A, Kyriazopoulos H, Draper B, Ullah S (2016) The effect of a personalized dementia care intervention for caregivers from Australian minority groups. Current Topics in Research. 31(1): 57-67**
Study type	RCT
Participants	Inclusion criteria: (1) caregivers were from a minority group and cared for a community–dwelling older person with dementia from the same minority group; (2) caregivers were the primary caregiver in the family; (3) caregivers had cared for the person with dementia for at least 1 year and had at least twice per week face-to-face contacts with the care recipients to ensure the intervention intensity required in the study was met; (4) caregivers were aged 18 or older; and (5) the care recipients had been diagnosed with dementia or had cognitive impairment determined by a score ≤22 of the 30 using the Rowland Universal Dementia Assessment Scale (RUDAS). Exclusion criteria: Caregivers were excluded from the trial if they themselves had cognitive impairment and/or a terminal illness or were in the first year of their caregiving role as there are a number of dementia education programs in Australia that target this period that may have affected the outcomes of the trial.
Sample characteristics	N= 61 carers of people living with dementia. They were from 10 minority groups. n= 31 experimental intervention: personalised caregiver support Baseline characteristics of the people living with dementia: 64.5% =female; 35.4% =male; mean age (interquartile range)= 83.0 years (77.0-87.0); Rowland Universal Dementia Assessment Scale (RUDAS) (interquartile range)= 14.1 (0-21.0) n= 30 comparator: usual care Baseline characteristics of the people living with dementia: 56.6% =female; 43.3% =male; mean age (IQR)= 82.5 years (76.0-86.); RUDAS (IQR)= 12.9 (0-22.0)
Intervention	Interventions used in this trial were mainly informed by a critique of current research evidence in case management intervention in caregiver support. In addition, findings from previous studies by the research team and consultations with the participating organisations about resources to support the trial were considered. Participating organisations appointed 8 care coordinators to participate in the project and qualifications among them varied including a registered nurse, a social worker, and 6 Community Home Care Certificate holders. These coordinators were chosen based on their role working with people with dementia and experience with the caregiver population being

Bibliographic reference	Xiao L D, De Bellis A, Kyriazopoulos H, Draper B, Ullah S (2016) The effect of a personalized dementia care intervention for caregivers from Australian minority groups. Current Topics in Research. 31(1): 57-67
	studied. Each caregiver in the intervention group was assigned to a care coordinator who was currently managing the person with dementia cared for by the caregiver, and 7 of the coordinators had cultural and linguistic concordance with caregivers. The caseload for a care coordinator varied and ranged from 1 to 6 cases. The care coordinators were trained to use the Personalised Caregiving Support Plan (PCSP) and a Caregiving Diary. ''The Inventory of Carer's Needs'' in the PCSP covered the following 5 areas of caregiver support: information needs, educational and skill needs, environmental safety needs, social–cultural care needs, and self-care needs that reflect the current research evidence in dementia caregiver support. The PCSP was used by the care coordinators when assessing caregivers' needs, taking actions to address these needs, and evaluating the outcomes of their actions. The care coordinators encouraged the caregivers to use the Caregiving Diary to record challenges they faced in daily care practice in a language of choice. The Caregiving Diary was translated to the language of choice and structured in a simple table for the caregiver to enter. The use of the Caregiving Diary allowed care staff to identify care needs for care recipients and provide face-to-face coaching with caregivers and evaluate the effectiveness of care staff's actions. The research team provided 3 standard training sessions with the care coordinators based on a consultation with them, that is, (1) using the Personalized Caregiving Support Plan and Family Caregiver Diary to identify and meet caregivers' needs, (2) managing challenging behaviours, and (3) managing incontinence. The care coordinators initially made a home visit to assess caregivers' needs and establish the PCSP in collaboration with care staff who had regular contact with the person with dementia and their caregivers. The care coordinators made a monthly phone contact with caregivers to allow the caregivers to discuss the needs of care recipients and the caregivers. They also made a quarterly home visit to reassess caregivers' needs and modify the PCSP. They referred caregivers to new services and education programs based on this needs assessment. When necessary, they organised conferences with caregivers and care staff to discuss ongoing challenges that the caregiver faced in order to identify the best solution to any problem identified.
Comparison	Usual care. The usual caregiver support included activities such as monthly caregiver support group meetings and information sessions that were funded by the National Respite for Carers Program (NRCP).
Outcome measures	Measurements were taken at baseline and at 12 months. Primary outcome was caregivers' competence measured by the Sense of Competence Questionnaire (SSCQ). The 7-item SSCQ is a validated instrument and rated on a 5-point Likert scale with higher scores indicating the better sense of competence. Health-related QoL that was measured using the validated Short Form Health Survey version 2 (SF-36v2). Components of SF-36 have been translated into 2 summary dimensions: physical component and mental component. Higher scores of QoL measured by the SF-36 mean better QoL. The dependence levels of care recipients were measured using the validated ''Blessed Dementia Score'' (ranging 0-

Bibliographic reference	**Xiao L D, De Bellis A, Kyriazopoulos H, Draper B, Ullah S (2016) The effect of a personalized dementia care intervention for caregivers from Australian minority groups. Current Topics in Research. 31(1): 57-67**
	27; Cronbach's with higher scores meaning higher levels of dependence. Severity of behavioural problems and caregiver distress were measured using the validated Neuropsychiatric Inventory with higher scores meaning higher levels of severity of behavioural problems and caregiver distress. Satisfaction with care support was measured using the validated Quality Of Care Through the Patients' Eyes (QUOTE-elderly) questionnaire-specific part. Three items were added to the QUOTE-elderly questionnaire to ask about satisfaction with the cultural and linguistic appropriateness of the services provided. The 21-item satisfaction survey was rated on a 5-point Likert scale, with higher scores indicating higher levels of satisfaction with services received. The usage of respite care, aged care services, and dementia services was measures on a 4-point Likert scale, with higher scores indicating the higher usage rates of these services. Content analysis of the PCSP and Caregiver Diary, and intervention fidelity were also analysed. Demographic information about the caregivers and care recipients were collected prior to the trial only.
Study dates	Not provided. This study was published in 2016.
Study location	Australia
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. A "simple random sampling" method was used. However, the method was not specified. • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Unclear. 93.5% of the caregivers in the intervention group were born overseas vs 66.7% in the usual care group. In the intervention group, 96.8% of caregivers spoke a language at home that was not English vs 76.7% in the usual care group. • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. The minority groups in this Australian study were: Cambodian, Chinese, Croatian, Dutch, Greek, Hungary, Italian, Macedonian, Ukraine, and Vietnamese. By contrast, the main minority groups in the UK are different. In descending order of size, the minority groups in the UK are: Black or Black British, Indian, Mixed or Multiple, Pakistani, Other Asian, Other ethnic group, Chinese, Bangladeshi, and Gypsy Traveller/Irish Traveller. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

E.3.2 Post diagnosis review for people living with dementia

- How should people living with dementia be reviewed post diagnosis?

Bibliographic reference	Bass DM, Clark PA, Looman WL, McCarthy CA, Eckert S (2003) The Cleveland Alzheimer's Managed Care demonstration: Outcomes after 12 months, The Gerentologist, 43 (1)73-85
Study type	Randomised control trial
Aim	To evaluate the effects of integrating a managed health care system with Alzheimer's Association consultation services
Patient characteristics	N=157 family caregiver/ patient records Other data not reported
Inclusion/ exclusion criteria	Inclusion: • Patients aged 55 years or older with either a specific diagnosis of dementia or indications of memory loss • Residing outside of a nursing home • Live in Cleveland Alzheimer's Association service area Exclusion: Not reported
Intervention	• Care reviews and consultations comprising use of managed health services in partnership with use of Alzheimer's associations services
Comparison	• Usual managed care services only
Length of follow up	12 months
Location	USA
Outcomes measures	Service utilisation • No of Emergency department visits • Hospital admissions • Physician visits • Case management visit • Use of direct care community services Use of non-Association support services
Authors conclusion	Some but not all service utilisation outcomes showed support for the primary hypotheses
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes. Clearly reported hypotheses

Bibliographic reference	Bass DM, Clark PA, Looman WL, McCarthy CA, Eckert S (2003) The Cleveland Alzheimer's Managed Care demonstration: Outcomes after 12 months, The Gerentologist, 43 (1)73-85
	• Was the assignment of patients to treatments randomised? Unclear –states randomisation but method not reported • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Unclear: Minimal baseline data provided • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? CIs. reported • How precise was the treatment effect? P values reported • Can the results be applied to the local population? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Crotty M, Halbert J, Rowett D, Giles L, Birks R, Williams H, Whitehead C (2004) An outreach geriatric medication advisory service in residential aged care: a randomised controlled trial of case conferencing, Age and Ageing, 33 (6) 612-617
Study type	Randomised controlled trial
Aim	To evaluate the effectiveness of multidisciplinary case conferences for people living in high residential aged care facilities with medication problems and difficult behaviours (pain and dementia related)
Patient characteristics	Within facility (people with problem behaviours and medication problems) • Intervention: N= 50 (mean age = 84 years; 44% male; 67% diagnosed with dementia) • Control N=50 (mean age = 85 years; 34% male; 63% diagnosed with dementia) Broader control (to observe carry-over effect for people in aged care facility without behavioural or medication issues) N= 54 (mean age = 84 years; 43% male; 72% diagnosed with dementia
Inclusion/ exclusion criteria	Inclusion: • Residents from 10 nursing homes who required daily nursing care and were no longer independent • Residents had to have difficult behaviour or be prescribed more than 5 medications Other residents were also recruited from these nursing homes as a wider control to observe any carry over effect on residents who were not discussed in the case conferences Exclusion:

Bibliographic reference	Crotty M, Halbert J, Rowett D, Giles L, Birks R, Williams H, Whitehead C (2004) An outreach geriatric medication advisory service in residential aged care: a randomised controlled trial of case conferencing, Age and Ageing, 33 (6) 612-617
	• Not reported
Intervention	• Received multidisciplinary case conferences conducted in the nursing home 6-12 weeks apart (involving a GP, geriatrician, pharmacist, residential care staff member, representative of Alzheimer's Association) • Expanded on case notes • Alzheimer's Association representative discussed non pharmacological management of dementia related behaviour
Comparison	• Did not receive case conferences
Length of follow up	3 months
Location	Australia
Outcomes measures	• Medication Appropriateness Index (MAI) • Behaviour (Nursing Home Behaviour Problem Scale)
Authors conclusion	Significant change in MAI between groups at follow up showing reduced medication use in case-conference group, but no significant change in NHBPS
Source of funding	Funded by Quality Use of Medicines Evaluation Program ; Health and Aged Care GP National Innovation Funding Pool; Health and Aged Care
Risk of bias	• Did the trial address a clearly focused issue? Yes. • Was the assignment of patients to treatments randomised? Yes- randomisation at centre, not individual level (computer generated numbers) • Were patients, health workers and study personnel blinded? Unclear- not reported if study personnel were blind. GPs unblinded. Participants in each facility also nominated for wider controls (to observe carry over effect) • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes- follow up at 6 and 12 months. Large loss at 12 months • How large was the treatment effect? CIs. reported • How precise was the treatment effect? Only Cis reported • Can the results be applied to the local population? Yes- proportion dementia • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

Bibliographic reference	Kohler L, Meinke-Franze C, Hein J, Fendrich K, Heymann R et al (2014) Does an interdisciplinary network improve dementia care? (IDemUck-study), Current Alzheimer Research, 11, 538-548
Study type	Randomised controlled trial
Aim	To assess the effectiveness of an already existing dementia network
Patient characteristics	N= 235 Network care n= 118 (mean age 78 years; 37% male) Care as usual n=117 (mean age 79 years; 29% male)
Inclusion/ exclusion criteria	Inclusion: • Aged 55 years or older • Living in study area • Positive screening in DemTect score <9 • No hint of severe depression (GDS<11) Exclusion • People living in residential care • Not able to participate due to sensory impairment • Limited command of German
Intervention	• An integrative network of dementia care across medical disciplines (GPs, medical specialists, social workers, hospitals, other inpatient/outpatient settings)
Comparison	Usual care
Length of follow up	6-12 months
Location	Germany
Outcomes measures	• Cognition (MMSE) • Functional (NAA; IADL) • Quality of life (EQ5D; QOL-AD)
Authors conclusion	There were no group differences on quality of life or treatment by time effects and no significant difference for caregiver quality of life
Source of funding	Federal Ministry of Health, Germany
Risk of bias	• Did the trial address a clearly focused issue? Yes. • Was the assignment of patients to treatments randomised? No- open assignment to intervention arms, by treating physician

Bibliographic reference	Kohler L, Meinke-Franze C, Hein J, Fendrich K, Heymann R et al (2014) Does an interdisciplinary network improve dementia care? (IDemUck-study), Current Alzheimer Research, 11, 538-548
	• Were patients, health workers and study personnel blinded? No- personnel and healthcare staff were all members of the network. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? SDs reported • How precise was the treatment effect? P values reported, imputations • Can the results be applied to the local population? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: High

Bibliographic reference	Meeuwsen EJ, Melis RJF, Van Der Aa GCHM, Goluke-Willemse GAM et al (2012) Effectiveness of dementia follow up care by memory clinics or general practitioners: randomised controlled trial, BMJ, ; 344:e3086
Study type	Randomised controlled trial
Aim	To determine the effectiveness of post-diagnosis treatment and care by memory clinics compared to care provided by GPs for people living with dementia
Patient characteristics	Memory clinic n= 87 (62% female; mean age 78 years MMSE 22.7) GP Group n= 88 (59% female; mean age 78 years; MMSE 22.7)
Inclusion/ exclusion criteria	Inclusion: • Newly diagnosed as having dementia (CDR 0.5, 1 or 2) • Had an informal carer Exclusion: • Living in a nursing home • Life expectancy of less than 1 year • Need specific memory clinic care
Intervention	• Usual review, monitoring and care by memory clinic based on specialist Dutch guideline of Dutch Institute of Healthcare Improvement • Prescribing and guidance of anti-dementia drugs

Bibliographic reference	Meeuwsen EJ, Melis RJF, Van Der Aa GCHM, Goluke-Willemse GAM et al (2012) Effectiveness of dementia follow up care by memory clinics or general practitioners: randomised controlled trial, BMJ, ; 344:e3086
	• Provide non drug interventions (Occupational therapy; day structure; referral to nurse specialist, day or home care)
Comparison	• Usual review, monitoring and care provided by GPs • Post diagnosis treatment and care based on Dutch GP and homecare general guidelines • GP received a discharge letter with advice about treatment after diagnostic investigation from memory clinic • Use of cholinesterase inhibitors was not recommended by GP guideline although some GPs did prescribe • Non drug interventions were available through GP clinic
Length of follow up	12 months
Location	Netherlands
Outcomes measures	• Quality of life (QOl-AD) • Depression (GDS) • Functional (Interview for deterioration in daily living in dementia)
Authors conclusion	No evidence was found of a difference in effectiveness for care for people with dementia provided by a memory clinic or by GPs
Source of funding	ZonMw (Netherlands Organisation for Health Research and Development)
Risk of bias	• Did the trial address a clearly focused issue? Yes. • Was the assignment of patients to treatments randomised? Unclear web based randomisation reported but methods used to allocate participants not reported in detail • Were patients, health workers and study personnel blinded? Unclear- only states that research assistants were blinded, blinding of other health staff/ study members not reported. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? CIs reported • How precise was the treatment effect? MIDs ; ANCOVA reported • Can the results be applied to the local population? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

Bibliographic reference	Nourhashemi F, Andrieu S, Gillette-Gouyonnet S, Giraudeau B, Canet C, Coley N, Velas B (2010) Effectiveness of a specific care plan in patients with Alzheimer's disease: Cluster randomised trial (PLASA study), BMJ, 340, c2466
Study type	Randomised controlled trial
Aim	To test the effectiveness of a specific care plan compared to usual care provided in memory clinics on decreasing the rate of functional decline in people living with Alzheimer's disease residing in the community
Patient characteristics	Specialised care in memory clinics n=574 (mean age 80 years 67% female) Usual care in memory clinic n=557 (mean age = 80 years; 71% female)
Inclusion/ exclusion criteria	Inclusion: • Consecutive patients meeting NINCDS/ADRDA criteria for probable or possible Alzheimer's disease • MMSE score 12-26 • Living in community • Not participating in any other research programmes • Have a caregiver Exclusion: • Not reported
Intervention	• Standard evaluations in memory clinics every 6 months based on a standardised management protocol • Assessments comprised cognitive and non-cognitive assessment, functional dependency, progression of cognitive decline, drugs review, nutritional status, gait and walking capacity, behavioural symptoms, caregivers psychological and physical health, legal safety of patient • Specific multidisciplinary care plan developed by neurologists, geriatricians, psychiatrists and general practitioners
Comparison	• Usual care in memory clinics based on diagnosis with no systematic follow-up or evaluation unless specifically requested by patient
Length of follow up	12 and 24 months
Location	France
Outcomes measures	• Functional decline (ADCS-ADL) • Mean time to admission • Risk of admission to residential care • Risk of mortality • Reason for admission (worsening medical conditions) • Reason for admission (caregiver related reasons)

Bibliographic reference	Nourhashemi F, Andrieu S, Gillette-Gouyonnet S, Giraudeau B, Canet C, Coley N, Velas B (2010) Effectiveness of a specific care plan in patients with Alzheimer's disease: Cluster randomised trial (PLASA study), BMJ, 340, c2466
Authors conclusion	At 2 years there was no difference in rate of functional decline or the annual rate of change in cognitive decline between groups. A specific care plan in memory clinics had no additional positive effect on functional decline
Source of funding	Grant from French Ministry of Health
Risk of bias	• Did the trial address a clearly focused issue? Yes. • Was the assignment of patients to treatments randomised? Yes- at cluster level; • Were patients, health workers and study personnel blinded? Yes- allocation concealment until treatment commence but open trial – design inappropriate for blinding • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes- large loss to follow up at 2 years • How large was the treatment effect? SEs reported • How precise was the treatment effect? SEs reported • Can the results be applied to the local population? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

E.4 Inpatient care

E.4.1 Caring for people living with dementia who are admitted to hospital

- How should people living with dementia be cared for when admitted to hospital?

Bibliographic reference	Baldwin R, Goring H, Marriott A, Roberts C (2004) Does a nurse-led mental health liaison service for older people reduce psychiatric morbidity in acute general medical wards? A randomised controlled trial, Age and Aging, 33 (5) 472-478
Study type	Randomised controlled trial
Aim	To determine the clinical effectiveness of a nurse-led mental health liaison service for managing mental health problems in older aged physically ill patients
Patient characteristics	N= 153 Intervention n= 77 (70.1% female; mean age 80.6; mean MMSE18.2; mean GDS 14.4) Control n= 76 (57.9% female; mean age 80.0; mean 18.8; mean GDS 14.0)MMSE
Inclusion/ exclusion criteria	Inclusion • A score of 4 or more on GDS 4 (4-item Geriatric depression scale) and over 10 on OMC (orientation memory test) • MMSE between 18 to 24 Exclusion • Discharge within 3 days of admission • Inability to complete research schedule • Acute risk of self-harm
Intervention	Nurse led intervention (multi-faceted intervention delivered by a nurse with 3 years post qualification experience
Comparison	Usual care (care and treatment delivered by acute ward staff)
Length of follow up	3 months
Location	UK
Outcomes measures	Scores on • Health of Nation outcome scale • Geriatric Depression Scale • MMSE • Length of stay in hospital (days)

Bibliographic reference	Baldwin R, Goring H, Marriott A, Roberts C (2004) Does a nurse-led mental health liaison service for older people reduce psychiatric morbidity in acute general medical wards? A randomised controlled trial, Age and Aging, 33 (5) 472-478
	• Readmissions at 3 months • Death at 3 months
Authors conclusion	Nurse led mental health liaison services which accept all screened cases are unlikely to be effective in reducing general psychiatric morbidity. Services which target specific patient groups are more likely to be effective
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Computer generated allocation with minimum control for factor (depression or cognitive impairment) • Were patients, health workers and study personnel blinded? Single blind- Participants un-blinded but asked to not disclose treatment group; researchers were blinded • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? 18 participants in intervention and 15 participants in control arm lost to follow up • Can the results be applied to the population of interest? Partly. Mixed population of depression/Cognitive impairment • Were all clinically important outcomes considered? Yes Overall Risk of bias: Moderate

Bibliographic reference	Boltz M, Chippendale T, Rosnick B, Galvin JE (2015) Testing family-centred, function-focused care in hospitalized persons with dementia, Neurodegenerative Disease Management, 5 (3) 203-215
Study type	Non-randomised control trial
Aim	To test the feasibility of a family centred function focused care program among hospitalised people with dementia and their family carers at discharge
Patient characteristics	N=86 Intervention n=44 (mean age 83.8 years; 52% female) Control n=42 (mean age 81 years; 67% female)
Inclusion/ exclusion	Patient inclusion

Bibliographic reference	Boltz M, Chippendale T, Rosnick B, Galvin JE (2015) Testing family-centred, function-focused care in hospitalized persons with dementia, Neurodegenerative Disease Management, 5 (3) 203-215
criteria	• Dyads of patient/ carers of people living with dementia admitted to five medical units of two hospitals. • English speaking/ reading • Positive mini cog • AD88 ≥ 2 Exclusion • Patients who were terminally ill or receiving hospice care or surgery Carer inclusion • English speaking/ reading • Blood relative of patient or related by marriage, adoption or affinity • Primary caregiver living with patient or providing care on a continuing basis
Intervention	Two units were intervention group implementing a family focused function centred care intervention comprising: • Environmental & policy assessment • Staff education & training • Ongoing training for nursing staff • Development of family/ patient care pathway
Comparison	Three units acted as a control receiving usual care and educational information only
Length of follow up	14 days and 60 days post discharge
Location	USA – 5 units across 3 hospitals
Outcomes measures	Patient outcomes • Hospital readmission • Occurrence of delirium • Activities of daily living • Gait/ Balance Carer outcomes • Preparedness for caregiving • Anxiety • Depression

Bibliographic reference	Boltz M, Chippendale T, Rosnick B, Galvin JE (2015) Testing family-centred, function-focused care in hospitalized persons with dementia, Neurodegenerative Disease Management, 5 (3) 203-215
	• Strain • Mutuality
Authors conclusion	Family centred function focused care may provide a possible pathway to improve patient care for people living with dementia
Source of funding	Not reported
Risk of bias	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes: questionnaire scales previously validated • Have the authors identified all important confounding factors? Yes - baseline data provided • Have they taken account of the confounding factors in the design and/or analysis? Yes - limited by small sample • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Yes Overall Risk of bias: High (non-randomised study)

Bibliographic reference	Campbell ML, Guzman JA (2004) A proactive approach to improve end-of-life care in a medical intensive care unit for patients with terminal dementia, Critical Care Medicine, 32 (9), 1839-1843
Study type	Retrospective and prospective cohort study (historical chart review acted as control for prospective approach)
Aim	To determine the patterns of care for patients with terminal dementia in the ICU and to determine the frequency and timing of consultation with the palliative care service To compare usual care with prospective case finding for critically ill patients with terminal dementia
Patient characteristics	N= 52; Comparison mean age = 80.8 years; APACHE II (Acute Physiology and Chronic Health Evaluation score)= 28.3; Control mean age = 81.2 years; APACHE II (Acute Physiology and Chronic Health Evaluation score)= 28.3
Inclusion/ exclusion criteria	Inclusion • Patients with advanced stage dementia included in both historical and prospective groups • Pre-hospital functional status included factors consistent with late stage disease (bed bound, largely nonverbal, incontinent, unable to self nourish or receiving nourishment by tube)

Bibliographic reference	Campbell ML, Guzman JA (2004) A proactive approach to improve end-of-life care in a medical intensive care unit for patients with terminal dementia, Critical Care Medicine, 32 (9), 1839-1843
	Exclusions not reported
Intervention	• Collaboration between palliative care service and intensive care unit staff to proactively identify treatment options for a cohort of people living with end-stage dementia
Comparison	• Retrospective chart review to identify usual care for the same cohort
Length of follow up	Not reported
Location	USA
Outcomes measures	• Hospital and ICU length of stay • Use of non-beneficial resources • Establishment of do not resuscitate goals
Authors conclusion	Proactive interventions from palliative care consultants improved end of life care and reduced superfluous resources for people in the ICU living with terminal dementia
Source of funding	Not reported
Risk of bias	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Unclear – does not specify if historical elements directly related to prospective group • Was the exposure accurately measured to minimise bias? Unclear- limited reporting • Was the outcome accurately measured to minimise bias? Unclear- historical outcomes (based on chart review) formed the control aspects • Have the authors identified all important confounding factors? Yes • Have they taken account of the confounding factors in the design and/or analysis? Yes- recognised small sample size • Was the follow up of subjects complete enough? Follow up not specified • Was the follow up of subjects long enough? Not reported Overall risk of bias: High

Bibliographic reference	Goldberg SE, Bradshaw LE, Kearney FC, Russell C, Whittamore KH, Foster PER et al (2013) Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial), British Medical Journal, f41312

Bibliographic reference	**Goldberg SE, Bradshaw LE, Kearney FC, Russell C, Whittamore KH, Foster PER et al (2013) Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial), British Medical Journal, f41312**
Study type	Randomised controlled trial
Aim	To develop a best practice model of general hospital acute medical care for older people with cognitive impairment
Patient characteristics	N= 600 Intervention n=310; median age = 85 (80-88) years; median MMSE = 14 (6-20); median DRS = 19 (11-27) Control n=290; median age = 85 (80-89) years; median MMSE = 13 (6-19); median DRS =20 (14-27)
Inclusion/ exclusion criteria	Inclusion • People aged over 65 and identified by a physician as being confused (covering both population with delirium and dementia) • Family carers were recruited as an informant (if available) Exclusion • People with a clinical need for another specialist service (critical care, surgery or stroke unit)
Intervention	Medical and Mental Health Unit - an acute geriatric ward with five components: Specialist mental health staff (3 nurses; an Occupational Therapist; twice weekly visits from a psychiatrist; physiotherapy; speech and language therapy; geriatrician) Staff trained to recognise and manage delirium and dementia (including person centred dementia care) Programme of therapeutic and diversionary activities An environment appropriate to people with cognitive impairment Proactive approach to include family carers
Comparison	Standard care - five acute geriatric medical wards and six general medical wards Practice based on comprehensive geriatric assessment Staff had general experience of management of delirium and dementia Mental health support provided on request
Length of follow up	Follow up 90 days
Location	UK (Large acute general hospital)
Outcomes measures	• Number of days spent in home or care home after randomisation • Quality of life (EQ-5D (short London handicap); DEMQOL; EuroQoL) • Behavioural and psychological scales (NPI)

<table>
<tr><td>Bibliographic reference</td><td>Goldberg SE, Bradshaw LE, Kearney FC, Russell C, Whittamore KH, Foster PER et al (2013) Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial), British Medical Journal, f41312</td></tr>
<tr><td></td><td>

Physical disability (Barthel Index)
Cognitive Impairment (MMSE)
Carer strain (Carer strain index)
Carer psychological wellbeing (GHQ-12)

Table showing days at home, hospital and care outcomes in patients at 90 days
<table>
<tr><td>Outcome</td><td>MMHU (n=310)</td><td>Standard care (n=290)</td><td>Effect (95%CI), P Unadjusted</td><td>Effect (95%CI), P Unadjusted</td></tr>
<tr><td>Median (IQR) total days at home</td><td>51 (0-79)</td><td>45 (0-78)</td><td>1.21 (0.85 to 1.73) p=0.29</td><td>0.88 (0.59 to 1.32) p=0.54</td></tr>
<tr><td>Median (IQR) days spent at home if >0</td><td>70.5 (40-83)</td><td>71 (40-82)</td><td>1.05 (0.85 to 1.31) p=0.64</td><td>0.93 (0.75 to 1.15) p=0.51</td></tr>
<tr><td>Median (IQR) length of index hospital stay/ days</td><td>11 (5-22)</td><td>11 (5-20)</td><td>1.03 (0.88 to 1.20) p=0.71</td><td>1.14 (0.99 to 1.32) p=0.08</td></tr>
<tr><td>Median (IQR) total days in hospital</td><td>16 (8-30)</td><td>16 (7-30)</td><td>1.00 (0.87 to 1.16) p=0.96</td><td>1.07 (0.93 to 1.23) p=0.32</td></tr>
</table>
</td></tr>
<tr><td>Authors conclusion</td><td>Specialist care improved participants experience and carers satisfaction but no convincing improvement in health or service use</td></tr>
<tr><td>Source of funding</td><td>NIHR</td></tr>
<tr><td>Risk of bias</td><td>

Did the trial address a clearly focused issue? Yes
Was the assignment of patients to treatments randomised? Yes – permuted block design stratified by residence (home or care home)
Were patients, health workers and study personnel blinded? Partly – staff involved in baseline data collection unconcealed staff involved in allocation were concealed
Were the groups similar at the start of the trial? Yes
Aside from the experimental intervention, were the groups treated equally? Yes
Were all of the patients who entered the trial properly accounted for at its conclusion? 462 participants lacked mental capacity for final inclusion

</td></tr>
</table>

Bibliographic reference	Goldberg SE, Bradshaw LE, Kearney FC, Russell C, Whittamore KH, Foster PER et al (2013) Care in specialist medical and mental health unit compared with standard care for older people with cognitive impairment admitted to general hospital: randomised controlled trial (NIHR TEAM trial), British Medical Journal, f41312
	• Can the results be applied to the population of interest? Yes- • Were all clinically important outcomes considered? Yes • Overall risk of bias: Low

Bibliographic reference	Villars H, Dupuy C, Soler P, Gardette V, Soto ME, Gillette S (2013) A follow-up intervention in severely demented patients after discharge from a special Alzheimer acute care unit: impact on early emergency room re-hospitalization rate, International Journal of Geriatric Psychatry, 28, 1131-1140
Study type	Before and after study
Aim	To establish if a geriatric team intervention could improve the care pathway and reduce the rate of re-hospitalisations for people with Alzheimer's disease
Patient characteristics	N= 390; mean age = 81.79 years; 60% female; mean MMSE = 12.34
Inclusion/ exclusion criteria	Inclusion • Patients hospitalised in a Special care acute unit (SCAU) presenting with at least one of the characteristics identified as increased risk for re-hospitalisation ○ Severe disruptive BPSD (agitation, aggression, psychotic symptoms) ○ Change of living environment related to BPSD ○ Principal carer exhaustion ○ Patient discharged with anosognosia and living alone in the community Exclusions not reported
Intervention	Intervention (at year 2) • Clinical evaluation of patient during hospital stay and development of an individualised follow up plan • Individualised care plan after discharge (visits and telephone calls from a multidisciplinary team and working collaboratively with primary care practitioners) Intervention (at year 3) • Discontinuation of home visits – replaced by extensive phone conversations

Bibliographic reference	Villars H, Dupuy C, Soler P, Gardette V, Soto ME, Gillette S (2013) A follow-up intervention in severely demented patients after discharge from a special Alzheimer acute care unit: impact on early emergency room re-hospitalization rate, International Journal of Geriatric Psychatry, 28, 1131-1140
	• Limitation of resource availability to 4 patients per week
Comparison	Pre intervention (at year 1) - SCAU functioned as usual
Length of follow up	Three follow ups=- 1 year; 2 year; 3 year
Location	France
Outcomes measures	• Rate of re-hospitalisations post discharge • ADL was reported but unable to calculate effects from results (based on one time point only)
Authors conclusion	Nonsignificant decrease in number of re-hospitalisations post establishing SCAU
Source of funding	Not reported
Risk of bias	• Did the study address a clearly focused issue? • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? N/a • Was the outcome accurately measured to minimise bias? Limited reporting of outcomes • Have the authors identified all important confounding factors? Not reported • Have they taken account of the confounding factors in the design and/or analysis? Not reported • Was the follow up of subjects complete enough Not reported • Was the follow up of subjects long enough? Not reported Overall risk of bias - High

E.5 Care setting transitions

E.5.1 Managing the transition between different settings for people living with dementia

- What are the most effective ways of managing the transition between different settings (home, care home, hospital, and respite) for people living with dementia?

Bibliographic reference	McGilton KS, Rivera TM, Dawson P. (2003). Can we help persons with dementia find their way in a new environment. Aging & Mental Health, 7(5): 363-371.

<table>
<tr><th>Bibliographic reference</th><th>McGilton KS, Rivera TM, Dawson P. (2003). Can we help persons with dementia find their way in a new environment. Aging & Mental Health, 7(5): 363-371.</th></tr>
<tr><td>Methods</td><td>Randomised controlled trial. Randomisation using a randomised table of numbers.</td></tr>
<tr><td>Participants</td><td>32 people living with Alzheimer's: 17 in the treatment group and 15 in the control group. The sample included all residents in the nursing home who met the inclusion criteria. The criteria were: (a) a diagnosis of Alzheimer's disease, as stated in the residents' medical chart; (b) moderate to severe cognitive decline as assessed by the Global Deterioration Scale (GDS), stages 3 to 6 (Reisberg et al., 1982); (c) able to ambulate; and (d) able to understand English. Exclusion criteria were: (a) residents with very severe cognitive decline (stage 7 of the GDS); and (b) residents who were acutely medically unwell. Written consent was obtained from a family member or guardian of the residents. Of the 180 residents on the four cognitive support units, 53 met the study criteria and were approached to participate in the study. Proxy consent from a family member was obtained for participating residents and of the 53 eligible, 36 family members consented (66.7%). Prior to the first data collection, four residents became ineligible because of medical illness. Following the collection of the demographic data and the GDS by a trained researcher, residents were randomly assigned to either treatment or a usual care control condition using a random table of numbers. Of the final 32 for whom baseline data were collected, a total of three were lost at post time 1 and three were lost at post time 2, which represented an attrition rate of 15%. Resident falls were the most common reason for subject loss.</td></tr>
<tr><td>Interventions</td><td>Two research assistants were trained on how to conduct backward chaining:
<table>
<tr><th colspan="2">Backward chaining protocol</th></tr>
<tr><td colspan="2">An example: trip from the bedroom to the dining room</td></tr>
<tr><td>1</td><td>The trip is broken down into manageable distances (let's say three). The first part of the trip to be learned is the part closest to the intended destination (for example the last hall before the dining room). At this stage prompting is provided 'OK, down this yellow hall' etc.</td></tr>
<tr><td>2</td><td>Each additional part of the trip, (the first two parts), is managed by providing assistance but not prompting (walking beside the individual).</td></tr>
<tr><td>3</td><td>When independence is achieved in the first part of the trip, (the resident finds his way from the last hall to the dining room), prompting is then moved to the second part of the trip (for example, the nursing station to the last hall) and assistance is given for the remaining details of the trip.</td></tr>
<tr><td>4</td><td>This combination of independence, prompting, and assisting continues until the entire trip can be made independently.</td></tr>
</table>

Training also included communication techniques, specifically the use of one step comments to facilitate the residents' understanding of the prompts during the backward chaining protocol. As well, a locational map was created for each resident in the study, that land marked the way to the dining room from the resident's bedroom, and also included pre-selected reference points along the path between the two rooms, such as an aquarium. The interventionists spent 30 minutes, three times a week, for four weeks, conducting</td></tr>
</table>

Bibliographic reference	McGilton KS, Rivera TM, Dawson P. (2003). Can we help persons with dementia find their way in a new environment. Aging & Mental Health, 7(5): 363-371.
	the backward chaining protocol with each of the participating residents. Each research assistant had the same clients for the duration of the intervention, one had eight residents and the other had nine. The rehearsals of way finding were spread out every other day since evidence by McKitrick, Camp and Black (1992) identified that a 'spacing effect' might improve learning. In essence, the effects of repetition on memory improvement are enhanced when repetitions are separated by days or a week rather than massed. During backward chaining, the research assistant would also ask the resident to refer to the map. The research assistant was instructed to conduct the backward chaining protocol in order for the residents to locate the dining room from their bedroom. The interventionists kept track of each session and recorded how much prompting was required, landmarks and cues used by the residents, and if the resident made the trip independently.
Outcomes	The outcome variables examined consisted of measures of agitation, spatial orientation, and the ability to find their way to specific destinations. **Residents' level of agitation**: Residents' agitation was determined by using the Pittsburgh Agitation Scale (PAS) (Rosen et al., 1994). Higher scores indicate increased levels of agitation. The range of responses varies from 0–16. The scale was completed by the research assistant (RA) while observing the resident attempting to find his/her way to the dining room. The PAS demonstrated inter-rater reliability of 0.80. The internal consistency of the scale was low at pretest (0.35) but at post-test 1 it was more acceptable (0.54). These low alphas were related to restriction in range for the responses to the items in the scale. The low internal consistency for the PAS was unexpected given that other researchers have demonstrated alphas > 0.80 (Wells et al., 2000). **Resident's spatial orientation:** A measure of the residents' global spatial orientation was completed by the primary nurse who knew the resident the best since relocation. The Spatial Orientation Subscale (SOS) is a subscale of the self-care component of the Abilities Assessment Instrument developed for persons with AD by Dawson et al. (1993). Higher scores of the SOS reflect greater ability to navigate in the environment. Internal consistency estimates of 0.94, and inter-rater reliability of 0.98, and concurrent validity of the subscales with London Psychogeriatric Rating Scale of -0.87 have been reported for the subscale (Dawson et al., 1998). Find their way to specific locations. The ability of the resident to locate the dining room and the bedroom was monitored with a dichotomous, yes/no scale that was developed for this study. The RA completed the simple rating after asking the residents to locate the dining room and their bedroom. Yes indicated that the resident could locate the room and no indicated the resident could not locate the requested room. The RA walked beside the resident and identification was made when the resident crossed the threshold of the room.
Notes	This research was funded by the Canadian Gerontological Nursing Association, Kunin-Lunenfeld Applied Research Unit and the Baycrest Center for Geriatric Care Nursing Research Fund. The ages of the people living with dementia for the treatment and control group were: 86.2 years (SD 6.6) and 89.2 years (SD 6.7) respectively. The Global Deterioration Score for the treatment group and the control group was 5.1 each with SDs of 0.81 and 1.1 respectively (these scores indicate severe cognitive impairment). The female gender of people living with dementia for the treatment group and the control group was 94% and 67% respectively. The length of stay in months for the treatment group and the control group was 41.1 and 27.5 respectively.

Bibliographic reference	McGilton KS, Rivera TM, Dawson P. (2003). Can we help persons with dementia find their way in a new environment. Aging & Mental Health, 7(5): 363-371.

Number of residents able to locate the dining room

	Post-test 1		Post-test 2	
	Treatment	Control	Treatment	Control
Yes[1]-Yes	2	3	2	2
Yes[1]-No	0	3	0	1
No[1]-Yes	6	3	1	0
No[1]-No	8	4	12	9
n	16	13	15	12

X2m=4.2; df=1; p=0.03; Yes[1]=can find location at baseline; No[1]=cannot find location at baseline

Number of residents able to locate their bedrooms

	Post-test 1		Post-test 2	
	Treatment	Control	Treatment	Control
Yes[1]-Yes	3	3	3	2
Yes[1]-No	0	1	1	1
No[1]-Yes	1	3	1	0
No[1]-No	12	6	10	8
n	16	13	15	12

Yes[1]=can find location at baseline; No[1]=cannot find location at baseline

Residents who received the 'way-finding' intervention demonstrated an increased ability to find their way to the dining room at post-test 1, as hypothesized. Among those who changed in the treatment group, two residents knew how to locate the dining room prior to the intervention (yes/yes) and one-week post intervention six additional residents could find their way to the dining room (no/yes). The significance of 0.03 indicates that more residents could find their way over time. To compare the change scores between the treatment and control groups the differences in raw counts were calculated and a significant difference was obtained ($x^2m=3.95$, p=0.03). This indicates more residents in the intervention group were able to find their way to the dining room. The effect was not sustained for the treatment group, as residents were not able to locate the dining room at post-test 2. No differences were found for the control group at post-test 1 or 2.

Bibliographic reference	McGilton KS, Rivera TM, Dawson P. (2003). Can we help persons with dementia find their way in a new environment. Aging & Mental Health, 7(5): 363-371.
	Residents who received the 'way-finding' intervention did not demonstrate or show an increased ability to find their way to the bedroom at post-test 1 or 2. No differences were found for the control unit. For all other outcomes measured at the interval level, the mean scores and standard deviations for the experimental and control groups observed at each point in time, are presented in Table 5. The results are reported for each of the outcome variables.
Risk of bias	• Random sequence generation (selection bias): Unclear. The investigators do not describe how the table of numbers was generated. • Allocation concealment (selection bias): High risk. • Blinding of participants and personnel (performance bias): High risk. Given the nature of the intervention, there was no blinding of participants. There was no blinding of personnel. • Blinding of outcome assessment (detection bias): Unclear • Incomplete outcome data (attrition bias): Moderate risk. The attrition rate was 15% (below 20%, the arbitrary cut-off point for high risk). • Selective reporting (reporting bias): Low risk • Recruitment bias (cluster trials only): Low risk • Other bias: High risk. This study may not be relevant because it took place 6 weeks post-relocation. Therefore, it is debateable as to whether this was a new environment. This study does not take into consideration the complexity (or straight-forwardness) of the route between the bedroom and the destination. The population of people living with dementia in this study were unusual. They had all been moved out of one Canadian care home together and placed in a new Canadian care home. This is not a usual situation for people living with dementia in the UK who normally stay in the same care home.

Bibliographic reference	Davies JD, Tremont G, Bishop DS, Fortinsky RH. (2010). A telephone-delivered psychosocial intervention improves dementia caregiver adjustment following nursing home placement. Int J Geriatr Psychiatry, 26: 380-387
Methods	Randomised controlled trial. Caregivers were assigned to intervention conditions using urn randomisation (Stout et al., 1994). This procedure randomly assigns patients to groups, but systematically biases the randomisation on variables that could be related to outcome variables in favour of balance among the treatment conditions. In particular, groups were balanced on caregiver gender, relationship type (spouse versus other), and nursing home unit (dementia special care versus general).
Participants	Fifty-six caregivers in total at the start. Twenty-seven caregivers were assigned to FITT-NH and 26 to the non-contact control condition. Forty-six caregivers remained in the study for analysis of treatment outcomes. Attrition was 13% and due to care recipient death (n=5), discharge from the nursing home (n=1), and study withdrawal (n=1). Attrition did not differ between groups (FITT, n=3; standard care, n=4).

Bibliographic reference	Davies JD, Tremont G, Bishop DS, Fortinsky RH. (2010). A telephone-delivered psychosocial intervention improves dementia caregiver adjustment following nursing home placement. Int J Geriatr Psychiatry, 26: 380-387
	Caregivers were recruited from 26 different nursing homes in the greater Providence, Rhode Island area. All nursing homes in the area were contacted, but some did not have new admissions of caregivers during the recruitment period who met criteria for the study. No nursing homes refused participation. The burden on the staff was minimal as they simply presented the study to caregivers at the time of admission. This was the first long-term placement for care-recipients, and all had recently been placed from home or from an acute hospital stay. Participants were then telephone screened for eligibility by a trained research assistant. Fifty-three family dementia caregivers who met the following criteria were enrolled: (1) placed the care recipient for permanent placement in nursing home care within the past 2 months; (2) cared for an individual with a formal diagnosis of dementia made by a physician; and (3) provided care for the care recipient for at least 6 months, 4 h per day, prior to admission. Both groups received a resource packet containing local resources and educational materials. Caregivers randomized to standard care did not receive any formal intervention. Both groups were allowed to use community services. Resource service was monitored in both groups during monthly research assessment telephone calls.
Interventions	This was a study of the preliminary efficacy of a telephone intervention, Family Intervention: Telephone Tracking-Nursing Home (FITT-NH) for improving dementia caregivers' adjustment following nursing home placement. FITT-NH was delivered in a standardized method based on a detailed treatment manual that includes sample dialog, a behavioural problems guide to generate solutions with the caregiver, and a specific interventions guide matched to specific caregiver situations. FITT-NH was delivered to caregivers by 10 telephone contacts over 3 months. Telephone calls included an initial call that orientated the caregiver to treatment and provided psychoeducation, 7 weekly follow-up calls, and 2 biweekly termination calls over the third month. Initial contacts lasted approximately 60 min and follow-up and termination calls lasted 35–45 min. The structure and content of the intervention is summarized in Table 1. Participation was terminated if the caregiver missed three consecutive calls. If the care recipient died during the intervention, the therapist continued to work with the participant for 1–3 sessions to facilitate the grief process and termination. FITT-NH provides emotional support, directs caregivers to appropriate resources, and teaches caregivers strategies to cope with ongoing problems during the transition to institutional placement. The skills necessary for long-term adaptation after treatment has ended are emphasized. The intervention did not provide case management, serve as a hotline, or provide psychotherapy over the telephone. For the current study, caregivers were dealing with emotional factors related to the decision to place, family conflict about the type of care needed, renegotiating their caregiver role, and coping with issues related to communication with staff. Calls also focused on helping the caregiver cope with difficult behaviours in the patient. The FITT model assesses caregiver and care recipient functioning in key areas (i.e., caregiver's emotional functioning, health, social support, family functioning, and communication with staff; care recipient's emotional adjustment, behaviour, and cognition). These key areas are repeatedly assessed throughout the treatment, and particular interventions are applied based on these assessments. Specific interventions include supportive approaches (i.e., empathy, giving permission, normalizing, validation, or venting) and active strategies (i.e., bibliotherapy, interpretation, positive reframing, problem solving, reference to resource packet, referral and setting task directive).

Bibliographic reference	Davies JD, Tremont G, Bishop DS, Fortinsky RH. (2010). A telephone-delivered psychosocial intervention improves dementia caregiver adjustment following nursing home placement. Int J Geriatr Psychiatry, 26: 380-387
	In the first contact, caregivers are provided with a rationale for the FITT, description of future telephone contacts, an introduction to resource materials, and an assessment of key areas thought to be instrumental in addressing caregiver coping and adjustment. The psychoeducation component reviews information about dementia, specialty care units, and common psychological and physical effects of caregiving. Scheduled telephone contacts identify new problems, discuss positive and negative changes, provide psychoeducation, and caregiver problem solving is assisted. The final two calls (bi-weekly) address termination by anticipating FITT contacts coming to an end and fostering reliance on the support network established in FITT-NH. This phase reviews caregiver progress and reinforces success, coping strategies, and positive change. The therapist summarised these sessions in a post-treatment letter sent to the caregiver.
Outcomes	Caregiver Guilt Questionnaire for Nursing Home Placement (Steadman-Wood et al., 2009). This is a 46-item scale developed for this study to assess feelings of guilt related to placing a family member in nursing home care. Caregivers were asked to report how often they had certain reactions or feelings to placement on a four-point likert scale ranging from 0 (never) to 4 (always). Sample items include, 'I feel my loved one is upset with me', 'I feel supported by family in the decision to place', 'I feel guilty when special family occasions come along', 'I feel that I was not a good caregiver because my loved one is not adjusting well', 'I feel this is not what I had hoped for'. The scale has good internal reliability (α=0.84). It also showed good convergent validity with a measure of depression (Center for Epidemiology Studies Depression Scale, Radloff, 1977) and guilt subscale of the Zarit Burden Interview (Zarit et al., 1980), as well as divergent validity with measures of social support, staff conflict, and health-related quality of life (Steadman-Wood et al., 2009). Higher scores reflect greater guilt. Center for Epidemiology Studies Depression Scale (Radloff, 1977). This is a 20-item measure of depressive symptoms with adequate reliability (coefficient α=0.85 in the general population and 0.90 in patients). Burden Interview (ZBI; Zarit et al., 1980). This 22-item inventory assessed caregivers' subjective feelings of the impact of caregiving on emotional and physical health functioning, social life, and financial status. Higher scores reflected greater burden. The scale has been shown to have good internal consistency, content validity, and test–retest reliability (Young and Kahana, 1989). Nursing Home Hassles Scale (Stephens et al., 1991). This measure contains 29 items used to assess the degree of the caregiver's experience of hassles with the nursing home staff. The α coefficient for this scale is 0.85, and test–retest reliabilities range from 0.79–0.89. Ohio Department of Aging Family Satisfaction Instrument (Ejaz et al., 2003). This measure contains 62 items assessing family members' satisfaction with the nursing home placement. The scale has good internal reliability (α=0.76 or greater), and test–retest reliability ranges from 0.49–88. Caregivers completed additional measures to address secondary goals of the intervention, including questions about visitation frequency and quality (adapted from McCallion et al., 1999), health-related quality of life (SF-36; Ware, 2008), social support (Zimet et al., 1988), and negative reactions to care recipient behaviour (Kinney and Stephens, 1989).

Bibliographic reference	Davies JD, Tremont G, Bishop DS, Fortinsky RH. (2010). A telephone-delivered psychosocial intervention improves dementia caregiver adjustment following nursing home placement. Int J Geriatr Psychiatry, 26: 380-387
Notes	This study was supported by a grant from the National Institute on Aging.
Risk of bias	Random sequence generation (selection bias): Low risk Allocation concealment (selection bias): Low risk Blinding of participants and personnel (performance bias): Unclear: blinding of participants was not possible. Personnel were blinded. Blinding of outcome assessment (detection bias): Unclear: blinding of participants was not possible. Personnel were blinded. Incomplete outcome data (attrition bias): Moderate: Attrition was 13%. Selective reporting (reporting bias): Low risk. Recruitment bias (cluster trials only): Low risk Other bias: None

Bibliographic reference	Gaugler JE, Reese M, Sauld J. (2015). A pilot evaluation of psychosocial support for family caregivers of relatives with dementia in long-term care: The Residential Care Transition Module. Research in Gerontological Nursing. 8(4): 161-172.
Methods	Randomised controlled trial. Caregivers were randomised using an online programme.
Participants	36 caregivers. They were randomized to either the Residential Care Transition Module (RCTM) intervention (n=17) or a usual care control group (n = 19). They were recruited from the University of Minnesota Caregiver Registry, which included more than 300 family members and professionals interested in participating in research on memory loss and long-term care. Inclusion criteria to participate in the pilot project were as follows: (a) the relative was admitted to a RLTC facility in the past 12 months; (b) the family member was the individual most responsible for caring for the relative; (c) the family member could speak and understand English; and (d) the family member could hear adequately.
Interventions	The RCTM includes six sessions with a transition counsellor that take place immediately after a pre- RCTM baseline survey. Sessions 1 through 3 are scheduled approximately 1 week apart and Sessions 4 through 6 are scheduled approximately 1 month apart. During Session 1, the transition counsellor builds rapport with the family member, obtains an autobiography of the family care experience, and establishes four to five key topics to explore in future sessions. In the remaining five sessions, the TC uses psychosocial consultation, mindfulness practices, and cognitive-behavioural and narrative-based therapeutic techniques to reduce the family member's perceived level of stress and strengthen resiliency. At the family member's discretion, sessions can include other family members or decision makers involved in the relative's residential care. Additional ad hoc sessions may take place via telephone, e-mail, or in-person based on the family member's needs and whether potential crisis events occur. The duration of each session ranges from 60 to 120 minutes. Family members in the usual care condition were provided with quarterly check-in calls by the transition counsellor but were not

Bibliographic reference	Gaugler JE, Reese M, Sauld J. (2015). A pilot evaluation of psychosocial support for family caregivers of relatives with dementia in long-term care: The Residential Care Transition Module. Research in Gerontological Nursing. 8(4): 161-172.
	provided with any psychosocial consultation.
Outcomes	Throughout delivery of the RCTM, the TC maintained detailed checklists and counsellor notes to assess the frequency, duration, and clinical content of each RCTM session. The TC also conducted follow-up interviews in-person, over the telephone, or via e-mail survey with family members at 4- and 8-month follow-up intervals; thus, the TC was not blinded to group assignment. Four- and 8-month intervals were used as these mirrored those of the NYUCI and similar psychosocial interventions for family caregivers of individuals with dementia. In addition, preliminary descriptive work conducted on family caregivers' burden and depressive symptoms before and following RLTC admission suggested that placement-related stressors may occur during similar post-admission time periods. All caregivers in the RCTM were invited to participate in three focus groups moderated by the transition counsellor following the six-session RCTM intervention (Kitzinger, 1994; Krueger, 2009). Telephone focus group sessions were used so that the complex schedules of family caregivers could be accommodated. Sociodemographic Context. A number of sociodemographic characteristics and context of care variables were assessed in the baseline RCTM interviews. Dementia Severity. The severity of the care recipient's cognitive impairment (seven items, alpha = 0.87; item range = 1 [not at all difficult] to 5 [cannot do at all]; Pearlin, Mullan, Semple, & Skaff, 1990), activities of daily living (ADL) dependencies (six items, alpha = 0.86; item range = 0 [no help] to 2 [a lot of help]; Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963), instrumental ADL (IADL) dependencies (five items, alpha = 0.91; item range = 0 [no help] to 2 [a lot of help]; Lawton & Brody, 1969), and neuropsychiatric symptoms (12-item Neuropsychiatric Inventory Questionnaire [NPI-Q], alpha = 0.79; item range = 1 [mild] to 3 [severe]; Cummings et al., 1994; Kaufer et al., 2000) were measured. Caregiver Stress. A 7-item version of the Zarit Burden Interview (ZBI) relevant for post-placement (alpha = 0.86; item range = 0 [never] to 4 [nearly always]; Gaugler et al., 2009; Zarit, Reever, & Bach-Peterson, 1980), the 10-item Perceived Stress Scale (PSS; alpha = 0.91; item range = 0 [never] to 4 [nearly always]; Cohen, 1988), the 3-item role overload measure (alpha = 0.89; Pearlin et al., 1990), and the caregiver distress scale of the NPI-Q (alpha = 0.84; item range = 0 [not at all] to 5 [extremely disruptive]) were used to assess caregivers' stress. Depressive Symptoms. The 20-item Center for Epidemiologic Studies-Depression scale (CES-D; alpha = 0.90; item range = 1 [rarely or none of the time] to 4 [most of the time]; Radloff, 1977) and the 30-item Geriatric Depression Scale (GDS; alpha = 0.84; item range = 0 [no] to 1 [yes]; Yesavage, Rink, Rose, & Aday, 1983) measured caregiver depressive symptoms. Caregiver Adaptation to Placement. The mean of family members' degree of satisfaction with residential care staff (25-item Family Caregiver Perception Role, alpha = 0.93; item range =1 [strongly disagree] to 7 [strongly agree]; Maas et al., 2004), the mean of family caregivers' satisfaction with RLTC (six items, alpha = 0.74; item range = 1 [very satisfied] to 4 [not at all satisfied]; Aneshensel, Pearlin, Mullan, Zarit, & Whitlatch, 1995), and the mean of closeness of relationship with the relative (seven items, alpha = 0.81; item range = 1 [strongly disagree] to 5 [strongly agree]; Aneshensel et al., 1995) were included.
Notes	This research was supported by two grants from the National Institute on Aging and the National Center for Advancing Translational

Bibliographic reference	Gaugler JE, Reese M, Sauld J. (2015). A pilot evaluation of psychosocial support for family caregivers of relatives with dementia in long-term care: The Residential Care Transition Module. Research in Gerontological Nursing. 8(4): 161-172.
	Sciences of the National Institutes of Health (NIH) Award.
Risk of bias	Random sequence generation (selection bias): Low risk. Allocation concealment (selection bias): Low risk. Blinding of participants and personnel (performance bias): High risk: Blinding of participants was not possible. The transition counsellors were not blinded. Blinding of outcome assessment (detection bias): High risk: The transition counsellors were not blinded. Incomplete outcome data (attrition bias): Low risk Selective reporting (reporting bias): Unclear: there was no blinding of the transition counsellors but they were methodical. Recruitment bias (cluster trials only): Low risk. Other bias: None.

Bibliographic reference	Gaugler J, Roth DL, Haley WE, Mittelman MS. (2011). Modeling trajectories and transitions: Results from the New York University Caregiver Intervention. Nurs Res. 60(3 Suppl): S28-S37.
Methods	Randomised controlled trial. The method of randomisation is not given. A sample of 406 spouse caregivers of community-dwelling people with Alzheimer's disease was enrolled over a 9.5-year time period in an Alzheimer's disease research centre in New York City.
Participants	Participants in the New York University Caregiver Intervention (NYUCI) included 406 spouses of persons with a clinical diagnosis of AD. Participants were recruited through the New York University Aging and Dementia Research Center (NYU-ADRC) and community referral sources. All participants had spouses with an AD diagnosis. All spouses were living with the person with AD and were residing at home at the time of study enrolment. Following completion of a comprehensive, in-person baseline assessment, caregivers were assigned randomly to the NYUCI condition (n = 203) or the usual care control condition (n = 203). Twelve percent of the participants (n = 48) had at least 10 years of follow-up data. Twenty-one caregivers were lost to follow-up; thus, the longitudinal sample available for analysis of nursing home admission included 385 caregivers. During the course of the study 210 persons with AD were placed in an institution. Analysis of attrition bias did not indicate significant differences between cases lost to follow-up and those who remained in the longitudinal analysis (Gaugler et al., 2008). Among the 210 care recipients who were placed in an institution, 9 were placed in a nursing home between baseline and the first post-baseline assessment and were not included in the present analysis. The median time to NHA for the NYUCI intervention and usual care groups were 4.8 and 3.3 years after baseline, respectively (Mittelman et al., 2006). For all 406 participants in the NYUCI, the mean follow-up period was 5.9 years and the median was 5.4 years. The analyses are based on 3,818 post-baseline assessments.

Bibliographic reference	Gaugler J, Roth DL, Haley WE, Mittelman MS. (2011). Modeling trajectories and transitions: Results from the New York University Caregiver Intervention. Nurs Res. 60(3 Suppl): S28-S37.
Interventions	The NYUCI consisted of three components: individual and family counselling, support group participation, and ad hoc counselling. During the 4 months following the baseline assessment, spouse caregivers participated in six individual and family sessions with the study counsellor (two with only the spouse caregiver and four with the spouse caregiver and at least one other family member; the person with AD did not participate in these sessions). The content of these sessions was individualized to address the unmet needs of each caregiver. These sessions generally included information, skills related to the management of behavioural problems, and strategies to bolster communication among involved and non-involved family members. Caregivers agreed at baseline that they would participate in a weekly support group (under the auspices of the Alzheimer's Association) after the 4-month follow-up. The third component, provided throughout the duration of the NYUCI, was ad hoc or ongoing counselling--caregivers and participating family members were free to contact the study counsellors via telephone to address any issues, crises, or other significant changes that occurred. The NYUCI was delivered by counsellors with advanced degrees in social work, psychology, counselling, or gerontology. Caregivers in the usual care group did not receive the formal counselling sessions, but were free to utilize supportive services in the community and could contact study counsellors for information or referral purposes. Participants were followed for up to 15.9 years.
Outcomes	In-person interviews of spouse caregivers took place every 4 months during the first year of participation and every 6 months thereafter for up to 16 years. Burden: Caregivers' burden was measured with a subset of questions from the Zarit Burden Interview (ZBI). The ZBI is one of the most widely used instruments to assess caregiving burden (Zarit, Reever, & Bach-Peterson, 1980). The shortened ZBI includes 15 questions to measure areas of potential stress (e.g., perceived time pressure, emotional distress, financial strain, guilt, overall burden) that could arise both before and following NHA for spouse caregivers. Depressive symptoms—The Geriatric Depression Scale (Yesavage, Rink, Rose, & Aday, 1983) was administered at baseline and each follow-up interval to measure spouse caregivers' mood and psychological well-being. The 30-item version has been validated widely (Brink et al., 1982). Pertinent to the present study, both the ZBI and Geriatric Depression Scale have demonstrated significant variance and utility in prior longitudinal analyses (e.g., growth curve modelling; Gaugler et al., 2009). Nursing home admission—Dates of NHA were derived from follow-up interviews, NYU-ADRC records, or ad hoc telephone contacts with spouse caregivers or other family members. Global Deterioration Scale—The severity of dementia was determined using the Global Deterioration Scale (Reisberg, Ferris, de Leon, & Crook, 1982), a semi-structured rating of the person with AD's functioning by the counsellor based on each caregiver interview (administered every 4 months in the first year of participation and every 6 months thereafter). The Global Deterioration Scale has demonstrated extensive reliability and validity as a method to stage dementia severity (Reisberg, Ferris, & Sclan, 1993).
Notes	This research was supported by grants from the National Institute of Mental Health and National Institute on Aging. Additional funding

Bibliographic reference	Gaugler J, Roth DL, Haley WE, Mittelman MS. (2011). Modeling trajectories and transitions: Results from the New York University Caregiver Intervention. Nurs Res. 60(3 Suppl): S28-S37.
	was provided through the New York University Alzheimer's Disease Center. One of the investigators was supported by Florida AD Research Center Grant.
Risk of bias	Random sequence generation (selection bias): High risk: The method of randomisation is not given. Allocation concealment (selection bias): High risk: There was no blinding. Blinding of participants and personnel (performance bias): High risk: Blinding of participants was not possible. The study did not say whether personnel were blinded. Blinding of outcome assessment (detection bias): High risk: There was no mention of blinding. Incomplete outcome data (attrition bias): Low risk. 21/385 caregivers were lost to follow-up. Selective reporting (reporting bias): Unclear: There was no blinding. However, the method of data collection was methodical. Recruitment bias (cluster trials only): Low risk. Other bias: None

E.6 Modifying risk factors for dementia progression

E.6.1 Risk factors for dementia progression

- What effect does modifying risk factors have on slowing the progression of dementia?

E.6.1.1 Studies evaluating antidiabetic medicines

Bibliographic reference	**Gold M, Alderton C, Zvartau-Hind M, et al. (2010) Rosiglitazone monotherapy in mild-to-moderate Alzheimer's disease: results from a randomized, double-blind, placebo-controlled phase III study. Dement Geriatr Cogn Disord. 30(2): 131-46.**
Study type	Randomised, multicentre placebo-controlled, double-blind trial. Duration: 6 months
Participants	581 participants with probable Alzheimer's disease (according to NINCDS/ADRDA criteria) treated by rosiglitazone, donepezil, or placebo Inclusion criteria: age between 50 and 90 years; a score of 10 to 23 on MMSE Exclusion criteria: possible, probable or definite vascular dementia; evidence of another type of dementia; a history of seizures; experienced a cardiovascular event within 6 months of enrolment; a significant psychiatric illness; type 1 diabetes; type 2 diabetes being treated with insulin, a PPAR-gamma agonist, or an insulin secretagogue; any other clinically significant medical conditions or laboratory findings
Intervention	Rosiglitazone 2 mg, rosiglitazone 8 mg, donepezil 10 mg
Comparison	Placebo
Outcomes measures	Cognitive outcomes (MMSE; ADAS-cog); Functional ability (Disability Assessment of Dementia test); Clinical global assessment (CIBIC+); Behavioural/Neuropsychological outcomes (NPI); adverse events
Study dates	October 2007 to February 2009
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? UNCLEAR - Participants were allowed to take antidepressants, vitamin E, ginkgo biloba, statins oestrogen, thyroid hormones, atypical antipsychotics and NSAIDS so long as stable doses were being used within 2 months of enrolment • At the end of the trial, were all patients accounted for? At final follow-up, 28 participants in the rosiglitazone 2 mg

Bibliographic reference	**Gold M, Alderton C, Zvartau-Hind M, et al. (2010) Rosiglitazone monotherapy in mild-to-moderate Alzheimer's disease: results from a randomized, double-blind, placebo-controlled phase III study. Dement Geriatr Cogn Disord. 30(2): 131-46.**
	group, 29 in the rosiglitazone 8 mg group, 21 in the donepezil 10 mg group and 28 participants in the placebo group withdrew from the study. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported mean changes from baseline • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Risner ME, Saunders AM, Altman JF et al. (2006) Efficacy of rosiglitazone in a genetically defined population with mild-to-moderate Alzheimer's disease. Pharmacogenomics J. 6(4): 246-54.**
Study type	Randomised, placebo-controlled, double-blind trial. Duration: 6 months
Participants	511 participants with mild to moderate Alzheimer's disease (diagnostic criteria not specified) treated by rosiglitazone or placebo Inclusion criteria: not specified Exclusion criteria: not specified
Intervention	Rosiglitazone 2 mg, rosiglitazone 4 mg or rosiglitazone 8 mg per day
Comparison	Placebo
Outcomes measures	Cognitive outcomes (ADAS-cog); Clinical global assessment (CIBIC+, collected but not reported); adverse events
Study dates	January 2004 to May 2005
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES (partially reported) • Were clinicians and investigators blinded? UNCLEAR (not reported) • Were the groups similar at the start of the trial? A lower proportion of patients in the rosiglitazone 8 mg group experienced worsening of symptoms within the 6 months preceding enrolment. • Aside from the experimental intervention, were the groups treated equally? UNCLEAR (minimal information reported) • At the end of the trial, were all patients accounted for? At final follow-up, 18 participants in the rosiglitazone 2 mg group, 16 in the rosiglitazone 4 mg group, 19 in the rosiglitazone 8 mg group and 16 participants from the placebo

Bibliographic reference	Risner ME, Saunders AM, Altman JF et al. (2006) Efficacy of rosiglitazone in a genetically defined population with mild-to-moderate Alzheimer's disease. Pharmacogenomics J. 6(4): 246-54.
	group withdrew from the study. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported mean changes from baseline • Can the results be applied to the local population? UNCLEAR (minimal information reported) • Were all clinically relevant outcomes reported? YES

E.6.1.2 Studies evaluating NSAIDs

Bibliographic reference	Aisen PS, Schafer KA, Grundman M et al. (2003) Effects of rofecoxib or naproxen vs placebo on Alzheimer disease progression: a randomized controlled trial. JAMA. 289(21):2819-26.
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 12 months
Participants	351 participants with probable Alzheimer's disease (diagnostic criteria not specified) treated by naproxen, rofecoxib or placebo Inclusion criteria: age > 50 years; a score of 13 to 26 on MMSE Exclusion criteria: active peptic ulcer within 5 years of enrolment; renal insufficiency; clinically significant liver disease; poorly controlled hypertension; congestive heart failure; comorbid conditions that might respond to NSAIDs; taking sedatives, neuroleptics, antidepressants or anti-Parkinsonian medications; regularly used NSAIDs within 2 months of enrolment
Intervention	Naproxen 220 mg bid. or rofecoxib 25 mg NB: data on rofecoxib was not included as it was withdrawn from the market in 2004 due to safety concerns.
Comparison	Matched placebo
Outcomes measures	Cognitive outcomes (ADAS-cog); Functional ability (ADCS-ADL); Behavioural/Neuropsychological outcomes (NPI); Dementia severity (CDR-SB); Quality of life (QoL-AD); adverse events
Study dates	Recruitment from December 1999 to November 2000
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? YES

Bibliographic reference	**Aisen PS, Schafer KA, Grundman M et al. (2003) Effects of rofecoxib or naproxen vs placebo on Alzheimer disease progression: a randomized controlled trial. JAMA. 289(21):2819-26.**
	• At the end of the trial, were all patients accounted for? At final follow-up, 28 patients in the naproxen group, 33 in the rofecoxib group and 23 patients in the placebo group were lost to follow-up. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported mean changes from baseline • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Bentham P, Gray R, Sellwood E et al. (2008) Aspirin in Alzheimer's disease (AD2000): a randomised open-label trial. Lancet Neurol. 7(1): 41-9.**
Study type	Randomised open label trial. Duration: 3 years
Participants	310 participants with probable Alzheimer's disease (according to DSM-IV criteria) randomised to receive aspirin or avoid aspirin Inclusion criteria: age ≥ 46 years; outpatient; no indication or contraindication for aspirin; receiving care from a regular carer Exclusion criteria: receiving secondary prophylaxis after myocardial infarction; unstable angina; cerebral transient ischaemic attack; active peptic ulcer; haemophilia or other bleeding disorders; acute gout; asthma; rhinitis; urticarial; angioedema; allergy to NSAIDs
Intervention	Aspirin 75 mg
Comparison	Aspirin avoidance
Outcomes measures	Cognitive outcomes (MMSE); Functional ability (BADLS); Behavioural/Neuropsychological outcomes (NPI, collected but not reported); caregiver outcomes (GHQ); adverse events
Study dates	October 2008 to May 2003
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? NO • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? YES

Bibliographic reference	**Bentham P, Gray R, Sellwood E et al. (2008) Aspirin in Alzheimer's disease (AD2000): a randomised open-label trial. Lancet Neurol. 7(1): 41-9.**
	• At the end of the trial, were all patients accounted for? 19 patients in the aspirin group and 17 patients in the avoidance group were lost to follow-up at 12 months. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported and compared mean changes in outcome measures from baseline. • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**de Jong D, Jansen R, Hoefnagels W et al. (2008) No effect of one-year treatment with indomethacin on Alzheimer's disease progression: a randomized controlled trial. PLoS One 3(1): e1475.**
Study type	Randomised, placebo-controlled, double-blind trial. Duration: 12 months (NB: 6 month follow-up results extractable)
Participants	51 participants with probable Alzheimer's disease (according to NINCDS/ADRDA criteria) treated by indomethacin or placebo Inclusion criteria: a score of 10 to 26 on MMSE; living at home or in a home for the elderly Exclusion criteria: history of recurrent peptic ulceration, gastric surgery or gastrointestinal bleeding; severe and unstable cardiovascular disease; severe pulmonary disease; renal failure; clinically significant liver disease; poorly controlled diabetes mellitus; hypersensitivity to NSAIDs or Aspirin; alcohol abuse; receiving oestrogen replacement therapy; long term NSAID or corticosteroid use; taking deprenyl, vitamin E, neuroleptic, aspirin, coumarin derivatives, angiotensin converting enzyme inhibitors, loop diuretics
Intervention	Indomethacin 50 mg bid.
Comparison	Placebo
Outcomes measures	Cognitive outcomes (ADAS-cog; MMSE); Clinical global assessment (CIBIC+); Functional ability (IDDD); Behavioural/Neuropsychological outcomes (NPI); caregiver outcomes (NPI-D); adverse events
Study dates	May 2000 to August 2004
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? YES

Bibliographic reference	de Jong D, Jansen R, Hoefnagels W et al. (2008) No effect of one-year treatment with indomethacin on Alzheimer's disease progression: a randomized controlled trial. PLoS One 3(1): e1475.
	• At the end of the trial, were all patients accounted for? 7 patients in the Indomethacin group and 6 patients in the avoidance group were lost to follow-up. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported and compared mean changes from baseline • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	Green RC, Schneider LS, Amato DA et al. (2009) Effect of tarenflurbil on cognitive decline and activities of daily living in patients with mild Alzheimer disease: a randomized controlled trial. JAMA. 302(23): 2557-64
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 18 months (NB: 6 month follow-up results extractable)
Participants	1,649 participants with mild to moderate Alzheimer's disease (according to NINCDS/ADRDA and DSM-IV criteria) treated by tarenflurbil or placebo Inclusion criteria: age ≥ 55 years; living in the community; a score of 15 to 26 on MMSE; no clinically significant intracranial pathology (assessed within 3 months of enrolment); a score of ≤ 4 on Hachinski scale; at least 6 years of education or sufficient work experience to exclude retardation; a reliable carer who saw the patient for a minimum of 4 days a week Exclusion criteria: epilepsy; focal brain lesion; head injury with loss of consciousness; psychiatric disorders including psychosis, major depression or bipolar disorder; a history of alcohol or substance abuse; history of upper gastrointestinal tract bleeding requiring surgery or transfusion within 3 years of enrolment; history or evidence of an active malignancy (except for prostate cancer ,basal cell carcinoma, or squamous cell carcinoma of the skin) within 2 years of enrolment; a chronic or acute renal, hepatic, or metabolic disorder; major surgery; an uncontrolled cardiac condition; taking anticoagulant within 3 months of enrolment; taking a CYP2C9 enzyme inhibitor or losartan, phenytoin, tamoxifen, torsemide, and fluvastatin within 2 weeks of enrolment; history of chronic NSAID use; hypersensitivity to NSAIDs
Intervention	Tarenflurbil 400 mg bid. or tarenflurbil 800 mg bid.
Comparison	Matched placebo
Outcomes measures	Cognitive outcomes (ADAS-cog; MMSE); Functional ability (ADCS-ADL); Behavioural/Neuropsychological outcomes (NPI); Dementia severity (CDR-SB); Quality of life (QOL-AD); caregiver outcomes (CBI); adverse events

Bibliographic reference	**Green RC, Schneider LS, Amato DA et al. (2009) Effect of tarenflurbil on cognitive decline and activities of daily living in patients with mild Alzheimer disease: a randomized controlled trial. JAMA. 302(23): 2557-64**
Study dates	February 2005 to April 2008
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? UNCLEAR • Aside from the experimental intervention, were the groups treated equally? UNCLEAR – Participants taking antidepressant, anti-psychotic, or anxiolytic drugs, vitamin E, or Ginkgo biloba were eligible • At the end of the trial, were all patients accounted for? 334 patients in the tarenflurbil group and 269 patients in the placebo group discontinued treatment. Analysis was performed using a modified intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported mean changes from baseline • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Pasqualetti P, Bonomini C, Dal Forno G et al. (2009) A randomized controlled study on effects of ibuprofen on cognitive progression of Alzheimer's disease. Aging Clin Exp Res. 21(2): 102-10.**
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 12 months
Participants	132 participants with probable Alzheimer's disease (according to NINCDS/ADRDA criteria) treated by ibuprofen or placebo. Inclusion criteria: age ≥ 65 years; a score of 16 to 25 on MMSE; a score of 0.5 to 1 on CDR scale; receiving care from a reliable carer Exclusion criteria: diagnosis of other types of dementia; other neurodegenerative and neurologic diseases; allergy to NSAIDs; active gastritis or peptic ulcerative disease; renal or hepatic insufficiency; active inflammatory, infectious or neoplastic disease; COPD; Chronic heart failure; history or current alcohol abuse; receiving rivastigmine, galantamine, memantine, anticoagulants or COX2 inhibitors; previous consistent use of NSAIDs; intake of vitamin E;
Intervention	Ibuprofen 400 mg bid. (with esomeprazole 20 mg per day)
Comparison	Placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE); Clinical global assessment (CIBIC+); Functional ability (BADLS);

Bibliographic reference	**Pasqualetti P, Bonomini C, Dal Forno G et al. (2009) A randomized controlled study on effects of ibuprofen on cognitive progression of Alzheimer's disease. Aging Clin Exp Res. 21(2): 102-10.**
	Behavioural/Neuropsychological outcomes (NPI); Dementia severity (CDR-SB); Depression (BDI; GDS); caregiver outcomes (STA1-Y1; STA1-Y2); adverse events
Study dates	April 2003 to September 2004
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? UNCLEAR – patients who were receiving stable doses of SSRIs, benzodiazepines and neuroleptics were allowed to participate. • At the end of the trial, were all patients accounted for? 20 patients in the ibuprofen group and 15 patients in the placebo group were lost to follow-up. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported and compared mean changes in outcome measures along with standard errors • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Reines SA, Block GA, Morris JC et al. (2004) Rofecoxib: no effect on Alzheimer's disease in a 1-year, randomized, blinded, controlled study. Neurology. 62(1): 66-71**
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 12 months
Participants	692 participants with probable or possible Alzheimer's disease (according to NINCDS/ADRDA criteria) treated by rofecoxib or placebo. Inclusion criteria: age ≥ 50 years; a score of 14 to 26 on MMSE; GDS score indicating moderate dementia Exclusion criteria: history of myocardial infarction, coronary artery bypass, angioplasty or stent placement within 1 year of enrolment; history of stroke, multiple lacunar infarcts, transient ischaemic events within 2 years of enrolment; history of gastrointestinal bleeding within 3 months of enrolment; history of angina or congestive heart disease; uncontrolled hypertension; consistent longer term use of NSAIDs during the 2 months preceding enrolment
Intervention	Rofecoxib 25 mg

Bibliographic reference	**Reines SA, Block GA, Morris JC et al. (2004) Rofecoxib: no effect on Alzheimer's disease in a 1-year, randomized, blinded, controlled study. Neurology. 62(1): 66-71**
Comparison	Matched placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE); Clinical global assessment (CIBIC+); Functional ability (ADCS-ADL); Dementia severity (CDR-SB); adverse events
Study dates	Not specified
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? UNCLEAR – patients on stable doses of donepezil or other cholinesterase inhibitors (except tacrine) were eligible; however percentages of usage were not reported in the manuscript. • At the end of the trial, were all patients accounted for? 93 patients in the rofecoxib group and 76 patients in the placebo group were lost to follow-up. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported and compared mean changes in outcome measures • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Rogers J, Kirby LC, Hempelman SR et al (1993) Clinical trial of indomethacin in Alzheimer's disease. Neurology. 43(8): 1609-1611**
Study type	Randomised, placebo-controlled, double-blind trial. Duration: 6 months
Participants	44 participants with probable Alzheimer’s disease treated by indomethacin or placebo. Inclusion criteria: a score ≥ 16 on MMSE; GDS score indicating moderate dementia Exclusion criteria: not reported
Intervention	Indomethacin (Dosage adjusted to weight)
Comparison	Matched placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE; BNT; Token test); adverse events

Bibliographic reference	**Rogers J, Kirby LC, Hempelman SR et al (1993) Clinical trial of indomethacin in Alzheimer's disease. Neurology. 43(8): 1609-1611**
Study dates	Not specified
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES (Partially reported) • Were clinicians and investigators blinded? YES (Partially reported) • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? YES • At the end of the trial, were all patients accounted for? 6 patients were lost to follow-up in each group. Analysis was performed using the per-protocol approach. • How large was the treatment effect? Significant • How precise was the outcome effect? “Efficacy was assessed by expressing changes in cognitive status scores from baseline to 6 month follow-up as percentage change from baseline”. Raw scores were then transformed to z scores. • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Scharf S, Mander A, Ugoni A (1999) A double-blind, placebo-controlled trial of diclofenac/misoprostol in Alzheimer's disease. Neurology. 53(1): 197-201.**
Study type	Randomised, placebo-controlled, double-blind trial. Duration: 6 months
Participants	41 participants with mild to moderate Alzheimer’s disease (according to DSM-IV criteria) treated by diclofenac plus misoprostol or placebo. Inclusion criteria: age ≥ 50 years; a score of 11 to 25 on MMSE; a score of < 4 on the modified Hachinski scale Exclusion criteria: history of peptic ulcer, GI bleeding or intolerance to NSAIDSs; significant medical problems (such as poorly controlled hypertension, cardiac failure or s significant renal or hepatic impairment); taking corticosteroids or acetylcholinesterase inhibitors
Intervention	Diclofenac plus misoprostol (Dosage not specified)
Comparison	Placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; ADAS-Noncog; MMSE); Clinical global assessment (GDS; CGIC); functional ability (IADL; PSMS); Caregiver outcomes (cGIC); adverse events, collected but insufficiently reported

Bibliographic reference	**Scharf S, Mander A, Ugoni A (1999) A double-blind, placebo-controlled trial of diclofenac/misoprostol in Alzheimer's disease. Neurology. 53(1): 197-201.**
Study dates	Not specified
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? YES • At the end of the trial, were all patients accounted for? 12 participants in the intervention group and 2 participants in the placebo group were lost to follow-up. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported mean changes in outcome measures accompanied with standard deviations • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Soininen H, West C, Robbins J, Niculescu L (2007) Long-term efficacy and safety of celecoxib in Alzheimer's disease. Dement Geriatr Cogn Disord. 23(1): 8-21.**
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 12 months
Participants	461 participants with probable or possible Alzheimer's disease (according to NINCDS and DSM-IV criteria) treated by celecoxib or placebo. Inclusion criteria: age ≥ 51 years with presence of symptoms for at least 1 year; a score of 12 to 26 on MMSE; score of 3 to 5 on GDS; normal values for B12, folate, thyroid-stimulating hormone and thyroxin Exclusion criteria: receiving anti-inflammatory or corticosteroid therapy within 2 weeks prior to the baseline assessment; hypersensitivity to celecoxib, sulphonamides or NSAIDs; receiving antipsychotic medications; presence of vascular dementia, stroke, epilepsy, depression, significant hypertension, active gastrointestinal disease, cancer or a neurologic disorder; Women of childbearing potential or those who required hormone replacement therapy for menopause and were not on a stable regimen for at least 12 months.
Intervention	Celecoxib 200 mg bid.
Comparison	Matched placebo

Bibliographic reference	**Soininen H, West C, Robbins J, Niculescu L (2007) Long-term efficacy and safety of celecoxib in Alzheimer's disease. Dement Geriatr Cogn Disord. 23(1): 8-21.**
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE); Clinical global assessment (CIBIC+); Nurses' Observation Scale For Geriatric Patients [NOSGER]); Behavioural/Neuropsychological outcomes (Behave-AD2); Depression (MADRS); adverse events
Study dates	Not specified
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? A higher proportion of patients in the intervention group had hypertension, diabetes, and were using aspirin during the study • Aside from the experimental intervention, were the groups treated equally? UNCLEAR - Participants were allowed to use acetaminophen or aspirin to alleviate arthritic or other pain • At the end of the trial, were all patients accounted for? 23% of patients in both groups were lost to follow-up. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Not significant • How precise was the outcome effect? Authors reported and compared mean changes in outcome measures • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Wilcock GK, Black SE, Hendrix SB et al. (2008) Efficacy and safety of tarenflurbil in mild to moderate Alzheimer's disease: a randomised phase II trial. Lancet Neurol. 7(6): 483-93.**
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 12 months
Participants	189 participants with probable Alzheimer’s disease (according to according to NINCDS and DSM-IV criteria) treated by tarenflurbil or placebo. Inclusion criteria: age ≥ 55 years; a score of 15 to 26 on MMSE; a score of ≤ 4 on the modified Hachinski scale; no clinically significant focal intracranial lesion on CT or MRI scans within 12 months of enrolment; at least 6 years of education or sufficient work experience to exclude mental retardation; English speaking with an English speaking care giver Exclusion criteria: evidence of epilepsy; focal brain lesion or head injury with loss of consciousness or immediate confusion after injury; any psychiatric disorder; hypersensitivity to any NSAID or cyclo-oxygenase-2-specific

Bibliographic reference	**Wilcock GK, Black SE, Hendrix SB et al. (2008) Efficacy and safety of tarenflurbil in mild to moderate Alzheimer's disease: a randomised phase II trial. Lancet Neurol. 7(6): 483-93.**
	inhibitor; recent history of chronic NSAID or aspirin use; history of upper gastrointestinal bleeding that required transfusion or surgery within 3 years of enrolment; documented evidence of an active gastric or duodenal ulcer within 3 months of enrolment; history of active malignancy except for basal cell carcinoma, prostate cancer or squamous cell carcinoma of the skin within 2 years of enrolment; a chronic renal, hepatic or metabolic disorder; previous major surgery; an uncontrolled cardiac condition; history of anticoagulant therapy within 3 months of enrolment; received a CYP2C9 inhibitor within 2 weeks of enrolment; received memantine therapy within 30 days of enrolment
Intervention	Tarenflurbil 400 mg bid. or tarenflurbil 800 mg bid.
Comparison	Placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog); Functional ability (ADCS-ADL); Dementia severity (CDR-SB); adverse evetns
Study dates	November 2003 to April 2006
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? UNCLEAR – patients who receiving chronic aspirin therapy or stable doses of antidepressants, antipsychotics, anxiolytics, vitamin E, or ginkgo biloba for at least 3 months were eligible for participation • At the end of the trial, were all patients accounted for? 47 patients in the tarenflurbil 800 mg group, 57 patients in the tarenflurbil group and 56 patients in the placebo group completed the intervention at 12 month follow-up. Analysis was performed using an intention-to-treat approach. • How large was the treatment effect? Significant for some outcome measures • How precise was the outcome effect? Authors reported and compared mean changes in outcome measures along with standard errors • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

E.6.1.3 Studies evaluating statins

Bibliographic reference	**Feldman HH, Doody RS, Kivipelto M et al (2010) Randomized controlled trial of atorvastatin in mild to moderate Alzheimer disease: LEADe. Neurology. 74(12): 956-64.**
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 18 month intervention phase followed by a 2 month withdrawal phase.
Participants	640 participants with probable Alzheimer's disease (according to DSM-IV and NINCDS-ADRDA criteria) treated by atorvastatin or placebo. Inclusion criteria: age between 50 and 90 years; a score of 13 to 25 on MMSE; a score of ≤ 4 on Hachinski scale; Low-density lipoprotein cholesterol ≥ 95 mg/dL and ≤ 195 mg/dL; CT or MRI brain scan consistent with the diagnosis of probable Alzheimer's disease. People with diabetes mellitus who had stable blood sugars with diet or treatment with antidiabetic drugs were permitted to enter the study if they had haemoglobin A1c levels of < 10% and fasting serum glucose levels of < 9.4 mmol/L and LDL-C values 2.5-3.5 mmol/L Exclusion criteria: receiving medications that affect lipid metabolism or cholinesterase activity; clinically significant or unstable medical conditions (including dermatological, haematological, pulmonary, cardiovascular, renal, hepatic, gastrointestinal, genitourinary, endocrine or neurological disease); dementia other than Alzheimer's disease; depression; delirium.
Intervention	Atorvastatin 40 mg bid.
Comparison	Matched placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE); Functional ability (ADFACS); Clinical global assessment (ADCS-CGIC); Behavioural/Neuropsychological outcomes (NPI); Dementia severity (CDR-SB); Caregiver outcomes; Healthcare resource
Study dates	Not specified
Comments	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? Participants were allowed to take putative cognitive enhancers (e.g. gingko biloba, high-dose vitamin E, non-steroidal anti-inflammatory drugs) so long as the dose remained stable 3 months before randomisation • At the end of the trial, were all patients accounted for? The trial dropout rate was 29.4%. Analyses were performed using the modified intention to treat approach. • How large was the treatment effect? Not significant

Bibliographic reference	**Feldman HH, Doody RS, Kivipelto M et al (2010) Randomized controlled trial of atorvastatin in mild to moderate Alzheimer disease: LEADe. Neurology. 74(12): 956-64.**
	• How precise was the outcome effect? Results were reported graphically, making it difficult to ascertain exact changes in outcome measures. • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Sano M, Bell KL, Galasko D et al. (2011) A randomized, double-blind, placebo-controlled trial of simvastatin to treat Alzheimer disease. Neurology. 77(6): 556-63.**
Study type	Randomised, multicentre (45 sites), placebo-controlled, double-blind trial: Duration: 18 months (NB: 6 month follow-up results extractable)
Participants	406 participants with probable Alzheimer's disease (according to NINCDS-ADRDA criteria) treated by simvastatin or placebo. Inclusion criteria: age > 50 years; a score of 12 to 26 on MMSE; stable use of cholinesterase inhibitors and/or memantine in the 3 months preceding enrolment. Exclusion criteria: neurologic or psychiatric condition could affect cognitive function (not specified); receiving anticholinergics, sedatives, anti-Parkinsonian or lipid-lowering medications; low density lipoprotein ≤ 80 mg/dL or triglycerides > 500 mg/dL
Intervention	Simvastatin 20 mg for 6 weeks, and simvastatin 40 mg thereafter
Comparison	Matched placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE); Functional ability (ADCS-ADL); Behavioural/Neuropsychological outcomes (NPI); Caregiving hours; adverse events
Study dates	December 2002 to January 2006
Comments	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? No – the simvastatin group had a higher proportion of people from a Hispanic origin. • Aside from the experimental intervention, were the groups treated equally? YES • At the end of the trial, were all patients accounted for? It 18 months, 15 patients in the simvastatin group were lost

Bibliographic reference	**Sano M, Bell KL, Galasko D et al. (2011) A randomized, double-blind, placebo-controlled trial of simvastatin to treat Alzheimer disease. Neurology. 77(6): 556-63.**
	to follow-up whereas 10 patients in the placebo group were lost to follow-up. • How large was the treatment effect? Not significant • How precise was the outcome effect? Mean changes (and standard deviations) in outcome measures were reported. • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Simons M, Schwärzler F, Lütjohann D et al. (2002) Treatment with simvastatin in normocholesterolemic patients with Alzheimer's disease: A 26-week randomized, placebo-controlled, double-blind trial. Ann Neurol. 52(3): 346-50.**
Study type	Randomised, placebo-controlled, double-blind trial: Duration: 6 months
Participants	44 participants with probable Alzheimer's disease (according to NINCDS criteria) treated by simvastatin or placebo. Inclusion criteria: a score of 12 to 26 on MMSE; a computed tomography scan ruling out vascular encephalopathy as the cause of dementia; a score of < 4 on Hachinski scale Exclusion criteria: continuous use of anti-inflammatory drugs
Intervention	Simvastatin (Dose not specified)
Comparison	Placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE); Lipid concentrations
Study dates	Not specified
Comments	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? NO – the simvastatin group had a higher proportion of females than the placebo group • Aside from the experimental intervention, were the groups treated equally? YES • At the end of the trial, were all patients accounted for? 4 people in the simvastatin group and 3 people in the placebo group withdrew from the study • How large was the treatment effect? Not significant

Bibliographic reference	**Simons M, Schwärzler F, Lütjohann D et al. (2002) Treatment with simvastatin in normocholesterolemic patients with Alzheimer's disease: A 26-week randomized, placebo-controlled, double-blind trial. Ann Neurol. 52(3): 346-50.**
	• How precise was the outcome effect? Authors reported mean baseline and final follow-up scores for some outcome measures, and mean changes in scores for other outcome measures. • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Sparks DL, Sabbagh MN, Connor DJ et al. (2005) Atorvastatin for the treatment of mild to moderate Alzheimer disease: preliminary results. Arch Neurol. 62(5): 753-7.** **NB: A second publication of the same study was produced by the same authors -** **Sparks DL, Connor DJ, Sabbagh MN et al (2006) Circulating cholesterol levels, apolipoprotein E genotype and dementia severity influence the benefit of atorvastatin treatment in Alzheimer's disease: results of the Alzheimer's Disease Cholesterol-Lowering Treatment (ADCLT) trial. Acta Neurol Scand Suppl. 185:3-7.**
Study type	Randomised, placebo-controlled, double-blind trial. Duration: 12 months
Participants	63 participants with probable or possible Alzheimer's disease (according to NINCDS/ADRDA and DSM-IV criteria) treated by atorvastatin or placebo. Inclusion criteria: age ≥ 51 years; English speaking with at least a 9th grade education; a score of 12 to 28 on MMSE; score of ≤ 4 on Hachinski scale; score of ≤ 20 on GDS; accompanied by an appropriate care giver. Exclusion criteria: neurological or psychiatric disease other than Alzheimer's disease (including Parkinson disease and dementia with Lewy bodies); significant systemic illness; organ failure; myocardial infarction; cardiac or thromboembolic vascular disease; major depression; already taking cholesterol-lowering medication; receiving an investigational treatment for Alzheimer's disease; history of head injury, significant liver disease and/or transaminase levels.
Intervention	Atorvastatin 40 mg bid.
Comparison	Matched placebo
Outcomes measures	Cognitive outcomes (ADAS-Cog; MMSE); Functional ability (ADCS-ADL, collected but not reported); Clinical global assessment (CGIC); Behavioural/Neuropsychological outcomes (NPI); Depression (GDS)
Study dates	Not specified
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES

Bibliographic reference	**Sparks DL, Sabbagh MN, Connor DJ et al. (2005) Atorvastatin for the treatment of mild to moderate Alzheimer disease: preliminary results. Arch Neurol. 62(5): 753-7.** **NB: A second publication of the same study was produced by the same authors -** **Sparks DL, Connor DJ, Sabbagh MN et al (2006) Circulating cholesterol levels, apolipoprotein E genotype and dementia severity influence the benefit of atorvastatin treatment in Alzheimer's disease: results of the Alzheimer's Disease Cholesterol-Lowering Treatment (ADCLT) trial. Acta Neurol Scand Suppl. 185:3-7.**
	• Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? UNCLEAR - Participants were allowed to continue using cholinesterase inhibitors and medications (including vitamin E) for treating non-excluded medical conditions. • At the end of the trial, were all patients accounted for? 6 patients were lost to follow-up in the atorvastatin group whereas 10 patients were lost to follow-up in the placebo group. • How large was the treatment effect? Significant • How precise was the outcome effect? Authors reported means and standard errors • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

E.6.1.4 Studies evaluating antihypertensive medicines

Bibliographic reference	**Kume K, Hanyu H, Sakurai H, et al. (2012) Effects of telmisartan on cognition and regional cerebral blood flow in hypertensive patients with Alzheimer's disease. Geriatr Gerontol Int. 12(2): 207-14.**
Study type	Randomised, single-blind. Duration: 6 months
Participants	20 participants with probable Alzheimer’s disease (according to NINCDS criteria) treated by telmisartan or amlodipine. Inclusion criteria: essential hypertension (systolic pressure ≥ 140 mm Hg or diastolic pressure ≥ 90 mm Hg) Exclusion criteria: taking neuroleptics, benzodiazepines, or antidepressants; comorbid neurological or psychiatric disorders known to cause memory impairment; anxiety or depression (scores > 5 on the GDS); major structural brain abnormalities or vascular lesions (identified by MRI or computed tomography); history of cancer within 3 years of enrolment; chronic renal failure, severe pulmonary disease; poorly controlled diabetes
Intervention	Telmisartan 40 mg to 80 mg
Comparison	Amlodipine 5 mg to 10 mg

Bibliographic reference	**Kume K, Hanyu H, Sakurai H, et al. (2012) Effects of telmisartan on cognition and regional cerebral blood flow in hypertensive patients with Alzheimer's disease. Geriatr Gerontol Int. 12(2): 207-14.**
Outcomes measures	Cognitive outcomes (MMSE; ADAS-Cog; WMS-R logical memory test); Blood pressure changes; cerebral blood flow
Study dates	Not reported
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES (partially reported) • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? YES • At the end of the trial, were all patients accounted for? YES • How large was the treatment effect? Not significant for most outcome measures • How precise was the outcome effect? Authors reported mean baseline and final follow-up scores of each treatment group. Mean changes were not reported. • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Ohrui T, Tomita N, Sato-Nakagawa T, et al. (2004) Effects of brain-penetrating ACE inhibitors on Alzheimer disease progression. Neurology. 63(7): 1324-1325.**
Study type	Randomised, multicentre, double-blind trial. Duration: 12 months
Participants	162 participants with probable Alzheimer's disease (according to NINCDS criteria) treated by a brain-penetrating ACE inhibitor, non-brain-penetrating ACE inhibitor, or a calcium-channel blocker. Inclusion criteria: age ≥ 65 years; ; a score of 13 to 23 on MMSE Exclusion criteria: evidence of stroke; insulin-dependent diabetes or other endocrine disorders; asthma or obstructive pulmonary disease; blood pressure higher than 140 mm Hg systolic or 90 mm Hg diastolic; vascular dementia or other neurodegenerative dementias; hypertension; congestive heart failure; psychiatric disorders such as schizophrenia; history of drug or alcohol abuse
Intervention	Brain-penetrating ACE inhibitors (perindopril 2 mg or captopril 37.5 mg)
Comparison	Non-brain-penetrating ACE inhibitor (enalapril 5 mg or imidapril 5 mg) or a calcium-channel blocker (nifedipine 20 mg or nilvadipine 4 mg)

Bibliographic reference	**Ohrui T, Tomita N, Sato-Nakagawa T, et al. (2004) Effects of brain-penetrating ACE inhibitors on Alzheimer disease progression. Neurology. 63(7): 1324-1325.**
Outcomes measures	Cognitive outcomes (MMSE)
Study dates	Not reported
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? Not reported • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? YES • At the end of the trial, were all patients accounted for? Withdrawals and losses to follow-up were not reported • How large was the treatment effect? Significant • How precise was the outcome effect? Authors reported mean changes in outcome measures accompanied with standard deviations • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Morich FJ, Bieber F, Lewis JM et al. (2012) Nimodipine in the Treatment of Probable Alzheimer's Disease. Neurology. 11(4): 185-195**
Study type	Pooled analysis of 2 **identical, previously unpublished,** randomised, multicentre, double-blind trials. Duration: 6 months
Participants	1,605 participants with Alzheimer's disease (According to DSM-III criteria) treated by nimodipine or placebo Inclusion criteria: age between 45 and 85 years; ; a score of 12 to 23 on MMSE; a score ≤ 4 on Hachinski scale; a score of 4 or 5 on GDS; a score ≤ 6 on HAM-D scale; diastolic blood pressure between 50 and 114 mmHg; systolic blood pressure between 100 and 200 mmHg Exclusion criteria: other types of dementia; intracranial haemorrhage; presence of brain lesions; substantial arrhythmia or history of myocardial infarction; recent diagnosis of anxiety or depression, schizophrenia, or manic depression
Intervention	Nimodipine 90 mg or nimodipine 180 mg
Comparison	Placebo
Outcomes measures	Cognitive outcomes (MMSE; ADAS-Cog; ADAS-total score; BSR; GERRI); Clinical global assessment (GDS; CGI-

Bibliographic reference	**Morich FJ, Bieber F, Lewis JM et al. (2012) Nimodipine in the Treatment of Probable Alzheimer's Disease. Neurology. 11(4): 185-195**
	S; CGI-I); adverse events
Study dates	Not reported
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? UNCLEAR – "shortly after the start of the study, a protocol amendment permitted the use of antidepressants, anxiolytics and antipsychotics". The proportions of participants using the aforementioned medications were not reported. • At the end of the trial, were all patients accounted for? Overall, 13 patients in the nimodipine 90 mg group, 7 in the nimodipine 180 mg group and 12 patients in the placebo group withdrew from the study. • How large was the treatment effect? Not significant for most outcome measures • How precise was the outcome effect? Authors reported mean changes in outcome measures • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

Bibliographic reference	**Pantoni L, del Ser T, Soglian AG, et al. (2005) Efficacy and safety of nimodipine in subcortical vascular dementia: a randomized placebo-controlled trial. Stroke. 36(3): 619-24**
Study type	Randomised, multicentre, placebo-controlled, double-blind trial. Duration: 12 months
Participants	242 participants with subcortical vascular dementia (according to ICD-10 criteria) treated by nimodipine or placebo. Inclusion criteria: age 55 to 87 years; dementia for > 6 months and < 3 years; a score of 12 to 24 on MMSE; a score of > 4 on Hachinski scale; a GDS ≥ 3 and ≤ 5; computed tomography performed not more than 3 months before baseline showing severe white matter changes; at least 1 definite image consistent with a lacunar infarct. Exclusion criteria: previous diagnosis of major depression, schizophrenia, major anxiety syndrome, bipolar disorder; Alzheimer's disease, Parkinson disease, Huntington disease or fronto-temporal dementia; other diseases known to cause dementia; contraindications to dihydropyridine derivatives; medical conditions that could interfere with the assessment of clinical and mental statuses; clinically relevant cardiac or pulmonary insufficiency; relevant electrocardiograph abnormalities; bradycardia (< 50 bpm) or tachycardia (> 120 bpm) under resting conditions; a history of myocardial infarction; stroke still requiring neurological rehabilitation; severe/untreated hypertension;

Bibliographic reference	**Pantoni L, del Ser T, Soglian AG, et al. (2005) Efficacy and safety of nimodipine in subcortical vascular dementia: a randomized placebo-controlled trial. Stroke. 36(3): 619-24**
	impaired liver function; insulin-dependent diabetes mellitus; idiopathic epilepsy and anti-epileptic treatment; severe anaemia; severe gastrointestinal disease; cancer.
Intervention	Nimodipine 30 mg tid.
Comparison	Placebo
Outcomes measures	Cognitive outcomes (MMSE; SCAG test; set test; digit span test for working memory); Clinical global assessment (NOSGER); Verbal fluency (Zahlen-Verbingdungs test; lexical production); Depression (HAM-D); motor performance
Study dates	December 1996 to February 2002
Comments (Risk of bias)	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? PROBABLY (methods not reported) • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES • Aside from the experimental intervention, were the groups treated equally? UNCLEAR – The use of angiotensin-converting enzyme inhibitors, diuretics, beta-blockers, verapamil, or diltiazem was allowed so long as treatment had started at least 6 weeks before enrolment. Participants were also allowed to use short-acting benzodiazepines, anti-arrhythmics, or antithrombotics • At the end of the trial, were all patients accounted for? 17 patients were lost to follow-up in the nimodipine group whereas 41 patients were lost to follow-up in the placebo group. • How large was the treatment effect? Not significant for most outcome measures • How precise was the outcome effect? Authors reported mean changes in outcome measures accompanied with standard deviations • Can the results be applied to the local population? YES • Were all clinically relevant outcomes reported? YES

E.7 Cholinesterase inhibitors and memantine for dementia

E.7.1 Cholinesterase inhibitors and memantine for people living with Alzheimer's disease

- Who should start and review the following pharmacological interventions: (donepezil, galantamine, rivastigmine, memantine) for people with Alzheimer's disease and how should a review be carried out?

Bibliographic reference	Aupperle,P.M., Coyne,A.C., 20000717, Primary vs subspecialty care: a structured follow-up of dementia patients and their caregivers, American Journal of Geriatric PsychiatryAm.J.Geriatr.Psychiatry, 8, 167-170, 2000
Country/ies where the study was carried out	USA
Study type	Observational: Retrospective cohort analysis
Aim of the study	To examine a cohort of people with Alzheimer's disease and their caregivers 1 year after receiving a diagnostic evaluation To compare usage of health services of those treated only by primary care physician (MED) with those receiving care by a geriatric psychiatrist (GERO)
Study dates	1997-1998
Source of funding	Not reported (pilot study)
Sample size	Original population receiving diagnosis N= 80 At 1 year follow up N= 58 (mean age 78.8 years) MED (n=31); mean age = 82.9 years GERO (n=27); mean age = 80.4 years
Inclusion criteria	All dementia patients and caregivers who received a neuropsychiatric evaluation and a diagnosis of Alzheimer's disease (AD) at a university based diagnostic clinic were surveyed 1 year after the initial assessment.
Exclusion criteria	Exclusion criteria was not reported
Details	All participants with a diagnosis of AD received an initial evaluation and were surveyed at 1 year follow up Data collected at baseline taken from initial evaluation Demographic data collected at initial assessment Assessment of physical impairment by Cumulative Illness Rating Scale (CIRS) taken from standardised chart reviews Data collected at baseline and follow up Assessments of cognition (Clinical Dementia Rating Scale; CDR)

Bibliographic reference	Aupperle,P.M., Coyne,A.C., 20000717, Primary vs subspecialty care: a structured follow-up of dementia patients and their caregivers, American Journal of Geriatric PsychiatryAm.J.Geriatr.Psychiatry, 8, 167-170, 2000
	Caregiver distress (Zarit Burden Interview; Zarit) Physician practices (prescription of donepezil) Utilisation of health services by patient Follow up data was collected by telephone contact with caregiver Data Analysis Nonparametric and correlational assessment of data was performed Loss of data at 1 year follow up Deceased (n=7) Not contacted (n=6) Caregivers not willing to participate (n=9)
Interventions	Two sub groups identified: Those being seen only by a primary care physician (MED) Those being seen in addition by a member of a geriatric psychiatry facility in collaboration with a case manager such as a geriatric social worker or geriatric nurse (GERO). Case management included education about AD, a detailed review of caregiver coping skills, behavioural management, community resources, long term care planning, legal and financial planning.
Results	Clinical outcome (including cognitive, functional, behavioural ability) Clinical Dementia Rating Scale CDR – Primary care physician baseline mean = 1.8 (SD= 0.7); 1 year follow up mean = 2.5 (SD= 0.6) Geriatric Psychiatrist baseline mean = 1.9 (SD= 0.7); 1 year follow up mean = 1.8 (SD= 0.7) Over prescribing/under prescribing and potentially avoidable adverse events Not reported Medication errors Not reported

Bibliographic reference	Aupperle,P.M., Coyne,A.C., 20000717, Primary vs subspecialty care: a structured follow-up of dementia patients and their caregivers, American Journal of Geriatric PsychiatryAm.J.Geriatr.Psychiatry, 8, 167-170, 2000
	Access to health care and social care support Service Usage (past 6 months) Number of hospitalisations at 1 year follow up Primary Care physician n=12 (38.7%) Geriatric Psychiatrist n=4 (14.8%) Use of Home health aide at 1 year follow up: Primary Care physician n=14 (45.2% Geriatric Psychiatrist n=5 (18.5%) Use of Dementia day program at 1 year follow up Primary Care physician n=5 (16.1%) Geriatric Psychiatrist n = 7 (25.9%) Concordance and compliance Provider practices Prescription of donepezil- Primary care physician baseline n=17 (53.1%); 1 year follow up n=11 (35.5%) Geriatric Psychiatrist baseline n=15 (46.9%); 1 year follow up n= 20 (64.5%] Patient and carer experience and satisfaction Caregiver distress ratings Zarit Burden Interview: Primary Care Physician baseline mean = 30.8 (SD= 16.9); 1 year follow up mean = 21.6 (SD= 12.2) Geriatric Psychiatrist baseline mean = 38.3 (SD=13.4); 1 year follow up mean = 19.2 (SD=12.9)

Bibliographic reference	Aupperle,P.M., Coyne,A.C., 20000717, Primary vs subspecialty care: a structured follow-up of dementia patients and their caregivers, American Journal of Geriatric PsychiatryAm.J.Geriatr.Psychiatry, 8, 167-170, 2000
	Resource use and cost Not reported
Overall Risk of Bias	Pilot study only provides limited outcomes
Other information	Was the allocation sequence adequately generated? N/A Was the allocation adequately concealed? N/A Were baseline outcome measurements similar? Yes Were baseline characteristics similar? Yes Were incomplete outcome data adequately addressed? Yes Was knowledge of the allocated interventions adequately prevented during the study? N/A Was the study adequately protected against contamination? N/A Was the study free from selective outcome reporting? Yes

Bibliographic reference	Aupperle,P.M., MacPhee,E.R., Coyne,A.C., Blume,J., Sanchez,B., 20030716, Health service utilization by Alzheimer's disease patients: a 2-year follow-up of primary versus subspecialty care, Journal of Geriatric Psychiatry & Neurology, 16, 15-17, 2003
Country/ies where the study was carried out	USA
Study type	Observational: Retrospective cohort analysis (Follow up of Aupperle, 2000)
Aim of the study	To examine a cohort of people with Alzheimer’s disease and their caregivers at 2 year follow up after receiving a diagnostic evaluation To compare usage of health services of those treated only by primary care physician (MED) with those receiving care by a geriatric psychiatrist (GERO)
Study dates	1997-1998
Source of funding	Not reported
Sample size	Original population receiving diagnosis N= 80 At 2 year follow up N= 39 (mean age 78.4 years)

Bibliographic reference	**Aupperle,P.M., MacPhee,E.R., Coyne,A.C., Blume,J., Sanchez,B., 20030716, Health service utilization by Alzheimer's disease patients: a 2-year follow-up of primary versus subspecialty care, Journal of Geriatric Psychiatry & Neurology, 16, 15-17, 2003**
	MED (n=22); mean age = not reported GERO (n=17); mean age = not reported
Inclusion criteria	This was a 2 year follow up of a cohort of dementia patients and caregivers who received a neuropsychiatric evaluation and a diagnosis of Alzheimer's disease (AD) at a university based diagnostic clinic and were originally surveyed 1 year after their initial assessment.
Exclusion criteria	Exclusion criteria not reported
Details	All participants with a diagnosis of AD received an initial evaluation and had previously been surveyed at 1 year follow up Data collected at baseline taken from initial evaluation Demographic data collected at initial assessment Assessment of physical impairment by Cumulative Illness Rating Scale (CIRS) taken from standardised chart reviews Data collected at baseline and at 2 year follow up: Assessments of cognition (Clinical Dementia Rating Scale; CDR) Physician practices (prescription of donepezil) Utilisation of health services by patient Follow up data was collected by telephone contact with caregiver Data Analysis Nonparametric and correlational assessment of data was performed Loss of data at 2 year follow up Information relating to attrition was not specifically reported at 2 year follow up.
Interventions	The cohort at 2 year follow up was a subset of the original cohort diagnosed with AD: Two sub groups identified: Those being seen only by a primary care physician (MED) Those being seen in addition by a member of a geriatric psychiatry facility in collaboration with a case manager such as a geriatric social worker or geriatric nurse (GERO). Case management included education about AD, a detailed review of caregiver coping skills, behavioural management, community resources, long term care planning, legal and financial planning.

Bibliographic reference	Aupperle,P.M., MacPhee,E.R., Coyne,A.C., Blume,J., Sanchez,B., 20030716, Health service utilization by Alzheimer's disease patients: a 2-year follow-up of primary versus subspecialty care, Journal of Geriatric Psychiatry & Neurology, 16, 15-17, 2003
Results	Clinical outcome (including cognitive, functional, behavioural ability) Clinical Dementia Rating Scale CDR Primary care physician baseline mean= 1.8 (SD= 0.7); 2 year follow up mean = 2.3 (SD not reported) Geriatric Psychiatrist baseline mean = 1.9 (SD= 0.7); 2 year follow up mean = 1.5 *SD not reported) Over prescribing/under prescribing and potentially avoidable adverse events Not reported Medication errors Not reported Access to health care and social care support Service Usage (past 6 months) Number of hospitalisations at 2 year follow up Primary Care physician n=5 (22.7%) Geriatric Psychiatrist n=2 (11.8%) Resident in nursing home at 2 year follow up Primary Care physician n=5 (22.7%) Geriatric Psychiatrist n=0 (0.0%) Use of assisted living at 2 year follow up Primary Care Physician n=4 (18.2%) Geriatric Psychiatrist n = 1 (5.9%) Assisted living/nursing home at 2 year follow up

Bibliographic reference	Aupperle,P.M., MacPhee,E.R., Coyne,A.C., Blume,J., Sanchez,B., 20030716, Health service utilization by Alzheimer's disease patients: a 2-year follow-up of primary versus subspecialty care, Journal of Geriatric Psychiatry & Neurology, 16, 15-17, 2003
	Primary Care physician n= 9 (40.9%) Geriatric Psychiatrist n=1 (5.9%) Concordance and compliance Provider practices Prescription of donepezil- Primary care physician [baseline n=17 (53.1%); 2 year follow up n=10 (45.5%)] Geriatric Psychiatrist [baseline n=15 (46.9%); 2 year follow up n= 13 (76.5%)] Patient and carer experience and satisfaction Caregiver distress ratings Not reported Resource use and cost Not reported
Overall Risk of Bias	Follow up of Aupperle (2000) but outcomes not comparative Incomplete reporting of CDR. Only provides mean change and not SD
Other information	Was the allocation sequence adequately generated? N/A Was the allocation adequately concealed? N/A Were baseline outcome measurements similar? Yes Were baseline characteristics similar?

Bibliographic reference	Aupperle,P.M., MacPhee,E.R., Coyne,A.C., Blume,J., Sanchez,B., 20030716, Health service utilization by Alzheimer's disease patients: a 2-year follow-up of primary versus subspecialty care, Journal of Geriatric Psychiatry & Neurology, 16, 15-17, 2003
	Yes Were incomplete outcome data adequately addressed? Yes Was knowledge of the allocated interventions adequately prevented during the study? N/A Was the study adequately protected against contamination? N/A Was the study free from selective outcome reporting? No

Bibliographic reference	Watanabe,N., Yamamura,K., Suzuki,Y., Umegaki,H., Shigeno,K., Matsushita,R., Sai,Y., Miyamoto,K., Yamada,K., 20121002, Pharmacist-based Donepezil Outpatient Consultation Service to improve medication persistence, Patient preference & adherence, 6, 605-611, 2012
Country/ies where the study was carried out	Japan
Study type	A two part observational study, before and after establishing an outpatient advisory service, conducted in a geriatric outpatient clinic of a university hospital.
Aim of the study	To examine the effectiveness of a donepezil outpatient consultation service (DOCS) for people with Alzheimer's disease (AD) compared to those who do not attend the DOCS. To assess patients and caregivers changes in understanding about donepezil treatment and AD To monitor medication persistence rate
Study dates	April 2008 to September 2010 enrolment of non DOCS group October 2010 to March 2012 enrolment of DOCS group
Source of funding	Not reported

Bibliographic reference	**Watanabe,N., Yamamura,K., Suzuki,Y., Umegaki,H., Shigeno,K., Matsushita,R., Sai,Y., Miyamoto,K., Yamada,K., 20121002, Pharmacist-based Donepezil Outpatient Consultation Service to improve medication persistence, Patient preference & adherence, 6, 605-611, 2012**
Sample size	non DOCS group N= 59 (15 male; 44 female; mean age 79.0 years; mean baseline CDR=1.32) DOCS group N= 52 (21 male; 31 female; mean age 77.2 years; mean baseline CDR= 1.27)
Inclusion criteria	Patients and caregivers of patients diagnosed with AD and receiving donepezil who were attending a University outpatient consultation service were enrolled. All participants had AD according to Diagnostic Statistical Manual of Mental Disorders criteria
Exclusion criteria	Not reported
Details	All patients and caregivers of patients who had been diagnosed with AD and were prescribed donepezil at a university geriatric outpatient clinic were included: Patients or family members who wished to use the DOCS after an outpatient appointment were offered an appointment.. A pharmacist provided advice to each patient/ family. All patients attending were surveyed to assess changes in their understanding of donepezil and AD treatment. Medical persistence rate was estimate using Kaplan-Meier analysis and Cox proportional hazards model was used to analyse factors influencing medical persistence Information related to use of donepezil was collected (adherence, timing of drug intake, patients swallowing function), instructions about dosing. A 6-item survey of understanding about the clinical features of Alzheimer's disease and donepezil therapy for caregivers was prepared in consultation with geriatricians. The 6 questions included: Do you know the difference between forgetfulness and dementia? Do you think dementia is an illness? Do you know about the effects of donepezil? Do you know the side effects of donepezil? Do you know that you must not stop the drugs even if taking the drug does not cause any change in symptoms?

Bibliographic reference	**Watanabe,N., Yamamura,K., Suzuki,Y., Umegaki,H., Shigeno,K., Matsushita,R., Sai,Y., Miyamoto,K., Yamada,K., 20121002, Pharmacist-based Donepezil Outpatient Consultation Service to improve medication persistence, Patient preference & adherence, 6, 605-611, 2012**
	Do you know that you must not take two doses together, even if you have forgotten to take a dose? Graded by giving a score of 1 for every correct answer and a 0 for each incorrect answer. The survey was repeated four weeks after first DOCS consultation and if information was not clear further instructions were provided via textbook.
Interventions	Two groups were identified: The group who were enrolled into an advisory service before it was established (non DOCS) The group who were enrolled into an advisory service after it was established (DOCS)
Results	Clinical outcome (including cognitive, functional, behavioural ability) Not reported Over prescribing/under prescribing and potentially avoidable adverse events Not reported Medication errors Not reported Access to health care and social care support Duration of first outpatient consultation: DOCS group - mean (SD) = 46.4 (7.2) minutes Duration of consultation at 4 week follow up: DOCS group - mean (SD) = 27.8 (6.1) minutes Concordance and compliance Medication persistence rate: Duration of donepezil treatment:

Bibliographic reference	Watanabe,N., Yamamura,K., Suzuki,Y., Umegaki,H., Shigeno,K., Matsushita,R., Sai,Y., Miyamoto,K., Yamada,K., 20121002, Pharmacist-based Donepezil Outpatient Consultation Service to improve medication persistence, Patient preference & adherence, 6, 605-611, 2012
	Non DOCS group- mean (SD) = 248.6 (184.1) days DOCS group mean (SD) = 379.1 (202.6) days Use of donepezil at one year DOCS group = 38 patients (73.1%) Non DOCS group = 29 patients (49.2%) Patient and carer experience and satisfaction Level of understanding in AD and donepezil: DOCS group (n=52) Score of understanding at initial consultation mean = 2.5 (SD=1.7) Score of understanding at 4 week follow up mean = 5.7 (SD=0.7) Resource use and cost Not reported
Overall Risk of Bias	Limited outcomes considered at follow up. Validation for scale used in survey of understanding not clearly reported Short follow up period (only 4 weeks) to assess effectiveness of outcomes from DOCS
Other information	Was the allocation sequence adequately generated? N/A Was the allocation adequately concealed? N/A

Bibliographic reference	**Watanabe,N., Yamamura,K., Suzuki,Y., Umegaki,H., Shigeno,K., Matsushita,R., Sai,Y., Miyamoto,K., Yamada,K., 20121002, Pharmacist-based Donepezil Outpatient Consultation Service to improve medication persistence, Patient preference & adherence, 6, 605-611, 2012**
	Were baseline outcome measurements similar? Unclear (unclear bias) Were baseline characteristics similar? Unclear (unclear bias) Were incomplete outcome data adequately addressed? Unclear (unclear risk) Was knowledge of the allocated interventions adequately prevented during the study? N/a Was the study adequately protected against contamination? Yes (low risk) Was the study free from selective outcome reporting? Yes (low risk)

E.7.2 Cholinesterase inhibitors and memantine in Alzheimer's disease

- How effective is the co-prescription of cholinesterase inhibitors and memantine for the treatment of Alzheimer's disease?
- When should treatment with donepezil, galantamine, rivastigmine, memantine be withdrawn for people with Alzheimer's disease?

E.7.2.1 Co-prescription of Cholinesterase inhibitors and/or memantine

Bibliographic reference	**Araki T, Wake R, Miyaoka T, Kawakami K et al (2014) The effects of combine treatment of memantine and donepezil on Alzheimer's disease patients and its relationship with cerebral blood flow in the prefrontal area (2014) International Journal of Geriatric Psychiatry, 29, 881-889**
Study type and aim	Randomised controlled trial to evaluate the effects of memantine on cognitive function and BPSD in people with moderate to severe Alzheimer's disease currently being treated with donepezil
Participants	Inclusion criteria: • Outpatients treated at Department of Clinical Psychiatry at University Hospital • Moderate to severe AD (based on DSM-IV criteria and ICD 10th edition classification • Score of 3 to 16 on Hasegawa dementia scale (revision) • Treated with donepezil for at least 6 months Exclusion criteria: • Not reported
Sample characteristics	N= 37 Intervention (combination group) n=19; mean age = 77.9 years Control (non memantine donepezil only group) n=18; mean age = 79.8 years
Intervention	Continued donepezil treatment and started oral memantine for 24 weeks. Memantine administered at 5mg/day increasing by 5mg every week to achieve maintenance dose of 20mg/day
Comparison	Control group continued to receive donepezil
Outcome measures	Clinical Global Impression – Improvement MMSE Clock Drawing Test Japanese Zarit Burden Interview
Study dates	Not reported
Study location	Japan

Bibliographic reference	**Araki T, Wake R, Miyaoka T, Kawakami K et al (2014) The effects of combine treatment of memantine and donepezil on Alzheimer's disease patients and its relationship with cerebral blood flow in the prefrontal area (2014) International Journal of Geriatric Psychiatry, 29, 881-889**
Follow up	24 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes random number table • Were clinicians and investigators blinded? Not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean (SD) reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High- lack of placebo control

Bibliographic reference	**Choi SH, Park KW, Na DL, Han JH, Kim E-J, Shim YS, Lee J-H (2011) Tolerability and efficacy of memantine add-on therapy to rivastigmine transdermal patches in mild to moderate Alzheimer's disease; a multicentre randomised, open label, parallel-group study, Current Medical Research and Opinion, 27 (7), 1375-1383**
Study type and aim	Multicentre randomised open-label study to compare the tolerability and efficacy of combination therapy of memantine plus rivastigmine transdermal patch and rivastigmine patch monotherapy in people with mild to moderate Alzheimer's disease
Participants	Inclusion criteria: • 50-90 years • Met criteria for probable AD (NINCDS-ADRDA) • Ambulatory or ambulatory aided • Korean MMSE score 10-20 • No clinical signs of other disease (eg brain tumour, normal pressure hydrocephalus, cerebrovascular disease) • Had a reliable caregiver who attended at least once a week Exclusion criteria:

Bibliographic reference	**Choi SH, Park KW, Na DL, Han JH, Kim E-J, Shim YS, Lee J-H (2011) Tolerability and efficacy of memantine add-on therapy to rivastigmine transdermal patches in mild to moderate Alzheimer's disease; a multicentre randomised, open label, parallel-group study, Current Medical Research and Opinion, 27 (7), 1375-1383**
	• Any primary neurodegenerative disorder other than AD • Clinical significant laboratory abnormalities • History of drug or alcohol addiction in last 10 years • Severe or unstable medical disease (eg asthma, active gastric u;lcer) • Bradychardia with less than 50 beats per minute • Sick sinus syndrome • Sinoatrial block • Second or third atrioventricular block • Hearing or visual impairment that could disturb efficient evaluation of patient
Sample characteristics	N=172 • Intervention (memantine plus rivastigmine transdermal patch) n= 88, mean age = 75 years; K MMSE = 16.8 (4.3) • Control (rivastigmine transdermal patch monotherapy) n= 83; mean age = 74.7 years; KMMSE = 16.4
Intervention	4 week run in period all treated with 5cm^2. Dosage increased to 10cm^2. Maintained at highest tolerated dose for 20 weeks. Memantine added at week 1 starting dose of 5mg/ day to 20mg/ day
Comparison	4 week run in period all treated with 5cm^2. Dosage increased to 10cm^2. Maintained at highest tolerated dose for 20 weeks
Outcome measures	• Korean MMSE • ADAS-Cog • NPI (caregivers assessment) • Frontal Assessment Battery • ADCS- ADL • CDR-SB • Koran CMAI Safety and tolerability
Study dates	Not reported
Study location	South Korea, study conducted in 26 centres

Bibliographic reference	**Choi SH, Park KW, Na DL, Han JH, Kim E-J, Shim YS, Lee J-H (2011) Tolerability and efficacy of memantine add-on therapy to rivastigmine transdermal patches in mild to moderate Alzheimer's disease; a multicentre randomised, open label, parallel-group study, Current Medical Research and Opinion, 27 (7), 1375-1383**
Follow up	16 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? • Was the assignment of patients to treatment randomised? Yes computer generated. Multicentre so stratified to site • Were clinicians and investigators blinded? No –open label • Were the groups similar at the start of the trial? • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High due to open label and lack of placebo control

Bibliographic reference	**Dysken MW, Sano M, Asthana S, Vertrees JE, Pallaki M et al (2014) Effect of vitamin E and memantine on functional decline in Alzheimer's disease The TEAM AD VA cooperative randomized trial, JAMA, 311, (1), 33-44**
Study type and aim	Randomised controlled trial to determine if memantine, vitamin E or both can slow progression of mild to moderate AD in people already taking a cholinesterase inhibitor.
Participants	Inclusion criteria: • Veterans with a diagnosis of mild to moderate possible or probable AD • MMSE 12-26 • Currently taking an AChEI Exclusion criteria: • Not reported
Sample characteristics	N=613 Relevant arms of trial = memantine versus placebo Intervention (memantine) n= 152 mean age = 79.4 years; MMSE = 20.8

Bibliographic reference	**Dysken MW, Sano M, Asthana S, Vertrees JE, Pallaki M et al (2014) Effect of vitamin E and memantine on functional decline in Alzheimer's disease The TEAM AD VA cooperative randomized trial, JAMA, 311, (1), 33-44**
	Control (placebo) n=155 n=155 mean age = 78.8 years; MMSE= 20.8
Intervention	Participants were already being treated with a cholinesterase inhibitor receive memantine titrated over 4 weeks to 10mg twice a day
Comparison	Participants were already receiving a cholinesterase inhibitor and received oral placebo
Outcome measures	ADCS ADL ADAS Cog MMSE NPI Caregiver Activity Survey All adverse events Serious adverse events
Study dates	Aug 2007- March 2012
Study location	USA 14 Centres
Follow up	Treatment duration lasted 6 months to 4 years
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- central randomisation in permuted blocks • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes- small loss to follow up due to incomplete data • How large was the treatment effect? How precise was the outcome effect? Mean (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Grossberg GT, Manes F, Allegri RF, Guttierez-Robledo LM, Gloger S, Xie L, Jia D, Pejovic V, Miller MT, Perhach JL, Graham SM (2013) The safety, tolerability and efficacy of once daily memantine (28mg): A multinational randomised double blind , placebo controlled trial in patients with moderate to severe Alzheimer's disease taking cholinesterase inhibitors , CNS Drugs, 27, 469-478**
Study type and aim	To evaluate the efficacy, safety and tolerability of 28 mg memantine in people with moderate to severe AD who were already taking a stable dose of any cholinesterase inhibitor
Participants	Inclusion criteria: • Community dwelling aged at least 50 years • Clinical diagnosis of probable AD (DSM IV-TR NINCDS-ADRDA) • MMSE 3-14 • Results of MRI or CT within past 12 months consistent with the diagnosis • Receiving any AChEI for at least 3 months • Clinically non-significant results on physical examination, laboratory results and ECG Exclusion criteria: • Clinically significant and active pulmonary, gastrointestinal, renal, hepatic, endocrine, or cardiovascular system disease; • Neurologic disorder (e.g., stroke, Parkinson's disease, seizure disorder, or head injury with loss of consciousness) within the past 5 years • Clinically significant B_{12} or folate deficiency • Any DSM-IV Axis I disorder other than AD • CT or MRI compatible with hydrocephalus, stroke, space-occupying mass lesion, cerebral infection, or any other clinically significant disease involving the central nervous system • Dementia complicated by other organic disease or predominant delusions • Systolic blood pressure >180 or <90 mmHg, or diastolic blood pressure >105 or <50 mmHg at screening or baseline • Treatment for an oncologic diagnosis within the previous 6 months; modified Hachinski Ischemic score >4 at screening • Known or suspected history of alcoholism or drug abuse within 10 years of screening • Memantine treatment within one month prior to screening • Clinician's judgment of likely nursing home placement within 6 months; • Hypersensitivity to memantine, neramexane, rimantadine, or amantadine

Bibliographic reference	**Grossberg GT, Manes F, Allegri RF, Guttierez-Robledo LM, Gloger S, Xie L, Jia D, Pejovic V, Miller MT, Perhach JL, Graham SM (2013) The safety, tolerability and efficacy of once daily memantine (28mg): A multinational randomised double blind , placebo controlled trial in patients with moderate to severe Alzheimer's disease taking cholinesterase inhibitors , CNS Drugs, 27, 469-478**
	• Cholinesterase inhibitor therapy that was likely to be interrupted or discontinued during course of the study, contraindication for cholinesterase inhibitor therapy, or therapy with multiple cholinesterase inhibitors; the inability to perform a minimum of one item on the Severe Impairment Battery (SIB) at baseline
Sample characteristics	N= 677 Intervention (memantine ER and AChEI) n=342; mean age = 76.2 years ; MMSE = 10.9 Control (placebo/ AChEI) n= 335 mean age = 76.8 years; MMSE = 10.6
Intervention	All taking AChEI Single blind placebo treatment for 4 to 14 days prior to treatment. Received initial dose of memantine 7mg/day titrated upwards in 7mg increments to 28mg/ day by week 4. Minimum tolerance at week 8 = 21mg/ day
Comparison	All taking AChEI but received identical placebo
Outcome measures	SIB CIBIC plus ADCS-ADL NPI Verbal Fluency Test
Study dates	1997
Study location	USA
Follow up	24 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- random number sequence • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean (SD)

Bibliographic reference	**Grossberg GT, Manes F, Allegri RF, Guttierez-Robledo LM, Gloger S, Xie L, Jia D, Pejovic V, Miller MT, Perhach JL, Graham SM (2013) The safety, tolerability and efficacy of once daily memantine (28mg): A multinational randomised double blind , placebo controlled trial in patients with moderate to severe Alzheimer's disease taking cholinesterase inhibitors , CNS Drugs, 27, 469-478**
	• Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Howard R, McShane R, Lindesay J, Ritchie C, Baldwin A, Barber R, Burns A, Dening T et al (2012) Donepezil and memantine for moderate to severe Alzheimer's disease, New England Journal of Medicine, 2012, 366, (10), 893-903**
Study type and aim	Multicentre double blind two by two factorial design randomised controlled trial to determine if people living with moderate to severe Alzheimer's disease in the community and already receiving donepezil would benefit from additionally receiving memantine at this course of the disease.
Participants	Inclusion criteria: • Community residents who had caregivers • Met standardised clinical criteria for probable or possible moderate or severe AD • Continuously prescribed donepezil for past 3 months and received at least 10mg for previous 6 weeks • Score 5-13 on SMMSE Exclusion criteria: • Severe or unstable medical conditions • Currently receiving memantine • Considered unlikely to adhere to study regimens
Sample characteristics	N=295 Continuing donepezil and active memantine added n=73 mean age = 77.5 years; SMMSE = 9.1 Continuing donepezil and placebo memantine added n= 73 mean age = 77.2 years; SMMSE= 9.0 Tapered discontinuation of donepezil and active memantine added n=76; mean age = 76.2 years; SMMSE= 9.2 Tapered discontinuation of donepezil and placebo memantine added n=73; mean age= 77.7 years; SMMSE = 9.2
Intervention	• Continuation of donepezil (10mg/ day) and active memantine (5mg/day) added in week 1 increasing by 5mg increments weekly to 20mg/ day from week 4 onwards

Bibliographic reference	**Howard R, McShane R, Lindesay J, Ritchie C, Baldwin A, Barber R, Burns A, Dening T et al (2012) Donepezil and memantine for moderate to severe Alzheimer's disease, New England Journal of Medicine, 2012, 366, (10), 893-903**
	• Tapered discontinuation of donepezil (5mg/day) and active memantine (5mg/ day) added in week 1 increasing by 5mg increments weekly to 20mg/ day from week 4 onwards
Comparison	• Continuation of donepezil (10mg/ day) with placebo memantine added in week 1 • Tapered discontinuation of donepezil (5mg/day) and placebo memantine added in week 1 with placebo donepezil added in week 5
Outcome measures	SMMSE Bristol Activities of Daily Living Scale NPI DEMQOL proxy GHQ 12
Study dates	Feb 2008 to March 2010
Study location	UK 15 centres
Follow up	52 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes. Centrally using randomised minimisation and stratified by centre • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Means (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Porsteinsson AP, Grossberg GT, Mintzer J, Olin JT(2008) Memantine treatment in patients with mild to moderate Alzheimer's disease already receiving a cholinesterase inhibitor: A randomized double-blind placebo-controlled trial, Current Alzheimer Research 5, 83-89**
Study type and aim	Multi centre randomised controlled trial to evaluate the efficacy and safety of memantine in people with mild to moderate AD already receiving a cholinesterase inhibitor.
Participants	Inclusion criteria: • 50 years of age or older • Diagnosis of possible or probable AD (NINCDS-ADRDA criteria, MRI or CT scan) within last year • MMSE 10-22 • Use of cholinesterase inhibitor for 6 months or more and stable dosing for 3 months (donepezil 5 or 10mg/day; rivastignine 6, 9 or 12 mg/day; galantamine 16 or 24mg/ day) • Reliable caregiver • Ambulatory • Sufficient vision and hearing to enable compliance with assessments • Montgomery Asberg Depression Rating scale <22 • Medical stability Exclusion criteria: • Clinically significant active pulmonary • Gastrointestinal, renal, hepatic, endocrine, cardiovascular system disease • Clinically significant B12 or folate deficiency • CT/ MRI evidence of other neurological or psychiatric disease • Dementia complicated by organic disease or AD with delusions or delirium • Undergoing treatment for oncology diagnosis • Completion of oncology treatment within 6 months of screening • Modified Hatchinski Ischaemia Scale (score >4) • Likely institutionalisation during trial • Poorly controlled hypertension • Substance abuse • Use of investigational drug within 30 days • Depot neuroleptic use within 6 months of screening

Bibliographic reference	**Porsteinsson AP, Grossberg GT, Mintzer J, Olin JT(2008) Memantine treatment in patients with mild to moderate Alzheimer's disease already receiving a cholinesterase inhibitor: A randomized double-blind placebo-controlled trial, Current Alzheimer Research 5, 83-89**
	• Positive urine drug test • Participation in investigational study of memantine • Likely cessation of AChEI during the trial
Sample characteristics	N=433 Intervention: Currently taking AChEI plus memantine n=217; mean age =74.9 years; MMSE=16.7 Control: AChEI plus matched placebo n=216; mean age = 76 years; MMSE= 17.0
Intervention	Memantine 20mg/ day administered at night
Comparison	Matched placebo
Outcome measures	ADAS Cog CIBIC plus ADCS-ADL NPI MMSE Adverse ecents
Study dates	05 June 2002 25 March 2003
Study location	USA 38 centres
Follow up	24 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Permuted blocks and sequential numbers • Were clinicians and investigators blinded? Yes- double blind and site staff blinded • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes

Bibliographic reference	**Porsteinsson AP, Grossberg GT, Mintzer J, Olin JT(2008) Memantine treatment in patients with mild to moderate Alzheimer's disease already receiving a cholinesterase inhibitor: A randomized double-blind placebo-controlled trial, Current Alzheimer Research 5, 83-89**
	Overall risk of bias: Low

Bibliographic reference	**Shao Z-Q, (2015) Comparison of the efficacy of four cholinesterase inhibitors in combination with memantine for the treatment of Alzheimer's disease**
Study type and aim	Randomised controlled trial to compare the efficacy of combined use of one of the cholinesterase inhibitors with memantine for treatment of AD
Participants	Inclusion criteria: • Diagnosis of AD based on DSM IV • Mild to moderate symptoms MMSE 10-24 Exclusion criteria: • Vascular or mixed dementia • Epilepsy • Depression • Schizophrenia • Administration of other psychotropic drugs in prior 2 weeks • Allergy to memantine or AChEI
Sample characteristics	N=110 Interventions: Memantine plus donepezil n= 22; mean age =73.40 years; MMSE =15.09 Memantine plus rivastigmine n=22; mean age = 73.13 years; MMSE =15.40 Memantine plus galantamine n= 22; mean age = 73.36 years; MMSE = 15.36 Memantine plus huperzine A n=22; mean age= 72.9 years; MMSE=15.45 Control: Memantine plus placebo n= 22; mean age = 73.04 years; MMSE =15.27:
Intervention	Memantine 5mg/ day increasing to 20mg/day plus donepezil- increasing to 5mg/day increasing to 10mg/day Memantine 5mg/ day increasing to 20mg plus rivastigmine- 1.5mg/ day increasing to 3mg/day Memantine 5mg/ day increasing to 20mg plus galantamine- 2mg/ day increasing to 12mg/day Memantine 5mg/ day increasing to 20mg plus huperzine A-200µg/day

Bibliographic reference	**Shao Z-Q, (2015) Comparison of the efficacy of four cholinesterase inhibitors in combination with memantine for the treatment of Alzheimer's disease**
Comparison	Control: Memantine plus placebo-
Outcome measures	MMSE ADCS ADL Incidence of adverse events
Study dates	Oct 2009 to Sept 2013
Study location	China
Follow up	Follow up 24 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- states randomised method not reported • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High due to lack of reported blinding and low numbers in each arm

Bibliographic reference	**Tariot PN, Farlow MR, Grossberg GT, Graham SM, McDonald S, Gergel I (2004) Memantine treatment in patients with moderate to severe Alzheimer's disease already receiving donepezil , JAMA, 291 (3),317-324**
Study type and aim	Randomised controlled trial to compare the efficacy and safety of memantine versus placebo in people with moderate to severe Alzheimer's disease receiving a cholinesterase inhibitor
Participants	Inclusion criteria: • Diagnosis of probable AD based on NINCDS-ADRDA • MMSE 5-14

Bibliographic reference	**Tariot PN, Farlow MR, Grossberg GT, Graham SM, McDonald S, Gergel I (2004) Memantine treatment in patients with moderate to severe Alzheimer's disease already receiving donepezil , JAMA, 291 (3),317-324**
	• Minimum age 50 years • Recent MRI or CT scan (in last 12 months) consistent with diagnosis of probable AD • Ongoing AChEI therapy (stable dose donepezil 5-10mg /d for at least 3 months) • Knowledgeable and reliable caregiver • Community resident • Ambulatory or ambulatory aided ability Exclusion criteria: • Clinically significant B12 or folate deficiency • Active pulmonary gastrointestinal, renal, hepatic, endocrine or cardiovascular disease • Other psychiatric or central nervous system disorders • CT or MRI evidence of other clinically significant CNS disorders • Dementia complicated by other organic disease • Modified Hachinsi Ischaemia Score >4
Sample characteristics	N=404 Interventions: memantine n= 202; mean age 75.5 years; MMSE 9.9 Control: placebo n=202 mean age = 75.5 years; MMSE=10.2
Intervention	Already receiving cholinesterase inhibitor additionally received memantine titrated upwards in 5mg /d weekly increments to 20mg/day(two 5mg tablets twice daily)
Comparison	Control: Already receiving cholinesterase inhibitor additionally received placebo memantine- treatment procedure same as intervention
Outcome measures	ADCS-ADL CIBIC plus NPI Behavioural rating scale for geriatric patients- care dependency subscale SIB Adverse events
Study dates	June 11 2001 to June 3 2002
Study location	USA 37 sites

Bibliographic reference	**Tariot PN, Farlow MR, Grossberg GT, Graham SM, McDonald S, Gergel I (2004) Memantine treatment in patients with moderate to severe Alzheimer's disease already receiving donepezil , JAMA, 291 (3),317-324**
Follow up	Follow up 24 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- permuted blocks • Were clinicians and investigators blinded? Yes- masked medication • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes- ns loss to follow up • How large was the treatment effect? How precise was the outcome effect? Mean (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Withdrawal

Bibliographic reference	**Herrmann, N., O'Regan, J., Ruthirakuhan, M., Kiss, A., Eryavec, G., Williams, E., Lanctot, K.L. A Randomized Placebo-Controlled Discontinuation Study of Cholinesterase Inhibitors in Institutionalized Patients With Moderate to Severe Alzheimer Disease. *Journal of the American Medical Directors Association*, 17:142-147, 2016.**
Study aim and type	8-week randomised controlled withdrawal study, recruiting people from 2 long-term care facilities
Participants	People with moderate to severe Alzheimer's Disease in institutional long-term care residences. Inclusion criteria: - Aged 55 or above - Fulfilled the National Institute of Neurologic and Communicative Disorders and Stroke and the AD and Related Disorders Association criteria for probable Alzheimer's disease - Met DSM-IV criteria for primary degenerative dementia - Score of 15 or lower on the standardised MMSE - Treated with donepezil, galantamine or oral rivastigmine for 2 or more years with a stable dose for at least 3 months prior to study entry - If receiving a concomitant psychotropic drug, dose had to be stable for at least 1 month prior to study entry

Bibliographic reference	**Herrmann, N., O'Regan, J., Ruthirakuhan, M., Kiss, A., Eryavec, G., Williams, E., Lanctot, K.L. A Randomized Placebo-Controlled Discontinuation Study of Cholinesterase Inhibitors in Institutionalized Patients With Moderate to Severe Alzheimer Disease. *Journal of the American Medical Directors Association*, 17:142-147, 2016.**
	Exclusion criteria: - Dementia unrelated to Alzheimer's disease - Treated with transdermal rivastigmine - Any uncontrolled illness which would interfere with study participation - Significant difficulty taking oral medication Number: Of 40 people randomised, 19 were allocated to placebo/cholinesterase inhibitor discontinuation, of whom 15 people completed 8 week visit, but all were included in the analysis. The other 21 people were allocated to continuation of cholinesterase inhibitors, of whom 18 completed the 8 week visit, and all were included in the analysis
Sample characteristics	Cholinesterase inhibitor group: - Characteristics: mean age 89.7 (SD 3.8), mean sMMSE 10.0(SD 5.1), mean NPI-NH 20.3 (SD 18.0) - Baseline medications: Cholinesterase inhibitors (n): 7 donepezil, 8 galantamine, 4 rivastigmine. Psychotropics (%): 31.6% memantine, 42.1% antidepressants, 26.3% antipsychotics Placebo group: - Characteristics: mean age 88.9 (SD 3.3), mean sMMSE 6.4 (SD 4.8), mean NPI-NH 21.9 (SD 14.0) - Baseline medications: Cholinesterase inhibitors (n): 10 donepezil, 8 galantamine, 3 rivastigmine. Psychotropics (%): 42.9% memantine, 47.6% antidepressants, 38.1% antipsychotics
Intervention	Withdrawal of existing cholinesterase inhibitor and allocation to placebo
Comparison	Continuation of existing cholinesterase inhibitor
Outcome measures	- Clinician's Global Impression of Change (CGI/CGI-C) - Standardised Mini Mental State Examination (sMMSE) - Severe Impairment Battery (SIB) - Neuropsychiatric inventory – Nursing Home version (NPI-NH) - Cohen-Mansfield Agitation Inventory (CMAI) - Apathy Evaluation Scale (AES) - Alzheimer's Disease Co-operative Study - Activities of Daily Living Inventory, modified for severe AD (ADCS-ADL-sev)

Bibliographic reference	**Herrmann, N., O'Regan, J., Ruthirakuhan, M., Kiss, A., Eryavec, G., Williams, E., Lanctot, K.L. A Randomized Placebo-Controlled Discontinuation Study of Cholinesterase Inhibitors in Institutionalized Patients With Moderate to Severe Alzheimer Disease. *Journal of the American Medical Directors Association*, 17:142-147, 2016.**
	- Quality of Life in Late-Stage Dementia (QUALID)
Study dates	Not reported
Study location	Canada
Comments **Risk of bias**	• Did the trial address a clearly focused issue? YES • Was the assignment of patients to treatment randomised? YES, 1:1 block randomisation. • Were clinicians and investigators blinded? YES • Were the groups similar at the start of the trial? YES/SOME LIMITATIONS. (In most characteristics except standardised MMSE) • Aside from the experimental intervention, were the groups treated equally? YES • At the end of the trial, were all patients accounted for? YES (intention to treat analysis was used) • How large was the treatment effect? How precise was the outcome effect? Measures of precision were reported • Can the results be applied to the local population? YES. Note that all participants were in residential care • Were all clinically relevant outcomes reported? YES Overall Risk of bias: Moderate risk of bias due to between-group imbalance at baseline in a key clinical measure

Bibliographic reference	**Howard R, McShane R, Lindesay J, Ritchie C, Baldwin A, Barber R, Burns A, Dening T et al (2012) Donepezil and memantine for moderate to severe Alzheimer's disease, New England Journal of Medicine, 2012, 366, (10), 893-903**
Study type and aim	Multicentre double blind two by two factorial design randomised controlled trial to determine if people living with moderate to severe Alzheimer's disease in the community and already receiving donepezil would benefit from additionally receiving memantine at this course of the disease.
Participants	Inclusion criteria: • Community residents who had caregivers • Met standardised clinical criteria for probable or possible moderate or severe AD • Continuously prescribed donepezil for past 3 months and received at least 10mg for previous 6 weeks • Score 5-13 on SMMSE

Bibliographic reference	**Howard R, McShane R, Lindesay J, Ritchie C, Baldwin A, Barber R, Burns A, Dening T et al (2012) Donepezil and memantine for moderate to severe Alzheimer's disease, New England Journal of Medicine, 2012, 366, (10), 893-903**
	Exclusion criteria: • Severe or unstable medical conditions • Currently receiving memantine • Considered unlikely to adhere to study regimens
Sample characteristics	N=295 Continuing donepezil and active memantine added n=73 mean age = 77.5 years; SMMSE = 9.1 Continuing donepezil and placebo memantine added n= 73 mean age = 77.2 years; SMMSE= 9.0 Tapered discontinuation of donepezil and active memantine added n=76; mean age = 76.2 years; SMMSE= 9.2 Tapered discontinuation of donepezil and placebo memantine added n=73; mean age= 77.7 years; SMMSE = 9.2
Intervention	• Continuation of donepezil (10mg/ day) and active memantine (5mg/day) added in week 1 increasing by 5mg increments weekly to 20mg/ day from week 4 onwards • Tapered discontinuation of donepezil (5mg/day) and active memantine (5mg/ day) added in week 1 increasing by 5mg increments weekly to 20mg/ day from week 4 onwards
Comparison	• Continuation of donepezil (10mg/ day) with placebo memantine added in week 1 • Tapered discontinuation of donepezil (5mg/day) and placebo memantine added in week 1 with placebo donepezil added in week 5
Outcome measures	SMMSE Bristol Activities of Daily Living Scale NPI DEMQOL proxy GHQ 12
Study dates	Feb 2008 to March 2010
Study location	UK 15 centres
Follow up	52 weeks
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes. Centrally using randomised minimisation and stratified by centre

Bibliographic reference	Howard R, McShane R, Lindesay J, Ritchie C, Baldwin A, Barber R, Burns A, Dening T et al (2012) Donepezil and memantine for moderate to severe Alzheimer's disease, New England Journal of Medicine, 2012, 366, (10), 893-903
	• Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Means (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

E.7.2.2 Additional data from Howard 2012 (DOMINO-AD trial data)

		All Patients									Moderate (Baseline SMMSE 10-13)									Severe (Baseline SMMSE 5-9)								
		Baseline			Week 52			Week 52: Change from baseline			Baseline			Week 52			Week 52: Change from baseline			Baseline			Week 52			Week 52: Change from baseline		
		n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
SMMSE	Placebo + Placebo	73	9.14	2.44	54	3.33	3.47	54	-5.89	3.14	34	11.35	1.18	26	4.42	4.07	26	-7.04	3.67	39	7.21	1.36	28	2.32	2.47	28	-4.82	2.09
	Placebo + Memantine	76	9.17	2.53	51	4.84	4.57	51	-4.53	3.86	37	11.38	1.06	26	6.85	5.15	26	-4.54	4.95	39	7.08	1.51	25	2.76	2.65	25	-4.52	2.37
	Donepezil + Placebo	73	9.04	2.78	54	5.46	5.18	54	-3.80	3.92	35	11.54	1.20	28	8.36	5.12	28	-3.32	4.55	38	6.74	1.54	26	2.35	3.03	26	-4.31	3.10
	Donepezil + Memantine	73	9.07	2.62	58	5.55	4.37	58	-3.53	3.59	35	11.43	1.14	27	8.15	4.27	27	-3.44	4.26	38	6.89	1.43	31	3.29	3.04	31	-3.61	2.96
BADLS	Placebo + Placebo	73	28.56	8.94	55	41.36	9.06	55	13.22	8.97	34	27.41	8.37	26	39.77	6.81	26	13.69	10.21	39	29.56	9.40	29	42.79	10.60	29	12.79	7.86
	Placebo + Memantine	76	27.14	9.04	51	37.16	10.34	51	10.10	8.10	37	24.81	8.90	26	32.65	9.76	26	7.96	7.75	39	29.36	8.71	25	41.84	8.86	25	12.32	8.00
	Donepezil + Placebo	73	28.21	9.02	54	36.67	10.57	54	9.83	8.52	35	25.91	8.93	28	33.07	9.79	28	8.50	8.43	38	30.32	8.70	26	40.54	10.16	26	11.27	8.54
	Donepezil + Memantine	73	26.95	9.76	58	34.66	9.45	58	8.76	8.36	35	25.34	9.07	27	34.00	9.04	27	10.37	6.52	38	28.42	10.25	31	35.23	9.90	31	7.35	9.56
NPI	Placebo + Placebo	73	22.92	17.04	54	27.72	17.47	54	5.30	18.77	34	20.88	15.26	26	28.81	17.85	26	8.35	15.88	39	24.69	18.47	28	26.71	17.38	28	2.46	20.99
	Placebo + Memantine	76	23.09	16.23	51	22.27	17.25	51	-2.51	21.33	37	22.41	17.85	26	21.73	19.93	26	-1.38	23.32	39	23.74	14.74	25	22.84	14.33	25	-3.68	19.46
	Donepezil + Placebo	73	22.34	16.73	54	28.65	23.42	54	6.17	21.19	35	24.11	19.17	28	26.14	25.97	28	1.75	22.37	38	20.71	14.20	26	31.35	20.51	26	10.92	19.14
	Donepezil + Memantine	73	20.30	14.39	58	21.43	20.16	58	1.40	19.01	35	18.63	13.53	27	19.56	18.84	27	2.22	18.76	38	21.84	15.16	31	23.06	21.41	31	0.68	19.51
DEMQOL	Placebo + Placebo	73	101.44	11.65	55	104.67	10.57	55	2.72	12.44	34	100.87	11.59	26	103.27	11.06	26	1.79	11.02	39	101.95	11.84	29	105.93	10.15	29	3.55	13.73
	Placebo + Memantine	76	96.51	15.30	51	101.57	14.89	51	5.94	17.35	37	96.71	11.65	26	102.38	12.39	26	4.85	15.78	39	96.33	18.26	25	100.72	17.34	25	7.08	19.11
	Donepezil + Placebo	73	98.33	13.55	54	101.04	13.43	54	3.00	14.06	35	98.49	12.56	28	102.11	12.99	28	4.75	14.11	38	98.18	14.56	26	99.88	14.05	26	1.12	14.03
	Donepezil + Memantine	73	100.92	12.91	58	101.86	12.06	58	1.00	11.02	35	101.14	12.29	27	101.85	12.10	27	0.30	11.92	38	100.71	13.61	31	101.87	12.23	31	1.61	10.34
GHQ-12	Placebo + Placebo	72	2.81	3.07	45	3.07	3.70	45	0.40	3.56	34	2.56	2.99	21	3.10	3.94	21	0.52	3.78	38	3.03	3.17	24	3.04	3.56	24	0.29	3.43
	Placebo + Memantine	75	3.13	3.14	47	2.77	3.30	47	-0.19	3.19	36	2.64	3.11	24	2.79	3.49	24	0.58	3.40	39	3.59	3.14	23	2.74	3.18	23	-1.00	2.80
	Donepezil + Placebo	73	2.29	2.30	51	2.12	2.73	51	-0.22	2.69	35	2.60	2.68	28	2.04	2.53	28	-0.39	2.97	38	2.00	1.87	23	2.22	3.00	23	0.00	2.35
	Donepezil + Memantine	73	1.85	2.33	54	1.70	2.48	54	-0.09	2.53	35	2.00	2.54	24	1.71	2.91	24	-0.08	3.02	38	1.71	2.13	30	1.70	2.14	30	-0.10	2.12

E.7.3 Pharmacological management of Parkinson's disease dementia

- What is the comparative effectiveness of donepezil, galantamine, memantine and rivastigmine for cognitive enhancement in dementia associated with Parkinson's disease?

Bibliographic reference	**Aarsland,D., Laake,K., Larsen,J.P., Janvin, C., Donepezil for cognitive impairment in Parkinson's disease: a randomised controlled study, J Neurol Neurosurg Psychiatry, 72, 708-712, 2002**
Study type	Double-blind randomised controlled trial
Aim of the study	To assess the safety and efficacy of donepezil in people with PD and cognitive impairment
Country/ies where the study was carried out	Norway
Study dates	Not stated, study published in 2002
Source of funding	Pfizer Norway
Sample size	N=14 randomised
Inclusion criteria	People aged 45-95 years with cognitive impairment associated with PD (MMSE score 16 to 26 inclusive) with caregiver support
Exclusion criteria	Brain disease other than PD, severe medical disorders, concomitant anticholinergics or psychotropic drugs with anticholinergic effects
Details	20-week double blind, placebo-controlled crossover RCT. Participants were randomised to either donepezil or placebo for 10 weeks, followed by crossover treatment for a further 10 weeks. There was no wash-out period.
Intervention(s)	Donepezil 5mg daily, increased to 10mg daily after 6 weeks if well tolerated
Comparator(s)	Placebo
Results	**Efficacy results after 10 weeks treatment:**

Outcome	**Donepezil (n=12)**	**Placebo (n=12)**
MMSE	22.8 (3.7)*	21.0 (5.0)
CIBIC+	3.3 (0.9)*	4.1 (0.8)
NPI	Results not presented (no significant difference)	

Bibliographic reference	**Aarsland,D., Laake,K., Larsen,J.P., Janvin, C., Donepezil for cognitive impairment in Parkinson's disease: a randomised controlled study, J Neurol Neurosurg Psychiatry, 72, 708-712, 2002**
	<table><tr><td>UPDRS III</td><td>31.8 (15.4)</td><td>35.1 (8.1)</td></tr><tr><td colspan="3">Values are mean (SD). * P<0.05 compared with placebo</td></tr></table> **Adverse events** 2 people receiving donepezil withdrew due to adverse events, 0 people withdrew due to adverse events on placebo Number of adverse events (any) was 12 (SD 11) for donepezil and 9 (SD 7) for placebo Number of adverse events per person, mean (SD) 4.2 (3.2) for donepezil and 2.8 (1.0) for placebo
Overall Risk of Bias	1. Has an appropriate method of randomisation been used? YES 2. Was there adequate concealment of allocation? YES 3. Were the groups comparable at baseline for all major confounding/prognostic factors? UNCLEAR 4. Did the comparison groups receive the same care apart from interventions studied? YES 5. Were participants receiving care kept blind to treatment allocation? YES 6. Were the individuals administering care kept blind to treatment allocation? YES 7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? NO 8. Did the study have an appropriate length of follow up? YES 9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? YES 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR
Other information	Included in NICE CG35

Bibliographic reference	**Aarsland,D., Ballard,C., Walker,Z., Bostrom,F., Alves,G., Kossakowski,K., Leroi,I., Pozo-Rodriguez,F., Minthon,L., Londos,E., 20090814, Memantine in patients with Parkinson's disease dementia or dementia with Lewy bodies: a double-blind, placebo-controlled, multicentre trial, Lancet Neurology, 8, 613-618, 2009**
Study type	Double-blind randomised controlled trial

Bibliographic reference	**Aarsland,D., Ballard,C., Walker,Z., Bostrom,F., Alves,G., Kossakowski,K., Leroi,I., Pozo-Rodriguez,F., Minthon,L., Londos,E., 20090814, Memantine in patients with Parkinson's disease dementia or dementia with Lewy bodies: a double-blind, placebo-controlled, multicentre trial, Lancet Neurology, 8, 613-618, 2009**
Aim of the study	To assess the safety and efficacy of memantine in people with PDD and DLB
Country/ies where the study was carried out	Norway, Sweden and UK
Study dates	2005-2008, study published 2009
Source of funding	The Western Norway Regional Health Authority and Lundbeck
Sample size	N=72 randomised
Inclusion criteria	People with PDD or DLB (MMSE score 12 or above). 47% of people in the memantine group and 63% of people in the placebo group were taking a cholinesterase inhibitor at baseline.
Exclusion criteria	Other brain disease, recent major changes in health status, major depression, moderate to severe renal impairment, heart disease, pulmonary disease, hepatic impairment, abnormal laboratory results, allergy to memantine
Details	Parallel group, 24-week double-blind, placebo-controlled RCT
Intervention(s)	Memantine 5mg daily, increasing to a maintenance dose of 10mg twice daily
Comparator(s)	Placebo
Results	**Efficacy results at week 24**

	n	Baseline	24 weeks (LOCF)	Change at 24 weeks	Between-group difference
Primary outcome					
CGIC score					
Memantine	30	—	3·5 (1.5)	—	
Placebo	33	—	4·2 (1.5)	—	0·7 (0·04 to 1·39)†
Secondary outcomes					
MMSE					
Memantine	30	20·1 (3·7)	21·5 (4·2)	–1·4 (3·2)‡	

Bibliographic reference	Aarsland,D., Ballard,C., Walker,Z., Bostrom,F., Alves,G., Kossakowski,K., Leroi,I., Pozo-Rodriguez,F., Minthon,L., Londos,E., 20090814, Memantine in patients with Parkinson's disease dementia or dementia with Lewy bodies: a double-blind, placebo-controlled, multicentre trial, Lancet Neurology, 8, 613-618, 2009

Placebo	33	20·6 (4·2)	20·0 (6·2)	0·5 (4·2)	1·9 (0·06 to 3·8)
NPI					
Memantine	29	15·2 (14·2)	13·7 (12·8)	1·5 (10·8)	
Placebo	33	13·0 (9·9)	11·6 (11·7)	1·4 (10·6)	–0·1 (-1·2 to 4·3)
DAD					
Memantine	30	21·6 (10·8)	20·6 (12·6)	1·0 (6·4)	
Placebo	33	23·8 (8·2)	21·2 (9·5)	2·5 (4·6)§	1·5 (-1·2 to 4·3)
Modified UPDRS III					
Memantine	28	11·1 (5·7)	11·3 (6·1)	0·3(3·1)	
Placebo	30	11·6 (4·1)	11·6 (4·6)	0·0 (4·3)	–0·3 (-2·4 to 1·8)
Numbers are mean (SD), mean (95% CI), or mean seconds taken to complete the test (SD) **Mann–Whitney test †P=0.03; ‡Wilcoxon Z test P=0.02; §Wilcoxon Z test P=0·004; ¶P=0.045*					

Overall Risk of Bias	1. Has an appropriate method of randomisation been used? YES 2. Was there adequate concealment of allocation? YES 3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES 4. Did the comparison groups receive the same care apart from interventions studied? YES 5. Were participants receiving care kept blind to treatment allocation? YES 6. Were the individuals administering care kept blind to treatment allocation? YES 7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES 8. Did the study have an appropriate length of follow up? YES 9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? YES 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR

<table>
<tr><th>Bibliographic reference</th><th>Dubois,B., Tolosa,E., Katzenschlager,R., Emre,M., Lees,A.J., Schumann,G., Pourcher,E., Gray,J., Thomas,G., Swartz,J., Hsu,T., Moline,M.L., 20130214, Donepezil in Parkinson's disease dementia: a randomized, double-blind efficacy and safety study, Movement Disorders, 27, 1230-1238, 2012</th></tr>
<tr><td>Study type</td><td>Double-blind randomised controlled trial</td></tr>
<tr><td>Aim of the study</td><td>To assess the efficacy and safety of donepezil in people with PDD</td></tr>
<tr><td>Country/ies where the study was carried out</td><td>Multicentre (UK, Germany, Austria, Spain, Russia, France, Australia, New Zealand, South Africa, Canada, Italy, Belgium, Portugal)</td></tr>
<tr><td>Study dates</td><td>2002-2005, study published 2012</td></tr>
<tr><td>Source of funding</td><td>Eisai</td></tr>
<tr><td>Sample size</td><td>N=550 randomised</td></tr>
<tr><td>Inclusion criteria</td><td>People aged 40 years and older with PDD (MMSE score 10 to 26 inclusive) with a reliable caregiver</td></tr>
<tr><td>Exclusion criteria</td><td>Other causes of dementia (including DLB), recurrent major depression, previous treatment with cholinesterase inhibitor, allergy to donepezil, concomitant anticholinergics</td></tr>
<tr><td>Details</td><td>Parallel group, 24-week double-blind, placebo-controlled RCT</td></tr>
<tr><td>Intervention(s)</td><td>Donepezil 5mg or 10mg daily</td></tr>
<tr><td>Comparator(s)</td><td>Placebo</td></tr>
<tr><td>Results</td><td>Efficacy results at week 24 (LOCF)
<table>
<tr><th></th><th>Donepezil 5mg vs placebo</th><th>Donepezil 10mg vs placebo</th></tr>
<tr><td colspan="3">Co-primary outcomes</td></tr>
<tr><td>ADAS-cog</td><td>MD –1.45, 95%CI –2.9 to 0.00, P=0.05</td><td>MD –1.45, 95%CI –3.04 to 0.15, P=0.076</td></tr>
<tr><td>CIBIC+ overall change score</td><td>3.7 (SD 1.12) vs. 3.9 (SD 1.27), P=0.113</td><td>3.6 (SD 1.29) vs. 3.9 (SD 1.27), P=0.04</td></tr>
<tr><td colspan="3">Secondary outcomes</td></tr>
<tr><td>MMSE</td><td>MD 1.44, 95%CI 0.81 to 2.07, P<0.001</td><td>MD 1.66, 95%CI 1.02 to 2.29, P<0.001</td></tr>
</table></td></tr>
</table>

Bibliographic reference	Aarsland,D., Ballard,C., Walker,Z., Bostrom,F., Alves,G., Kossakowski,K., Leroi,I., Pozo-Rodriguez,F., Minthon,L., Londos,E., 20090814, Memantine in patients with Parkinson's disease dementia or dementia with Lewy bodies: a double-blind, placebo-controlled, multicentre trial, Lancet Neurology, 8, 613-618, 2009

D-KEFS: • Letter fluency • Category fluency • Category switching	 MD 2.56, 95%CI 0.99 to 4.14, P=0.001 MD 3.67, 95%CI 2.26 to 5.09, P<0.001 MD 1.14, 95%CI 0.46 to 1.82, P=0.001	 MD 3.12, 95%CI 1.52 to 4.72, P<0.001 MD 4.22, 95%CI 2.78 to 5.65, P=0.001 MD 1.21, 95%CI 0.52 to 1.90, P<0.001
BTA	MD 0.78, 95%CI 0.22 to 1.34, P=0.007	MD 1.00, 95%CI 0.42 to 1.57, P<0.001
DAD	MD 2.27, 95%CI –0.74 to 5.28, P=0.138	MD 2.24, 95%CI –0.82 to 5.30, P=0.15
SE scale	MD –0.68, 95%CI –3.19 to 1.84, P=0.598	MD –0.33, 95%CI –2.90 to 2.23, P=0.797
NPI	MD –1.52, 95%CI –3.68 to 0.63, P=0.166	MD –1.15, 95%CI –3.34 to 1.04, P=0.303

Adverse events

	Donepezil 5mg (n=195)	Donepezil 10mg (n=182)	Placebo (n=173)
All adverse events (%)	76.9	73.1	71.1
Adverse events leading to discontinuation (%)	13.8	17	11
Severe adverse events (%)	19	16.5	12.7
Visual hallucinations	5.1	0.5	1.2

Overall Risk of Bias

1. Has an appropriate method of randomisation been used? YES
2. Was there adequate concealment of allocation? UNCLEAR
3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES
4. Did the comparison groups receive the same care apart from interventions studied? YES
5. Were participants receiving care kept blind to treatment allocation? YES
6. Were the individuals administering care kept blind to treatment allocation? YES
7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES
8. Did the study have an appropriate length of follow up? YES

Bibliographic reference	Aarsland,D., Ballard,C., Walker,Z., Bostrom,F., Alves,G., Kossakowski,K., Leroi,I., Pozo-Rodriguez,F., Minthon,L., Londos,E., 20090814, Memantine in patients with Parkinson's disease dementia or dementia with Lewy bodies: a double-blind, placebo-controlled, multicentre trial, Lancet Neurology, 8, 613-618, 2009
	9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? UNCLEAR 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR

Bibliographic reference	Emre,M., Aarsland,D., Albanese,A., Byrne,E., Deuschl,G., De Deyn,P., Durif,F., Kulisevsky,J., van Laar,T., Lees,A., Poewe,W., Robillard,A., Rosa,M., Wolters,E., Quarg,P., Tekin,S., Lane,S., Rivastigmine for dementia associated with Parkinson's disease, N Engl J Med, 351, 2509-2518, 2004
Study type	Double-blind randomised controlled trial
Aim of the study	To assess the efficacy and safety of rivastigmine in people with PDD
Country/ies where the study was carried out	Multicentre (Europe and Canada)
Study dates	Recruitment 2002-2003, study published 2004
Source of funding	Not stated in paper
Sample size	N=541 randomised
Inclusion criteria	People aged at least 50 years old with PDD (MMSE 10 to 24)
Exclusion criteria	Any primary neurodegenerative disorder other than PD or other causes of dementia, history of a major depressive episode, presence of an active, uncontrolled seizure disorder, presence of any disability or unstable disease unrelated to PD, known hypersensitivity to drugs similar to rivastigmine, use of a cholinesterase inhibitor or anticholinergic drugs during the 4 weeks before randomisation. No changes were permitted in the dose of current dopaminergic medicines within 4 weeks before and throughout the study, nor was the start of treatment with new psychotropic medications (except atypical neuroleptic agents for acute psychosis) permitted during this period
Details	Parallel group, 24-week double-blind, placebo-controlled RCT

Bibliographic reference	Emre,M., Aarsland,D., Albanese,A., Byrne,E., Deuschl,G., De Deyn,P., Durif,F., Kulisevsky,J., van Laar,T., Lees,A., Poewe,W., Robillard,A., Rosa,M., Wolters,E., Quarg,P., Tekin,S., Lane,S., Rivastigmine for dementia associated with Parkinson's disease, N Engl J Med, 351, 2509-2518, 2004
Intervention(s)	Rivastigmine 1.5mg twice daily, increasing to a maximum well tolerated dose (up to 6mg twice daily)
Comparator(s)	Placebo

Results

Efficacy results at week 24

	n	Baseline (mean ± SD)	Change at 24 weeks (mean ± SD)	Between-group difference (value)	P value
Primary outcome					
ADAS-cog					
Rivastigmine	329	23.8±10.2	–2.1±8.2	2.90†	
Placebo	161	24.3±10.5	0.7±7.5		<0.001
ADCS-CGIC					
Rivastigmine	329	—	3.8±1.4	0.5	
Placebo	165	—	4.3±1.5		0.007
Secondary outcomes					
MMSE					
Rivastigmine	335	19.5±3.8	0.8±3.8	1.00	
Placebo	166	19.2±4.0	–0.2±3.5		0.03
D-KEFS					
Rivastigmine	258	13.9±9.5	1.7±6.8	2.80	
Placebo	144	14.5±9.4	–1.1±6.4		<0.001‡
CDR					
Rivastigmine	328	2197.0±1170.2	–31.0±989.8	294.84†	
Placebo	158	2490.5±2314.8	142.7±1780.2		0.009
Clock drawing test					
Rivastigmine	49	3.4±3.7	0.5±2.5	1.10	
Placebo	30	2.9±3.8	–0.6±2.4		0.02‡

Bibliographic reference	Emre,M., Aarsland,D., Albanese,A., Byrne,E., Deuschl,G., De Deyn,P., Durif,F., Kulisevsky,J., van Laar,T., Lees,A., Poewe,W., Robillard,A., Rosa,M., Wolters,E., Quarg,P., Tekin,S., Lane,S., Rivastigmine for dementia associated with Parkinson's disease, N Engl J Med, 351, 2509-2518, 2004

ADCS-ADL					
Rivastigmine	333	41.6±18.6	–1.1±12.6	2.50	
Placebo	165	41.2±17.7	–3.6±10.3		0.02
NPI					
Rivastigmine	334	12.7±11.7	–2.0±10.0	2.15†	
Placebo	166	13.2±13.0	0.0±10.4		0.02

† The value is the modelled treatment difference (difference of least-square means)
‡ Because executive-function tests were not performed at all sites, analyses involving these tests included only patients who actually took these tests

Adverse events

	Rivastigmine (n=362) No. (%)	Placebo (n=179) No. (%)	P value
All adverse events	303 (83.7)	127 (70.9)	<0.001
Serious adverse events	(13)	(14.5)	0.69
Hallucinations	17 (4.7)	17 (9.5)	0.04

Overall Risk of Bias

1. Has an appropriate method of randomisation been used? YES
2. Was there adequate concealment of allocation? UNCLEAR
3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES
4. Did the comparison groups receive the same care apart from interventions studied? YES
5. Were participants receiving care kept blind to treatment allocation? YES
6. Were the individuals administering care kept blind to treatment allocation? YES
7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES
8. Did the study have an appropriate length of follow up? YES
9. Did the study use a precise definition of outcome? YES
10. Was a valid and reliable method used to determine that outcome? YES

Bibliographic reference	Emre,M., Aarsland,D., Albanese,A., Byrne,E., Deuschl,G., De Deyn,P., Durif,F., Kulisevsky,J., van Laar,T., Lees,A., Poewe,W., Robillard,A., Rosa,M., Wolters,E., Quarg,P., Tekin,S., Lane,S., Rivastigmine for dementia associated with Parkinson's disease, N Engl J Med, 351, 2509-2518, 2004
	11. Were investigators kept blind to participant's exposure to the intervention? YES 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR
Other information	Included in NICE CG35

Bibliographic reference	Emre,M., Tsolaki,M., Bonuccelli,U., Destee,A., Tolosa,E., Kutzelnigg,A., Ceballos-Baumann,A., Zdravkovic,S., Bladstrom,A., Jones,R., Study,Investigators, 20101018, Memantine for patients with Parkinson's disease dementia or dementia with Lewy bodies: a randomised, double-blind, placebo-controlled trial, Lancet Neurology, 9, 969-977, 2010
Study type	Double-blind randomised controlled trial
Aim of the study	To assess the efficacy and safety of memantine in in people with mild to moderate PDD or DLB
Country/ies where the study was carried out	Multicentre (UK, Germany, Austria, France, Greece, Italy, Spain, Turkey)
Study dates	Recruitment 2007-2008, study published 2010
Source of funding	Lundbeck
Sample size	N=199 randomised
Inclusion criteria	People aged 50 years and older with PDD or DLB (MMSE score 10 to 24 inclusive) with a caregiver
Exclusion criteria	Cholinesterase inhibitors within 6 weeks before screening or memantine in the last 6 months, or any investigational drug within 30 days of screening. Psychiatric disorders, clinically significant or unstable systemic disease. Use of cholinesterase inhibitors, antipsychotic, antidepressant or benzodiazepine drugs were not allowed
Details	Parallel group, 24-week double-blind placebo-controlled RCT
Intervention(s)	Memantine 5mg daily, increasing to a maintenance dose of 20mg daily
Comparator(s)	Placebo

Bibliographic reference	Emre,M., Aarsland,D., Albanese,A., Byrne,E., Deuschl,G., De Deyn,P., Durif,F., Kulisevsky,J., van Laar,T., Lees,A., Poewe,W., Robillard,A., Rosa,M., Wolters,E., Quarg,P., Tekin,S., Lane,S., Rivastigmine for dementia associated with Parkinson's disease, N Engl J Med, 351, 2509-2518, 2004

Results

Efficacy results at week 24 – people with PDD

Outcome	n	Change from baseline at 24 weeks Mean value (95%CI)	Between-group difference Mean value (95%CI)	P value
ADCS-CGIC				
Memantine	62	3.6 (3.3 to 4.0)	–0.1 (–0.6 to 0.3)	
Placebo	58	3.8 (3.4 to 4.1)		0.576
ADCS-ADL23				
Memantine	62	0.5 (–2.3 to 3.3)	0.7 (–3.0 to 4.5)	
Placebo	58	–0.3 (–3.3 to 2.8)		0.703
NPI				
Memantine	62	–1.6 (–4.9 to 1.8)	–1.4 (–5.9 to 3.0)	
Placebo	58	0.1 (–3.8 to 3.5)		0.522
UPDRS III				
Memantine	62	1.5 (–1.0 to 4.1)	0.6 (–2.6 to 3.8)	
Placebo	58	1.0 (–1.7 to 3.6)		0.719
ZBI				
Rivastigmine	62	–0.5 (–3.6 to 2.7)	–2.9 (–6.9 to 1.1)	
Placebo	58	2.4 (–0.8 to 5.7)		0.153

Efficacy results at week 24 – people with DLB

Outcome	n	Change from baseline at 24 weeks Mean value (95%CI)	Between-group difference Mean value (95%CI)	P value
ADCS-CGIC				
Memantine	34	3.3 (2.8 to 3.8)	–0.6 (–1.2 to –0.1)	
Placebo	41	3.9 (3.5 to 4.3)		0.023
ADCS-ADL23				

Bibliographic reference	Emre,M., Aarsland,D., Albanese,A., Byrne,E., Deuschl,G., De Deyn,P., Durif,F., Kulisevsky,J., van Laar,T., Lees,A., Poewe,W., Robillard,A., Rosa,M., Wolters,E., Quarg,P., Tekin,S., Lane,S., Rivastigmine for dementia associated with Parkinson's disease, N Engl J Med, 351, 2509-2518, 2004

Memantine Placebo	34 41	–0.1 (–5.2 to 5.1) –1.7 (–6.1 to 2.7)	1.7 (–4.2 to 7.6)	 0.569
NPI Memantine Placebo	 34 41	 –4.3 (–9.2 to 0.7) 1.7 (–2.5 to 5.9)	 –5.9 (–11.6 to –0.2)	 0.041
UPDRS III Memantine Placebo	 34 41	 1.5 (–1.0 to 4.1) 1.0 (–1.7 to 3.6)	 0.6 (–2.6 to 3.8)	 0.719
ZBI Rivastigmine Placebo	 34 41	 –0.5 (–3.6 to 2.7) 2.4 (–0.8 to 5.7)	 –2.9 (–6.9 to 1.1)	 0.153

Adverse events – people with PDD

	Memantine (n=62) No. (%)	Placebo (n=58) No. (%)
All adverse events	28 (45)	26 (45)
Serious adverse events	8 (13)	7 (12)
Adverse events leading to study withdrawal	6 (10)	5 (9)

Adverse events – people with DLB

	Memantine (n=34) No. (%)	Placebo (n=41) No. (%)
All adverse events	18 (53)	17 (41)
Serious adverse events	6 (18)	3 (7)
Adverse events leading to	5 (15)	7 (17)

Bibliographic reference	**Emre,M., Aarsland,D., Albanese,A., Byrne,E., Deuschl,G., De Deyn,P., Durif,F., Kulisevsky,J., van Laar,T., Lees,A., Poewe,W., Robillard,A., Rosa,M., Wolters,E., Quarg,P., Tekin,S., Lane,S., Rivastigmine for dementia associated with Parkinson's disease, N Engl J Med, 351, 2509-2518, 2004**
	study withdrawal | |
Overall Risk of Bias	1. Has an appropriate method of randomisation been used? YES 2. Was there adequate concealment of allocation? YES 3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES 4. Did the comparison groups receive the same care apart from interventions studied? YES 5. Were participants receiving care kept blind to treatment allocation? YES 6. Were the individuals administering care kept blind to treatment allocation? YES 7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES 8. Did the study have an appropriate length of follow up? YES 9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? YES 12. Were investigators kept blind to other important confounding and prognostic factors? YES

Bibliographic reference	**Emre,M., Poewe,W., De Deyn,P.P., Barone,P., Kulisevsky,J., Pourcher,E., van,Laar T., Storch,A., Micheli,F., Burn,D., Durif,F., Pahwa,R., Callegari,F., Tenenbaum,N., Strohmaier,C., 20140911, Long-term safety of rivastigmine in parkinson disease dementia: an open-label, randomized study, Clinical Neuropharmacology, 37, 9-16, 2014**
Study type	Open-label randomised controlled trial
Aim of the study	To assess the safety of rivastigmine and effects on motor symptoms in people with mild to moderately severe PDD
Country/ies where the study was carried out	Multicentre (Europe, USA, Argentina Canada and Australia)
Study dates	Recruitment 2008-2010, study published 2014
Source of funding	Novartis

Bibliographic reference	**Emre,M., Poewe,W., De Deyn,P.P., Barone,P., Kulisevsky,J., Pourcher,E., van,Laar T., Storch,A., Micheli,F., Burn,D., Durif,F., Pahwa,R., Callegari,F., Tenenbaum,N., Strohmaier,C., 20140911, Long-term safety of rivastigmine in parkinson disease dementia: an open-label, randomized study, Clinical Neuropharmacology, 37, 9-16, 2014**
Sample size	N=583 randomised
Inclusion criteria	People aged 50 to 85 years with PDD (MMSE score 10 to 26 inclusive) with caregiver support
Exclusion criteria	Other causes of dementia, Hoehn and Yahr stage of 5 in on-state, use of cholinesterase inhibitors or cholinergic drugs within 4 weeks before randomisation
Details	76-week prospective open-label RCT
Intervention(s)	Rivastigmine 4.6mg/24h patch, increasing to 9.5mg/24h patch
Comparator(s)	Rivastigmine 1.5mg twice daily, increasing to a maximum well tolerated dose (up to 6mg twice daily)
Results	**Efficacy results**

Outcome	Rivastigmine caps		Rivastigmine patch		Least squares means difference (95%CI)	P value
	n	Mean (SD)	n	Mean (SD)		
MDRS						
Baseline	273	109.5 (19.3)	273	109.4 (19.6)		
Change from baseline at week 24	273	6.5 (13.0)	273	4.4 (12.9)	2.3 (0.2 to 4.4)	0.035
Change from baseline at week 76	273	3.9 (16.8)	273	–1.4 (17.4)	5.5 (2.6 to 8.4)	<0.001
ADCS-ADL						
Baseline	273	49.2	270	50.1		
Change from baseline at week 24	273	–0.6 (10.1)	270	–1.5 (10.9)	0.8 (–0.9 to 2.6)	0.355
Change from baseline at week 76	273	–4.4 (13.3)	270	–7.8 (15.6)	3.4 (1.0 to 5.7)	0.006
NPI						
Baseline	273	11.3 (11.8)	273	11.4 (11.9)		
Change from baseline at week 24	273	–2.6 (10.3)	273	–1.0 (10.3)	–1.7 (–3.2 to –0.1)	0.032
Change from baseline at week 76	273	–1.6 (11.2)	273	0.7 (12.6)	–2.4 (–4.1 to –0.7)	0.007
Note: Results for change from baseline at week 52 also reported in paper						

Bibliographic reference	Emre,M., Poewe,W., De Deyn,P.P., Barone,P., Kulisevsky,J., Pourcher,E., van,Laar T., Storch,A., Micheli,F., Burn,D., Durif,F., Pahwa,R., Callegari,F., Tenenbaum,N., Strohmaier,C., 20140911, Long-term safety of rivastigmine in parkinson disease dementia: an open-label, randomized study, Clinical Neuropharmacology, 37, 9-16, 2014

Adverse events

	Rivastigmine patch (n=288)	Rivastigmine capsules (n=294)
All adverse events (%)	91.3	93.2
Serious adverse events	28.8	29.6
Adverse events leading to study withdrawal (including deaths)	24.7	27.2
Deaths	24.7	27.2
Visual hallucinations	6.6	5.1

Overall Risk of Bias

1. Has an appropriate method of randomisation been used? UNCLEAR
2. Was there adequate concealment of allocation? NO
3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES
4. Did the comparison groups receive the same care apart from interventions studied? YES
5. Were participants receiving care kept blind to treatment allocation? NO
6. Were the individuals administering care kept blind to treatment allocation? NO
7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES
8. Did the study have an appropriate length of follow up? YES
9. Did the study use a precise definition of outcome? YES
10. Was a valid and reliable method used to determine that outcome? YES
11. Were investigators kept blind to participant's exposure to the intervention? NO
12. Were investigators kept blind to other important confounding and prognostic factors? NO

Bibliographic reference	Ikeda,M., Mori,E., Matsuo,K., Nakagawa,M., Kosaka,K., 20150225, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled, confirmatory phase III trial, Alzheimer's Research & Therapy, 7, 4-, 2015

<table>
<tr><th>Bibliographic reference</th><th>Ikeda,M., Mori,E., Matsuo,K., Nakagawa,M., Kosaka,K., 20150225, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled, confirmatory phase III trial, Alzheimer's Research & Therapy, 7, 4-, 2015</th></tr>
<tr><td>Study type</td><td>Double-blind randomised controlled trial</td></tr>
<tr><td>Aim of the study</td><td>To assess the efficacy of donepezil in people with DLB to confirm superiority over placebo</td></tr>
<tr><td>Country/ies where the study was carried out</td><td>Not stated in paper</td></tr>
<tr><td>Study dates</td><td>Not stated in paper, study published 2015</td></tr>
<tr><td>Source of funding</td><td>Eisai</td></tr>
<tr><td>Sample size</td><td>N=142 randomised</td></tr>
<tr><td>Inclusion criteria</td><td>People aged 50 years and older with DLB (MMSE score 10 to 26 inclusive) with caregiver support</td></tr>
<tr><td>Exclusion criteria</td><td>PD that was diagnosed at least 1 year prior to the onset of dementia; focal vascular lesions, other neurological or psychiatric diseases, clinically significant systemic disease, complications or a history of severe gastrointestinal ulcer, severe asthma or COPD, systolic hypotension, bradycardia, other significant cardiac problems, hypersensitivity to donepezil or piperidine derivatives, severe PD, treatment with cholinesterase inhibitors or any investigational drug within 3 months prior to screening. Cholinesterase inhibitors, antipsychotics and anti-parkinsons drugs other than levodopa or dopamine agonists were not allowed during the study</td></tr>
<tr><td>Details</td><td>Parallel group, 12-week double-blind placebo-controlled RCT</td></tr>
<tr><td>Intervention(s)</td><td>Donepezil 5mg or 10mg daily</td></tr>
<tr><td>Comparator(s)</td><td>Placebo</td></tr>
<tr><td>Results</td><td>Efficacy results at week 12
<table>
<tr><th colspan="5">Co-primary outcomes</th></tr>
<tr><th></th><th>n</th><th>Baseline
Mean value ± SD</th><th>Change at week 12 (LOCF)
Mean value ± SD</th><th>P value</th></tr>
<tr><td>MMSE</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Placebo</td><td>44</td><td>20.3 ± 4.2</td><td>0.6 ± 3.0</td><td></td></tr>
<tr><td>Donepezil 5mg</td><td>45</td><td>20.6 ± 4.1</td><td>1.4 ± 3.4</td><td>0.232</td></tr>
</table></td></tr>
</table>

Bibliographic reference	Ikeda,M., Mori,E., Matsuo,K., Nakagawa,M., Kosaka,K., 20150225, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled, confirmatory phase III trial, Alzheimer's Research & Therapy, 7, 4-, 2015

Donepezil 10mg	49	20.3 ± 4.8	2.2 ± 2.9	0.016
NPI-2				
Placebo	44	6.9 ± 4.5	–2.0 ± 4.2	
Donepezil 5mg	45	6.9 ± 4.5	–1.7 ± 4.3	0.661
Donepezil 10mg	49	7.3 ± 4.7	–2.9 ± 4.7	0.391
Secondary outcomes				
	n	**Baseline Mean value ± SE**	**Change at week 12 (LOCF) Mean value ± SE**	**P value**
NPI				
Placebo	44	–20.5 ± 15.0	–6.4 ± 1.5	
Donepezil 5mg	45	–18.9 ± 15.3	–3.3 ± 1.4	0.143
Donepezil 10mg	49	–16.6 ± 11.7	–5.5 ± 1.4	0.660
UPDRS III				
Placebo	44	Data not reported	–0.9 ± 0.9	
Donepezil 5mg	45		–1.7 ± 0.9	0.525
Donepezil 10mg	49		–0.4 ± 0.9	0.306
ZBI				
Placebo	44	28.4 ± 16.2	–0.1 ± 1.8	
Donepezil 5mg	45	28.3 ± 18.5	–5.0 ± 1.8	NS
Donepezil 10mg	49	31.4 ± 17.8	–0.8 ± 1.7	NS

NPI-2; 2 domains of NPI - hallucinations and cognitive fluctuations
NS; No significant difference between groups, but P value not reported in paper

Adverse events

	Donepezil 5mg (n=47) No. (%)	**Donepezil 10mg (n=49) No. (%)**	**Placebo (n=46) No. (%)**
All adverse events	30 (63.8)	34 (69.4)	31 (67.4)

Bibliographic reference	Ikeda,M., Mori,E., Matsuo,K., Nakagawa,M., Kosaka,K., 20150225, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled, confirmatory phase III trial, Alzheimer's Research & Therapy, 7, 4-, 2015
	Treatment-related adverse events: 12 (25.5) / 14 (28.6) / 11 (23.9) Serious adverse events: 4 (8.5) / 1 (2.0) / 5 (10.9) Withdrawal due to adverse events: 10 (21.3) / 1 (2.0) / 5 (10.9)
Overall Risk of Bias	1. Has an appropriate method of randomisation been used? YES 2. Was there adequate concealment of allocation? NO 3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES 4. Did the comparison groups receive the same care apart from interventions studied? YES 5. Were participants receiving care kept blind to treatment allocation? YES 6. Were the individuals administering care kept blind to treatment allocation? YES 7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES 8. Did the study have an appropriate length of follow up? YES 9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? YES 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR

Bibliographic reference	Leroi,I., Overshott,R., Byrne,E.J., Daniel,E., Burns,A., 20090917, Randomized controlled trial of memantine in dementia associated with Parkinson's disease, Movement Disorders, 24, 1217-1221, 2009
Study type	Double-blind randomised controlled trial
Aim of the study	To assess the safety and tolerability of memantine in people with PDD
Country/ies where the study was carried out	UK
Study dates	Not stated in paper, study published 2009

Bibliographic reference	**Leroi,I., Overshott,R., Byrne,E.J., Daniel,E., Burns,A., 20090917, Randomized controlled trial of memantine in dementia associated with Parkinson's disease, Movement Disorders, 24, 1217-1221, 2009**
Source of funding	Lundbeck
Sample size	N=25 randomised
Inclusion criteria	People with PDD (MMSE score 10 to 27). Those taking cholinesterase inhibitors (2 people in each group) had to have been stable on the medication for at least 6 months prior to study entry with no recorded improvement in cognitive and behavioural symptoms for at least 4 weeks prior to randomisation.
Exclusion criteria	Known sensitivity to NMDA receptor antagonists, current use of amantadine, ranitidine or cimetidine, brain disease other than PD, history of neurosurgery, meeting criteria for probable DLB
Details	Parallel group, 22-week double-blind, placebo-controlled RCT. Memantine was discontinued at week 16 with final evaluation (off-drug) at week 22
Intervention(s)	Memantine 20mg daily
Comparator(s)	Placebo
Results	**Efficacy results**

	Placebo mean (SD)			**Memantine mean (SD)**			**Difference in mean scores between baseline and end of drug treatment**		
Outcome	**Baseline**	**Week 16[a]**	**Week 22[b]**	**Baseline**	**Week 16[a]**	**Week 22[b]**	**Delta[c]**	**Delta 95%CI**	**P value**
MMSE	18.9 (6.2)	20.9 (6.0)	18.5 (6.7)	19.3 (5.9)	19.9 (6.3)	16.9 (7.2)	–1.5	–4.9 to 1.3	0.2
DRS	94.1 (38.5)	100.3 (33.9)	101.2 (37.5)	88.4 (31.7)	94.7 (32.8)	92.0 (28.4)	0.1	–19.3 to 19.6	1.0
NPI	14.3 (10.6)	13.5 (12.4)	19.6 (11.0)	14.9 (10.9)	11.5 (11.5)	18.2 (14.6)	–2.6	–15.6 to 10.3	0.7
UPDRS III	23.8 (10.1)	21.9 (9.1)	48.8 (15.1)	24.6 (10.0)	24.3 (8.8)	46.3 (19.9)	1.6	–1.4 to 4.7	0.3

[a] Week 16 was the end of drug treatment
[b] Week 22 was the end of the 6-week drug withdrawal phase
[c] Delta value = (end of study drug memantine – baseline memantine) – (end of study drug placebo – baseline placebo)

Bibliographic reference	**Leroi,I., Overshott,R., Byrne,E.J., Daniel,E., Burns,A., 20090917, Randomized controlled trial of memantine in dementia associated with Parkinson's disease, Movement Disorders, 24, 1217-1221, 2009**
	At week16, in mean CIBIC+ in the memantine group was 60% vs. 43% in the placebo group (χ^2= 5.4, df 2, P=0.07). After 6 weeks off the study drug (week 22), 70% of the memantine treated participants deteriorated compared with 29% of people treated with placebo (χ^2=4.0, df1, P =0.04). The magnitude of this deterioration was significantly greater in the memantine group vs. placebo (mean CIBIC+ score 5.4 (SD 1.2) vs. 4.4 (SD 0.5), respectively) (t=3.2, df22, P=0.004) **Adverse events** There were 2 serious adverse events (1 in each group), which were considered unlikely to have been related to study medication.

	Placebo	Memantine
Minor adverse events (%)	54.5	64.3

Overall Risk of Bias	1. Has an appropriate method of randomisation been used? UNCLEAR 2. Was there adequate concealment of allocation? UNCLEAR 3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES 4. Did the comparison groups receive the same care apart from interventions studied? YES 5. Were participants receiving care kept blind to treatment allocation? YES 6. Were the individuals administering care kept blind to treatment allocation? YES 7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES 8. Did the study have an appropriate length of follow up? YES 9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? UNCLEAR 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR

Bibliographic reference	**McKeith,I., Del,Ser T., Spano,P., Emre,M., Wesnes,K., Anand,R., Cicin-Sain,A., Ferrara,R., Spiegel,R., Efficacy of rivastigmine in dementia with Lewy bodies: A randomised, double-blind, placebo-controlled international study, Lancet.356 (9247) (pp 2031-2036), 2000.Date of Publication: 16 Dec 2000., 2031-2036, 2000**

<table>
<tr><th>Bibliographic reference</th><th>McKeith,I., Del,Ser T., Spano,P., Emre,M., Wesnes,K., Anand,R., Cicin-Sain,A., Ferrara,R., Spiegel,R., Efficacy of rivastigmine in dementia with Lewy bodies: A randomised, double-blind, placebo-controlled international study, Lancet.356 (9247) (pp 2031-2036), 2000.Date of Publication: 16 Dec 2000., 2031-2036, 2000</th></tr>
<tr><td>Study type</td><td>Double-blind randomised controlled trial</td></tr>
<tr><td>Aim of the study</td><td>To assess the efficacy, tolerability and safety of rivastigmine in people with DLB</td></tr>
<tr><td>Country/ies where the study was carried out</td><td>Spain, UK and Italy</td></tr>
<tr><td>Study dates</td><td>Not stated in paper, study published 2000</td></tr>
<tr><td>Source of funding</td><td>Not stated in paper</td></tr>
<tr><td>Sample size</td><td>N=120 randomised</td></tr>
<tr><td>Inclusion criteria</td><td>People with DLB (MMSE score over 9) with caregiver support</td></tr>
<tr><td>Exclusion criteria</td><td>Severe extrapyramidal symptoms, asthma, known hypersensitivity to rivastigmine or similar drugs. Neuroleptics, anticholinergics, selegiline or similar drugs were not allowed</td></tr>
<tr><td>Details</td><td>Parallel group, 20-week double-blind, placebo-controlled RCT</td></tr>
<tr><td>Intervention(s)</td><td>Rivastigmine 1.5mg twice daily, increasing to a maximum well tolerated dose (up to 6mg twice daily)</td></tr>
<tr><td>Comparator(s)</td><td>Placebo</td></tr>
<tr><td>Results</td><td>Efficacy results at week 20
<table>
<tr><th></th><th>n</th><th>Baseline mean (SD)</th><th>Change from baseline at 20 weeks (SD)</th><th>Between-group difference (95%CI)</th><th>P value</th></tr>
<tr><td colspan="6">Primary outcome – NPI-4</td></tr>
<tr><td>ITT
Rivastigmine
Placebo</td><td>
59
61</td><td>
12.2 (8.2)
11.7 (8.6)</td><td>
2.5 (8.4)
0.8 (7.3)</td><td>1.7 (–1.1 to 4.6)</td><td>0.088</td></tr>
<tr><td>LOCF
Rivastigmine</td><td>
47</td><td>
12.1 (7.9)</td><td>
3.1 (9.1)</td><td>2.3 (–0.9 to 5.7)</td><td>0.045</td></tr>
</table></td></tr>
</table>

Bibliographic reference	McKeith,I., Del,Ser T., Spano,P., Emre,M., Wesnes,K., Anand,R., Cicin-Sain,A., Ferrara,R., Spiegel,R., Efficacy of rivastigmine in dementia with Lewy bodies: A randomised, double-blind, placebo-controlled international study, Lancet.356 (9247) (pp 2031-2036), 2000.Date of Publication: 16 Dec 2000., 2031-2036, 2000

Placebo	53	11.2 (8.4)	0.8 (7.4)		
OC					
Rivastigmine	41	12.0 (7.9)	4.1 (8.3)	3.4 (0.06 to 6.6)	0.010
Placebo	51	11.3 (8.6)	0.7 (7.4)		
NPI-10					
LOCF					
Rivastigmine	47	23.2 (15.0)	5.0 (16.2)	3.8 (–1.6 to 9.2)	0.048
Placebo	53	20.2 (14.2)	1.2 (10.7)		
OC					
Rivastigmine	41	22.7 (15.0)	7.3 (13.7)	6.4 (1.4 to 11.5)	0.005
Placebo	51	20.1 (14.4)	0.9 (10.4)		
ITT; Intention to treat dataset, LOCF; Last observation carried forward dataset, OC; Observed cases dataset					

There were no significant differences between groups in MMSE, CGC+ score and UPDRS III (data not reported in paper)

	Placebo (n=61)	Rivastigmine (n=59)
Adverse events (%)	46 (75%)	54 (92%)
Severe adverse events	8 (13%)	10 (17%)

Overall Risk of Bias

1. Has an appropriate method of randomisation been used? YES
2. Was there adequate concealment of allocation? UNCLEAR
3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES
4. Did the comparison groups receive the same care apart from interventions studied? YES
5. Were participants receiving care kept blind to treatment allocation? YES
6. Were the individuals administering care kept blind to treatment allocation? YES
7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES
8. Did the study have an appropriate length of follow up? YES

Bibliographic reference	McKeith,I., Del,Ser T., Spano,P., Emre,M., Wesnes,K., Anand,R., Cicin-Sain,A., Ferrara,R., Spiegel,R., Efficacy of rivastigmine in dementia with Lewy bodies: A randomised, double-blind, placebo-controlled international study, Lancet.356 (9247) (pp 2031-2036), 2000.Date of Publication: 16 Dec 2000., 2031-2036, 2000
	9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? YES 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR
Other information	Included in CG42

Bibliographic reference	Mori,E., Ikeda,M., Kosaka,K., Donepezil-DLB,Study,I, 20121024, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled trial, Annals of Neurology, 72, 41-52, 2012
Study type	Double-blind randomised controlled trial
Aim of the study	To assess the efficacy and safety of donepezil in 3 different doses compared with placebo, in people with DLB
Country/ies where the study was carried out	Japan
Study dates	Recruitment 2007-2010, study published 2012
Source of funding	Not stated in paper
Sample size	N=140 randomised
Inclusion criteria	People aged 50 years and older with DLB (MMSE score 10 to 26 inclusive) with caregiver support
Exclusion criteria	PD diagnosed at least 1 year prior to the onset of dementia, focal vascular lesions that might cause cognitive impairment, other neurological or psychiatric diseases, clinically significant systemic disease, complications or history of severe gastrointestinal ulcer, severe asthma or COPD, systolic hypotension and other significant CV problems (e.g. QT interval prolongation), hypersensitivity to donepezil or piperidine derivatives, severe PD, treatment with cholinesterase inhibitors or any investigational drug within 3 months prior to screening. Cholinesterase inhibitors, antipsychotics, and antiparkinson drugs other than levodopa or dopamine agonists were not allowed.
Details	Parallel group, 12-week double blind, placebo controlled RCT

Bibliographic reference	Mori,E., Ikeda,M., Kosaka,K., Donepezil-DLB,Study,I, 20121024, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled trial, Annals of Neurology, 72, 41-52, 2012
Intervention(s)	Donepezil 3mg, 5mg or 10mg daily
Comparator(s)	Placebo

Results

Efficacy results for donepezil

Outcome	Baseline n	Baseline Mean (SD)	Baseline P (ANOVA)	Change n	Change Mean (SD)	Change Difference (95%CI)	Change P value (*t* test)	Change P value (ANCOVA)
MMSE								
Placebo	32	18.3 (4.7)	0.271	31	–0.4 (2.7)			
3mg	35	20.4 (4.1)		35	1.6 (3.8)	2.0 (0.4 to 3.7)	0.017	0.013
5mg	32	19.8 (4.4)		32	3.4 (3.2)	3.8 (2.3 to 5.3)	<0.001	<0.001
10mg	36	19.8 (4.4)		36	2.0 (3.3)	2.4 (0.9 to 3.9)	0.001	<0.001
NPI								
Placebo	32	18.3 (8.9)	0.079	32	0.3 (17.5)			
3mg	35	20.7 (12.8)		35	–3.9 (22.0)	–4.2 (–13.9 to 5.6)	0.396	0.602
5mg	32	14.0 (8.3)		32	–5.5 (6.7)	–5.8 (–12.4 to 0.8)	0.086	0.047
10mg	36	19.5 (12.8)		35	–8.0 (12.8)	–8.3 (–15.8 to –0.9)	0.029	0.019
NPI-2								
Placebo	32	6.3 (4.0)	0.443	32	1.1 (5.7)			
3mg	35	7.1 (4.1)		35	–2.1 (6.3)	–3.2 (–6.1 to –0.3)	0.032	0.025
5mg	32	6.3 (4.8)		32	–3.3 (3.8)	–4.4 (–6.8 to –2.0)	<0.001	<0.001
10mg	36	7.9 (5.4)		35	–4.6 (4.5)	–5.8 (–8.2 to –3.3)	<0.001	<0.001
NPI-4								
Placebo	32	12.1 (6.3)	0.269	32	–0.3 (8.5)			
3mg	35	11.5 (7.0)		35	–2.4 (10.8)	–2.1 (–6.9 to 2.6)	0.377	0.261
5mg	32	9.0 (5.3)		32	–4.2 (4.9)	–3.9 (–7.3 to –0.4)	0.028	0.008
10mg	36	11.9 (8.8)		35	–5.1 (7.4)	–4.8 (–8.7 to –1.0)	0.015	0.006

Bibliographic reference	Mori,E., Ikeda,M., Kosaka,K., Donepezil-DLB,Study,I, 20121024, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled trial, Annals of Neurology, 72, 41-52, 2012

ZBI								
Placebo	32	21.8 (10.1)	0.197	31	4.2 (10.4)			
3mg	35	27.9 (13.9)		33	–1.3 (13.2)	–5.5 (–11.5 to 0.5)	0.069	0.301
5mg	32	22.9 (11.5)		31	–0.7 (15.7)	–4.9 (–11.7 to 1.8)	0.149	0.172
10mg	36	26.5 (16.1)		31	–5.0 (13.6)	–9.2 (–15.3 to –3.0)	0.004	0.035
UPDRS III								
Placebo	33	20.8 (10.6)	0.702	31	0.7 (3.8)			
3mg	35	17.9 (9.0)		34	–0.5 (7.4)	–1.3 (–4.2 to 1.7)	0.393	0.397
5mg	33	19.1 (10.7)		32	–0.5 (5.4)	–1.3 (–3.6 to 1.1)	0.281	0.358
10mg	37	18.9 (11.6)		33	–1.0 (6.7)	–1.8 (–4.5 to 1.0)	0.200	0.258
NPI-2; 2 domains of NPI – hallucinations + cognitive fluctuation *NPI-4; 4 domains of NPI – delusions + hallucinations + dysphoria + apathy*								

	Mean CIBIC+ score (range 1-7)	P value (difference from placebo)
Placebo	3.73	—
Donepezil 3mg	4.78	0.010
Donepezil 5mg	5.03	0.004
Donepezil 10mg	4.86	0.034

Adverse events

	Placebo (n=34)	3mg (n=35)	5mg (n=33)	10mg (n=37)
All adverse events (%)	24 (71)	24 (69)	27 (82)	32 (87)
Serious adverse events (%)	2 (5.9)	2 (5.7)	2 (6.1)	4 (10.8)
Adverse events leading to study withdrawal (%)	4 (11.8)	3 (8.6)	1 (3.0)	3 (8.1)
No statistically significant differences between placebo and each active group				

Bibliographic reference	Mori,E., Ikeda,M., Kosaka,K., Donepezil-DLB,Study,I, 20121024, Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled trial, Annals of Neurology, 72, 41-52, 2012
Overall Risk of Bias	1. Has an appropriate method of randomisation been used? YES 2. Was there adequate concealment of allocation? UNCLEAR 3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES 4. Did the comparison groups receive the same care apart from interventions studied? YES 5. Were participants receiving care kept blind to treatment allocation? YES 6. Were the individuals administering care kept blind to treatment allocation? YES 7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES 8. Did the study have an appropriate length of follow up? YES 9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? YES 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR

Bibliographic reference	Ravina,B., Putt,M., Siderowf,A., Farrar,J.T., Gillespie,M., Crawley,A., Fernandez,H.H., Trieschmann,M.M., Reichwein,S., Simuni,T., 20050719, Donepezil for dementia in Parkinson's disease: a randomised, double blind, placebo controlled, crossover study, Journal of Neurology, Neurosurgery & Psychiatry, 76, 934-939, 2005
Study type	Double-blind randomised controlled trial
Aim of the study	To assess the safety and efficacy of donepezil in people with PDD
Country/ies where the study was carried out	USA
Study dates	Not stated in paper, study published 2005
Source of funding	National Institutes of Neurological Disorders and Stroke, National Institute on Aging
Sample size	N=22 randomised

<table>
<tr><th>Bibliographic reference</th><td>Ravina,B., Putt,M., Siderowf,A., Farrar,J.T., Gillespie,M., Crawley,A., Fernandez,H.H., Trieschmann,M.M., Reichwein,S., Simuni,T., 20050719, Donepezil for dementia in Parkinson's disease: a randomised, double blind, placebo controlled, crossover study, Journal of Neurology, Neurosurgery & Psychiatry, 76, 934-939, 2005</td></tr>
<tr><td>Inclusion criteria</td><td>People aged 40 years and older with PDD (MMSE score 17 to 26 inclusive)</td></tr>
<tr><td>Exclusion criteria</td><td>Other causes of dementia, pregnancy or lactation, use of cholinergic or anticholinergic drugs (except amantadine or tolterodine within 2 weeks prior to screening), medical conditions or uncontrolled psychosis that would interfere with the safe conduct of the study</td></tr>
<tr><td>Details</td><td>26-week double blind, placebo-controlled crossover RCT. Participants were randomised to either donepezil or placebo for 10 weeks, with a 6-week washout period prior to crossover treatment for a further 10 weeks</td></tr>
<tr><td>Intervention(s)</td><td>Donepezil 5mg daily or 5mg twice daily</td></tr>
<tr><td>Comparator(s)</td><td>Placebo</td></tr>
<tr><td>Results</td><td>Efficacy results after 10 weeks treatment
<table>
<tr><th>Outcome</th><th>Donepezil
Mean score (SD)</th><th>Placebo
Mean score (SD)</th><th>Treatment effect
(SE)</th><th>P value</th><th>Adjusted P value[a]</th></tr>
<tr><td>ADAS-cog</td><td>22.5 (6.9)</td><td>24.4 (9.4)</td><td>–1.9 (1.4)</td><td>0.18</td><td>0.54</td></tr>
<tr><td>MMSE</td><td>24.5 (3.2)</td><td>22.5 (4.7)</td><td>2.0 (0.61)</td><td>0.0044</td><td>0.018</td></tr>
<tr><td>MDRS</td><td>108.3 (17.1)</td><td>108.5 (18.2)</td><td>–0.2 (1.9)</td><td>0.98</td><td>0.98</td></tr>
<tr><td>CGI</td><td>3.58 (0.77)</td><td>3.95 (0.85)</td><td>–0.37 (N/A)</td><td>0.0056</td><td>0.022</td></tr>
<tr><td>UPDRS III</td><td>40.3 (13.6)</td><td>40.5 (13.7)</td><td>—</td><td>0.76</td><td>—</td></tr>
<tr><td colspan="6">[a] Adjusted for multiple comparisons using Hommel method</td></tr>
</table>
Adverse events
<table>
<tr><th></th><th>Donepezil (n=21)</th><th>Placebo (n=20)</th><th>P value</th></tr>
<tr><td>Tolerability (%)</td><td>17 (81)</td><td>18 (90)</td><td>0.41</td></tr>
<tr><td>All adverse events (%)</td><td>11 (52)</td><td>9 (45)</td><td>0.64</td></tr>
<tr><td colspan="4">Tolerability was defined as the proportion of study participants remaining on study drug for the full period</td></tr>
</table></td></tr>
<tr><td>Overall Risk of Bias</td><td>1. Has an appropriate method of randomisation been used? YES</td></tr>
</table>

Bibliographic reference	**Ravina,B., Putt,M., Siderowf,A., Farrar,J.T., Gillespie,M., Crawley,A., Fernandez,H.H., Trieschmann,M.M., Reichwein,S., Simuni,T., 20050719, Donepezil for dementia in Parkinson's disease: a randomised, double blind, placebo controlled, crossover study, Journal of Neurology, Neurosurgery & Psychiatry, 76, 934-939, 2005**
	2. Was there adequate concealment of allocation? UNCLEAR 3. Were the groups comparable at baseline for all major confounding/prognostic factors? YES 4. Did the comparison groups receive the same care apart from interventions studied? YES 5. Were participants receiving care kept blind to treatment allocation? YES 6. Were the individuals administering care kept blind to treatment allocation? YES 7. Were groups comparable with respect to availability of outcome data and for how many participants were no outcome data available? YES 8. Did the study have an appropriate length of follow up? YES 9. Did the study use a precise definition of outcome? YES 10. Was a valid and reliable method used to determine that outcome? YES 11. Were investigators kept blind to participant's exposure to the intervention? UNCLEAR 12. Were investigators kept blind to other important confounding and prognostic factors? UNCLEAR
Other information	Included in NICE CG35

E.7.4 Cholinesterase inhibitors and memantine for types of dementia other than typical Alzheimer's disease

- How effective are cholinesterase inhibitors and memantine for types of dementia other than typical Alzheimer's disease?

Bibliographic reference	Auchus AP, Brashear HR, Salloway S, Korczyn AD et al (2007) Galantamine treatment of vascular dementia, Neurology, 69, 448-458
Study type	Randomised placebo controlled multi centre double blind parallel group trial. Study duration 26 weeks
Participants	Participants with probable vascular dementia (defined by NINDSA-AIREN criteria plus MRI confirmation of VaD diagnosis). Inclusion criteria: Age at onset 40-90 years; a score of 10 to 26 on MMSE; score of ≥12 on ADAS-Cog-11; availability of reliable caregiver Exclusion: Diagnosis of Alzheimer's disease, Parkinson's disease or Huntington's disease or other neurological dementia; serious coexisting medical conditions;
Patient characteristics	N=786 (Galantamine n= 396; mean age = 72.3 ± 9.0 years; MMSE= 20.3 ± 3.9; placebo n= 390; mean age = 72.2 ± 6.8; MMSE = 20.2 ± 3.9)
Intervention	Galantamine 4mg twice daily for 4 weeks increasing to 8mg twice daily for 4 weeks, upon which it was either maintained or increased to 12mg twice daily
Comparison	Placebo- using the same escalation
Outcome measures	Cognitive outcomes (ADAS-cog and ADAS-cog//11) Behavioural outcomes (ADCS-ADL and EXIT-25) Discontinuation due to adverse events
Study dates	August 2001 to August 2003
Comments (Risk of bias)	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? CIs reported. How precise was the outcome effect? Measures of dispersion, p values and Cis reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes

Bibliographic reference	Auchus AP, Brashear HR, Salloway S, Korczyn AD et al (2007) Galantamine treatment of vascular dementia, Neurology, 69, 448-458
	Overall Risk of bias: Low

Bibliographic reference	Ballard C, Sauter M, Scheltens P, He Y (2008) Efficacy, safety and tolerability of rivastigmine capsules in patients with probable vascular dementia: The VantagE study
Study type	A randomised placebo controlled multi centre double-blind placebo controlled trial to evaluate the safety and efficacy of rivastigmine capsules for people with probable vascular dementia (VantagE- Vascular Dementia trial studying Exelon). Study duration 24 weeks
Participants	472 participants recruited from clinical research centres in Austria, Canada, France, Germany, Italy, Korea, Russia, Spain, Switzerland, Taiwan, UK and USA Inclusion criteria: Men and women aged 50-85 years with probable vascular dementia (according to DSM-IV and NINDS-AIREN criteria)score of 10 to 24 on MMSE; availability of responsible caregiver on at ;least 3 days of the week Exclusion: Primary neurodegenerative disorder other than VaD or other causes of dementia; major depressive episode; active uncontrolled seizure disorder; any disability or unstable disease
Patient characteristics	N= 710 (Rivastigmine n= 365; mean age = 72.9 ± 8.3; MMSE = 19.2 ± 4.1; placebo n= 345 mean age 72.7 ± 7.6; MMSE = 19.2 ± 3.9)
Intervention	Rivastigmine 1.5 mg given twice daily. Dose escalation over 16 weeks whereby doses increased at 4 weekly intervals by 1.5mg twice daily/. Highest well tolerated dose then maintained for study duration
Comparison	Placebo given twice a day
Outcome measures	Cognitive outcomes at 24 weeks (ADAS-cog; MMSE); Global assessment at 24 weeks (VaDAS and ADCS-CGIC; GDS); Functional ability at 24 weeks (ADCS-ADL)
Study dates	July 2001 to December 2004
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? • At the end of the trial, were all patients accounted for?

Bibliographic reference	**Ballard C, Sauter M, Scheltens P, He Y (2008) Efficacy, safety and tolerability of rivastigmine capsules in patients with probable vascular dementia: The VantagE study**
	• How large was the treatment effect? How precise was the outcome effect? ITT sample; Sds P values reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

ibliographic reference	**Black S,Roman GC, Geldmacher DS, Salloway S, Hecker J, Burns A, Perdomo C, Kumar D, Pratt R, et al (2003) Efficacy and tolerability of Donepezil in vascular dementia. Positive results of a 24-week multicentre international randomized placebo-controlled clinical trial, Stroke, 34, 2323-2332**
Study type	A randomised placebo controlled multi centre, international, double-blind placebo controlled parallel group trial to evaluate the efficacy and tolerability of donepezil 5mg and 10mg in people with vascular dementia (Donepezil 307)
Participants	Inclusion criteria: outpatients aged ≥ 40 years with a diagnosis of possible or probable vascular dementia (according to NINDS--AIREN criteria)> 3 months duration; Exclusion: Evidence of other neurodegenerative disorders ; Alzheimer's dementia or other conditions not associated with CVD; prior diagnosis of AD; cognitive impairment due to stroke or other CVD; MMSE > 26 or <10; occurrence of new strokes in 28 days prior to study entry; major depression or other psychiatric disorder;
Patient characteristics	N= 603 (5mg n=198; mean age = 73.7 ± 8.44 years ; MMSE = 21.9 ± 4.22; 10mg n= 206; mean age = 73.9 ± 8.61 years; MMSE = 21.8 ± 4.31; placebo n = 199; mean age = 74.2 ± 8.46 years; MMSE = 21.7 ± 4.23)
Intervention	Donepezil 5mg per day. Donepezil 10mg given per day. Patients in this arm received 5mg for first 4 weeks.
Comparison	Matched placebo
Outcome measures	Cognitive outcomes at 24 weeks (ADAS-cog); global assessment at 24 weeks (CIBICplus and CDR-SB); Functional assessment at 24 weeks(ADFACS); Withdrawal due to adverse events
Study dates	June 1997 to September 2001
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes

ibliographic reference	**Black S,Roman GC, Geldmacher DS, Salloway S, Hecker J, Burns A, Perdomo C, Kumar D, Pratt R, et al (2003) Efficacy and tolerability of Donepezil in vascular dementia. Positive results of a 24-week multicentre international randomized placebo-controlled clinical trial, Stroke, 34, 2323-2332**
	• At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? ITT,MITT safety populations, full details reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Boxer AL, Knopman DS, Kaufer D, Grossman M, Onyike C, et al (2013) Memantine in patients with frontotemporal lobar degeneration: a multicentre randomised double-blind placebo-controlled trial, The Lancet Neurology,**
Study type	A multicentre randomised double blind parallel group placebo controlled trial to test the efficacy and safety of memantine for behavioural variant frontotemporal dementia. Study duration 26 weeks
Participants	Inclusion: Participants with Bv FTD or semantic dementia aged 40 to 80 years MMSE ≥15, reliable caregiver. Exclusion: Diagnosis of progressive non fluent aphasia ; use of memantine or AChEIs ; antipsychotic drugs; valproate lithium; benzodiazapines 4 weeks before randomisation; evidence of disorders that preclude diagnosis of FTD
Patient characteristics	Placebo N= 42 (bvFTD n= 33; mean age 65.6; MMSE =25.0; tvFTD n= 9 ; mean age =68.6 ; MMSE 25.2) Memantine N = 39 (bvFTD n= 31; mean age 65.6; MMSE =24.0; tvFTD n= 9 ; mean age =67.0 ; MMSE 25.8)
Intervention	Memantine 10mg twice a day
Comparison	Placebo
Outcomes measures	Cognitive outcomes at 26 weeks (MMSE; EXIT-25) Global assessment at 16 weeks (CIGIC) Functional assessment at 26 weeks (CDR-SB-FTD; FAQ; TFLS) Neuropsychological outcomes at 52 weeks (NPI)
Study dates	Dec 2007 to May 2012
Comments	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes

Bibliographic reference	**Boxer AL, Knopman DS, Kaufer D, Grossman M, Onyike C, et al (2013) Memantine in patients with frontotemporal lobar degeneration: a multicentre randomised double-blind placebo-controlled trial, The Lancet Neurology,**
	• Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? ITT,MITT safety populations, full details reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Kertesz A, Morlog D, Light M, Blair M,Davidson W, Jeso S (2008) Galantamine in frontotemporal dementia and primary progressive aphasia , Dement Geriatr Cogn Disord, 25, 178-185**
Study type	An 18 week open label trial of galantamine treatment followed by an 8 week double blind placebo controlled phase II trial to assess the safety and tolerability of galantamine in people with FT dementia or PPA (stratified by diagnostic type)
Participants	Inclusion: outpatients aged 30-80 years with PPA ≥ 1 year (defined by Mesulams criteria) or FTD (defined by Neary's 5 criteria) MMSE>5; ability to complete neuropsychiatric tests; have a responsible caregiver and opportunity to perform activities of daily living Exclusion criteria: Other neurodegenerative disorders, Alzheimer's disease, traumatic brain injury, cerebrovascular disease, hypoxic cerebral damage, vitamin deficiency, infection, cerebral neoplasia, uncontrolled epilepsy, clinically significant psychiatric, cardiovascular, pulmonary, metabolic or endocrine disorder, history of alcohol or drug abuse and treatment with agents for dementia or other cognitive impairment
Patient characteristics	N= 39 (Galantamine n=18; mean age = 63.6 ± 1037 years ; MMSE = 19.0 ± 7.1; placebo n = 18; mean age = 63.1 ± 7.1 years; MMSE = 20.2 ± 6.1)
Intervention	Double blind phase weeks 19-26 Flexible dosing based on tolerability Galantamine 16-24mg per day (8 or 12 mg twice daily)
Comparison	Placebo
Outcome measures	Cognitive outcomes at weeks 19-26 (MMSE, DRS;)

	Functional assessment at 19- 26 weeks (FAB; ; ADC-ADL) Neuropsychological outcomes at 19-26 weeks (NPI)
Study dates	Not reported
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Open label plus double blind phase • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Unclear reporting of attrition at endpoint • How large was the treatment effect? How precise was the outcome effect? SEs p values, • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Primary outcome presented as figure (no dispersion) Unclear reporting of n values in secondary outcomes at endpoint Overall risk of bias: High
Bibliographic reference	**Krupp LB, Christodoulou C, Melville P, Scherl WF, Pai LY et al (2011) Multicenter randomized clinical trial of donepezil for memory impairment in multiple sclerosis , Neurology, 76, 1500-1507**
Study type	A multicentre double blind placebo controlled randomised controlled trial to determine if donepezil improves memory in people with MS. Study duration 24 weeks
Participants	Inclusion: Participants aged 18-59 years with clinically definite MS and EDSS score ≤7 Exclusion criteria: Not received steroids in previous 4 weeks; prior use of donepezil ; diagnosis of depression; alcohol or substance abuse; history of other neurologic disorders
Patient characteristics	N=120 (donepezil group n= 61; mean age = 46.2± 7.5 years; mean EDSS = 3.96 ± 1.78; MSNq= 30.3 ± 10.5; placebo group n=59; mean age = 47.3 ± 8.9 years; mean EDSS = 3.74 ± 1.98; mean MSNQ = 30.2 ± 10.8)
Intervention	Initial dose donepezil 5mg per day increasing to 10 mg a day at week 4
Comparison	Placebo
Outcome measures	Cognitive outcomes at 24 weeks (total recall on SRT) Neuropsychological outcomes at 24 weeks (BRB)
Study dates	June 2005 to October 2008
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	**Krupp LB, Christodoulou C, Melville P, Scherl WF, Pai LY et al (2011) Multicenter randomized clinical trial of donepezil for memory impairment in multiple sclerosis , Neurology, 76, 1500-1507**
	• Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Cis P values • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Maurer M, Ortler S, Baier M, Meergans M, Scherer P (2012) Randomised multicentre trial on safety and efficacy of rivastigmine in cognitively impaired multiple sclerosis patients, Multiple Sclerosis journal, 19, 631-638**
Study type	A multicentre double blind placebo controlled randomised controlled trial. To assess the efficacy of rivastigmine on memory function in people with MS. Study duration 16 weeks.
Participants	Inclusion people with a diagnosis of MS (according to 2005 McDonald series) aged 18 to 65 years and cognitive impairment (defined by FST ≥ 3 and MUSIC score ≤ 19); received IFN-β=1b therapy in last 60 days Exclusion : Use AD medications; taking psychoactive medications; used muscle relaxants or lithium; Pregnancy or breastfeeding diabetes; malignancy; any cognition affecting medical condition; drug addiction; alcohol abuse; depression based on MADRs score ≥14; cognitive screening with B\rb-N in previous year ; attended cognitive rehabilitation in previous 3 months
Patient characteristics	N= 81 (Rivastigmine n =43 mean age – 44.6 (±9.4) years; MUSIC = 15.28 ± 5.29; placebo n= 38; mean age = 44.0 (± 7.3) years; MUSIC 16.14 ± 5.29)
Intervention	4 week run in period = rivastigmine patch 5cm^2 (4.6mg per day) followed by 12 weeks rivastigmine patch 10cm^2 (9.5 mg per day)
Comparison	Placebo patches matched in size
Outcome measures	Cognitive outcomes at 16 weeks (SRT) Number of serious adverse events

Bibliographic reference	**Maurer M, Ortler S, Baier M, Meergans M, Scherer P (2012) Randomised multicentre trial on safety and efficacy of rivastigmine in cognitively impaired multiple sclerosis patients, Multiple Sclerosis journal, 19, 631-638**
Study dates	Commenced in January 2009
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Open label and double blind phase • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? CIs , p values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Mok V, Wong A, Ho S, Leung T, Lam WWM, Wog, KS (2007) Rivastigmine in Chinese patients with subcortical vascular dementia, Neuropsychiatric disease and treatment, 3, 943-948**
Study type	A randomised placebo controlled single centre double-blind placebo controlled trial to evaluate the efficacy and tolerability of rivastigmine among Chinese people with subcortical vascular dementia. Study duration 26 weeks
Participants	Participants recruited from the neurology clinic. Inclusion criteria: 40 Chinese patients aged 40-90 years with subcortical vascular dementia (according to a modified version of NINDS-AIREN criteria). People with poor literacy were included due to use of simple validated Chinese versions of psychometric tests and questionnaires. Exclusion: Any other concurrent dementing disease (e.g., vitamin B12 deficiency); unstable medical conditions; stroke in previous 3 months of study commencing; concurrent use of cholinergic drugs; frequent change in dose of centrally acting drugs in 3 months prior to study entry(e.g., benzodiazapines); severe dementia or language problems; Caregivers with use of < 3 visits per week
Patient characteristics	N= 40 (rivastigmine n= 20; mean age = 75.7 ± 5.1; MMSE = 13.0 ± 4.2; Placebo n= 20; mean age = 74.1 ± 6.6; MMSE = 13.4 ± 5.9)
Intervention	Rivastigmine 1.5 mg given twice daily. Dose escalation to 3 mg twice daily after 4 weeks and maintained for study

Bibliographic reference	**Mok V, Wong A, Ho S, Leung T, Lam WWM, Wog, KS (2007) Rivastigmine in Chinese patients with subcortical vascular dementia, Neuropsychiatric disease and treatment, 3, 943-948**
	duration
Comparison	Placebo
Outcome measures	Cognitive outcomes at 26 weeks (MMSE score, FAB); Behavioural outcomes at 26 weeks (NPI); Functional outcomes at 26 weeks (IADL; CDR-SB); Withdrawal due to adverse events
Study dates	November 2002 to December 2004
Comments **Risk of bi**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Unclear- not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? SDs, P values reported; small sample (20 per arm) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Orgogozo JM, Rigaud, AS, Stoffler, A, Mobius, HJ, Forette, F (2002) Efficacy and safety of memantine in patients with mild to moderate vascular dementia : A randomized placebo-controlled trial MMM300, Stroke, 33, 1834-1839**
Study type	A multicentre double blind placebo controlled parallel group randomised controlled trial to evaluate the efficacy and tolerability of memantine in the treatment of mild to moderate vascular dementia. Study duration 28 weeks
Participants	Inclusion: Male and female participants aged ≥ 60 years with mild to moderate VaD (defined by NINDSA-AIREN criteria) of 6 months duration MMSE 12 to 20 Exclusion criteria: Alzheimer's disease or secondary types of dementia (NINCDS-ADRDA), history of seizures, drug abuse or alcoholism, chronic use of other medications,
Patient characteristics	N= 288 (memantine n=147; mean age = 76.6 ± 6.5 years; MMSE = 16.9 ± 2.6; placebo n = 141; mean age = 76.1 ± 6.86 years; MMSE = 16.9 ± 2.44)

Bibliographic reference	**Orgogozo JM, Rigaud, AS, Stoffler, A, Mobius, HJ, Forette, F (2002) Efficacy and safety of memantine in patients with mild to moderate vascular dementia : A randomized placebo-controlled trial MMM300, Stroke, 33, 1834-1839**
Intervention	Memantine 20mg per day (following an initial titration period of 5mg a day at week 1; 10mg a day at week 2; 15mg a day at week 3)
Comparison	Matched placebo
Outcome measures	Cognitive outcomes at 28 weeks (ADAS-cog; MMSE) Global assessment (CIBICplus)
Study dates	June 1996 to Jan 1999
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? ITT analysis P values SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Roman GC, Salloway S, Black SE, Royall DR et al (2010) Randomized placebo-cntrolled trial of donepezil in vascular dementia, Stroke, 41, 1213-1221**
Study type	A randomised double blind multi centre, international, placebo-controlled trial. Study duration 24 weeks to assess the efficacy and tolerability of donepezil in people with probable or possible vascular dementia
Participants	Inclusion criteria: Outpatients aged 35-94 years with probable or possible vascular dementia (according to NINDSA-AIREN criteria). Stroke free in previous 3 months; had not taken AChEinhibitors or memantine for at least 6 weeks; did not have unstable medical conditions. Exclusions: Not reported, but write up describes as similar entry criteria were similar to prior studies of donepezil in VaD (Donepezil 307 and 308 trials- see evidence tables for Black 2003, Wilkinson 2003)
Patient characteristics	N= 974 (Donepezil n=648; mean age = 73.4 ± 10.18 years ; MMSE = 23.49 ± 5.09; placebo n = 326; mean age =

Bibliographic reference	**Roman GC, Salloway S, Black SE, Royall DR et al (2010) Randomized placebo-cntrolled trial of donepezil in vascular dementia, Stroke, 41, 1213-1221**
	72.3 ± 9.03 years; MMSE = 23.57 ± 4.87)
Intervention	Donepezil 5mg per day
Comparison	Placebo once per day
Outcome measures	Cognitive outcomes at 24 weeks (VaDAS- cog; ADAS-cog; MMSE; CDR-SB) Global assessment at 24 weeks (CIBICplus) Number of serious adverse events
Study dates	March 2003 to August 2005
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? • Can the results be applied to the local population? ITT, SDs P values • Were all clinically relevant outcomes reported? Primary outcome only presented as a figure (no measures of dispersion) Overall risk of bias: Low

Bibliographic reference	**Saint Paul LP, Creveuil C, Heinzle O, De Seze J, Vermesch P et al (2016) Efficacy and safety of memantine in cognitive impairment in multiple sclerosis: randomized placebo-controlled study, Journal of the neurological sciences, 363, 69-76**
Study type	A multicentre double blind placebo controlled randomised controlled trial to examine the safety and efficacy of long term memantine administration in people with MS and moderate cognitive impairment. Study duration 52 weeks
Participants	Inclusion: Males and females aged 18 – 60 years with a diagnosis of Relapsing Remitting-MS and presenting with a cognitive complaint or demonstrating moderate cognitive impairment; a dementia rating score ≥130 EDSS ≤ 5.5; PASAT score >15 but lower than mean -1.5 SD Exclusion criteria: Progressive form of MS or tumoral form of MS visible on MRI; MS relapse in previous 30 days;

Bibliographic reference	**Saint Paul LP, Creveuil C, Heinzle O, De Seze J, Vermesch P et al (2016) Efficacy and safety of memantine in cognitive impairment in multiple sclerosis: randomized placebo-controlled study, Journal of the neurological sciences, 363, 69-76**
	intravenous or oral corticoid treatment in previous month; any symptomatic or non-medical cognitive therapy or neuropsychological training for cognitive disorders , antidepressant or anxiolytic treatment 3 months prior to randomization; MADRS score > 19
Patient characteristics	N= 86 mean age = 41.5 ± 8.8 (Memantine group n= 48; mean age = 39.6 ±9.1 ; placebo group n=38; mean age =43.9 ± 7.9)
Intervention	Memantine twice daily (starting at 5mg dose increasing by 5mg doses to to 20mg after 3 weeks) Downward titration was not permitted
Comparison	Placebo twice daily
Outcome measures	Cognitive outcomes at 52 weeks (PASAT, EDSS)
Study dates	Not reported
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? ITT population, p values SE • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Sesok S, Bolle N, Kobal J, Bucik V, Vodusek DB (2014) Cognitive function in early clinical phase Huntington disease after rivastigmine treatment , Psychiatria Damubina, 26, 239-248**
Study type	A randomised controlled double blind trial
Participants	Inclusion: male and female outpatients aged 18 to 65 years clinically diagnosed with genetic Huntington's disease(measured by UHDRS score 5-25 Exclusion: contraindication to rivastigmine ; history or presence of other neurological disease; traumatic brain injury;

Bibliographic reference	**Sesok S, Bolle N, Kobal J, Bucik V, Vodusek DB (2014) Cognitive function in early clinical phase Huntington disease after rivastigmine treatment , Psychiatria Damubina, 26, 239-248**
	brain surgery; psychiatric disease; heart rhythm disorder; heart failure; severe and uncontrolled hypertension; severe chronic obstructive pulmonary disease; liver or kidney failure, endocrine disorder; study obstructive conditions (eyesight loss; language incompatibility)
Patient characteristics	N= 18 (Rivastigmine group n= 11 mean age = 47.7 ± 10.7 years; placebo n= 6 mean age =n43.0 ± 12.5 years)
Intervention	Rivastigmine capsules 1.5mg twice a day increasing to 3mg after 3 months
Comparison	Matched placebo
Outcome measures	Neuropsychological outcomes at 26 weeks (CVLT-II; SDMT; RFFT;TOL)
Study dates	Not reported
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? SDs p values, small sample (18 participants) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Small G, Erkinjuntti T , Kurz A, Lilienfeld S (2003) Galantamine in the treatment of cognitive decline in patients with vascular dementia or Alzheimer's disease with cerebrovascular disease, CNS Drugs, 905-914**
Study type	Post hoc sub analysis of a randomised placebo controlled multi centre double-blind trial. Study duration 6 months followed by a 6 month open label extension
Participants	A sub group of 195 participants with probable vascular dementia (defined by NINDS-AIREN criteria) (sub group analysis of Erkinjuntti) Inclusion criteria: Disease onset between 40- 90 years; a score of 10 to 26 on MMSE; score of ≥12 on ADAS-Cog-

Bibliographic reference	**Small G, Erkinjuntti T , Kurz A, Lilienfeld S (2003) Galantamine in the treatment of cognitive decline in patients with vascular dementia or Alzheimer's disease with cerebrovascular disease, CNS Drugs, 905-914**
	11; availability of reliable caregiver Exclusion: Receiving an investigational drug in previous 30 days; Other nootropic, cholinomimetic, choline or oestrogen prescribed for dementia, non-steroidal anti-inflammatory use ≥ 30 consecutive days; tocopherol (vitamin E) >30IU daily; or use of selegiline.
Patient characteristics	Sub sample with VaD N= 190 (Galantamine n= 125; mean age = 73.8 ± 7.49 ; MMSE = 20.9 ± 3.24 Placebo n= 70; mean age = 73.4 ± 7.86; MMSE = 20.3 ± 3.35)
Intervention	Galantamine 24mg a day
Comparison	Placebo (for 6 months only)
Outcome measures	Cognitive outcomes (ADAS-cog/11)
Study dates	November 1998 – June 2000 (Original studies -Erkinjuntti, 2002, 2003)
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? P values, effect sizes written in text • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Vercelletto M, Boutoleau-Bretonniere C, Volteau C, Puel M et al (2011) Memantine in benavioral variant frontotemporal dementia: Negative results , Journal of Alzheimer's disease, 23, 749-759**
Study type	A multi-centre, phase II, double blind placebo controlled parallel group randomised controlled trial to evaluate the efficacy and tolerability of one year treatment with memantine in the treatment of behavioural variant frontotemporal dementia. Study duration 52 weeks
Participants	Inclusion: Ambulatory patients with bv FTD (based on Neary's five criteria) aged 45 to 75 years; BvFTD for at least 1 year; MMSE ≥ 19; FTD behavioural score >3; MADRS score <3; stable psychotropic treatment for at least 1 year

Bibliographic reference	**Vercelletto M, Boutoleau-Bretonniere C, Volteau C, Puel M et al (2011) Memantine in benavioral variant frontotemporal dementia: Negative results , Journal of Alzheimer's disease, 23, 749-759**
	prior to inclusion Exclusion: tv FVTD (semantic dementia or progressive aphasia); motor neuron disease or people treated with AChEIs
Patient characteristics	N= 49 (memantine n=23; mean age = 64.4 ± 7.5 years ; MMSE = 25.3 ± 3.40; placebo n = 26; mean age = 66.6 ± 7.4 years; MMSE = 24.5 ± 3.0)
Intervention	Memantine 10mg twice a day
Comparison	Matched placebo
Outcome measures	Cognitive outcomes at 52 weeks (MMSE; MDRS) Global assessment at 52 weeks (CIBIC-plus; FBI; DAD,ZBI) Neuropsychological outcomes at 52 weeks (NPI)
Study dates	September 2006 to June 2008
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? P values SDs reported; small sample • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Wilcock G, Mobius HJ, Soffler A (2002) A double-blind placebo controlled multicentre study of memantine in vascular dementia (MMM500), Int Clin Psychopharmacol, 17, 297-305**
Study type	A multicentre double blind placebo controlled parallel group randomised controlled trial to evaluate the efficacy and tolerability of memantine in the treatment of mild to moderate vascular dementia. Study duration 28 weeks
Participants	Inclusion: Outpatients with probable vascular dementia (DSM-III-R; NINDSA-AIREN); MMSE scores between 10-22;

Bibliographic reference	**Wilcock G, Mobius HJ, Soffler A (2002) A double-blind placebo controlled multicentre study of memantine in vascular dementia (MMM500), Int Clin Psychopharmacol, 17, 297-305**
	disease onset at least 1 year prior to inclusion Exclusion: Secondary dementia; depressive pseudo dementia; psychomotor excitation; psychotic episodes; history of epilepsy; acute or poorly controlled illnesses
Patient characteristics	N= 548 (memantine n=277; mean age = 77.2 ± 6.9 years ; MMSE = 17.5 ± 3.29; placebo n = 271; mean age = 77.6 ± 7.0 years; MMSE = 17.7 ± 3.22)
Intervention	Memantine 10mg twice a day at week 4 till week 28 (following an initial dose of 5mg daily with weekly incremental titration by 5mg a day)
Comparison	Matched placebo
Outcome measures	Cognitive outcomes at 28 weeks (ADAS-cog; MMSE; GBS; NOSGER) Global assessment at 28 wees (CGI-C)
Study dates	Not reported
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes – double blind plus open label phase in full trial • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? ITT population, p values SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias : Low

Bibliographic reference	**Wilkinson D, Doody R, Helme R, Taubman K, Mintzer J, Kertesz A Pratt M (2003) Donepezil in vascular dementia a randomized placebo=-controlled study, Neurology, 61, 479-486**
Study type	A randomised placebo controlled multi centre, international, double-blind placebo controlled parallel group trial to evaluate the efficacy and tolerability of donepezil in people with vascular dementia (Donepezil308)
Participants	Inclusion criteria: 616 men or non-pregnant women aged ≥ 40 years with a diagnosis of possible or probable

Bibliographic reference	**Wilkinson D, Doody R, Helme R, Taubman K, Mintzer J, Kertesz A Pratt M (2003) Donepezil in vascular dementia a randomized placebo=-controlled study, Neurology, 61, 479-486**
	vascular dementia (according to NINDS--AIREN criteria)> 3 months duration; participants were required to show clinical and radiological evidence of cerebrovascular disease and people with stable (controlled for at least 3 months) risk factors of hypertension, type 1 and type 2 diabetes, cardiac disease or stroke were enrolled Exclusion: Evidence of other neurodegenerative disorders ; Alzheimer's dementia or other conditions not associated with CVD; prior diagnosis of AD; cognitive impairment due to stroke or other CVD; MMSE > 26 or <10; occurrence of new strokes in 28 days prior to study entry; major depression or other psychiatric disorder;
Patient characteristics	N= 616 (5mg n=208; mean age = 74.7 ± 8.65 years ; MMSE = 21.8 ± 4.33; 10mg n= 215; mean age = 75.7 ± 8.80 years; MMSE = 21.5 ± 4.40; placebo n = 193; mean age = 74.4 ± 8.34 years; MMSE = 22.2 ± 4.17)
Intervention	Donepezil 5mg per day. Donepezil 10mg given per day. Patients in this arm received 5mg for first 4 weeks.
Comparison	Matched placebo
Outcome measures	Cognitive outcomes at 24 weeks (ADAS-cog; MMSE); Global assessment at 24 weeks (CIBICplus and CDR-SB); Functional assessment at 24 weeks(ADFACS); Withdrawal due to adverse events
Study dates	June 1997 to September 2001
Comments	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How precise was the outcome effect? How large was the treatment effect? P values SEs, results in text, small sample size • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Primary outcomes only presented in figures Overall risk of bias: High

E.8 Drugs that may worsen cognitive decline

E.8.1 Drugs that may cause cognitive decline

- What drugs that may worsen cognitive decline are commonly prescribed in people diagnosed with dementia?
- What are the most effective tools to identify whether drugs may be the cause of cognitive decline in someone suspected of having dementia?

Bibliographic reference	**Salahudeen MS, Duffull SB, Nishtala PS (2015) Anticholinergic burden quantified by anticholinergic risk scales and adverse outcomes in older people: a systematic review, BMC Geriatrics, 15(31)**
Study type	Systematic review
Aim	To compare anticholinergic burden quantified by anticholinergic risk scales and evaluate associations with adverse outcomes in older people
Population characteristics	7 anticholinergic risk scales were included
Inclusion/ exclusion criteria	Inclusion: Full text studies reporting the use of expert opinion quantification tools / scales to measure anticholinergic burden Studies of either sex , people with a mean age of 65 years or older living in primary care, nursing homes or hospitals
Assessment scales	• Anticholinergic Drug Scale (ADS)- 0-3 point scale ranking drugs on expert opinion • Anticholinergic Burden Classification (ABC) – 0-3 point scale based on SAA and expert opinion • Clinician rated Anticholinergic Score (CrAS) – 0-3 point scale based on pre-existing published anticholinergic scales and expert opinion • Anticholinergic Risk Scale (ARS) – 0-3 point scale based on extensive literature review and expert opinion • Anticholinergic Burden Scale (ACB) – 0-3 point scale based on published data and expert opinion • Anticholinergic Activity Score (AAS) – 0-4 point scale based on existing evidence and expert opinion • Anticholinergic Loading Scale (ALS) – 0-3 point scale based on pre-existing anticholinergic scales and expert opinion
Location	Papers were English language but review did not restrict to locations
Outcomes measures	ADS (originally referred to as CrAS)- validated for adverse outcomes relating to cognitive, functional, risk of hospitalisation and mortality ARS validated for outcomes relating to cognitive, functional, quality of life, length of hospital stay, mortality ABS validated for adverse outcomes relating to cognition and physical functioning AAS validated for adverse outcomes relating to cognition

Bibliographic reference	Salahudeen MS, Duffull SB, Nishtala PS (2015) Anticholinergic burden quantified by anticholinergic risk scales and adverse outcomes in older people: a systematic review, BMC Geriatrics, 15(31)
	ACL validated for adverse outcomes relating to cognition Validated outcome measures for ACB were not reported
Authors conclusion	There is not one individual standardised tool to measure cognitive burden although cohort studies have shown higher anticholinergic burden is associated with negative brain effects, poorer cognition and functional status
Source of funding	Not reported
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? MEDLINE, EMBASE, PSYCINFO • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Citation searching • Was a list of studies (Included and excluded) provided? Includes only • Were the characteristic of the included studies provided? Summarised in text and summary table • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? N/a • Were the methods used to combine the findings of studies appropriate? Yes- composite score based on individual results • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes- no competing interests Overall quality: Moderate

Bibliographic reference	Ancelin ML, Aretero S, Portet F, Dupuy AM, Touchon J, Ritchie K (2006) Non-degenerative mild cognitive impairment in elderly people and use of anticholinergic drugs: longitudinal cohort study, BMJ, 332 (7539) 455-459
Study type	Longitudinal cohort
Aim	To assess whether drug induced anticholinergic burden is associated with cognitive dysfunction
Population characteristics	N=372
Inclusion/ exclusion criteria	Inclusion: • People aged greater than 60 years

Bibliographic reference	Ancelin ML, Aretero S, Portet F, Dupuy AM, Touchon J, Ritchie K (2006) Non-degenerative mild cognitive impairment in elderly people and use of anticholinergic drugs: longitudinal cohort study, BMJ, 332 (7539) 455-459
	• Without dementia (DSM IIIR)
Assessment scales and method	• Calculated an anticholinergic burden classification using both serum radioreceptor assay and summation of estimated clinical effects of specific drugs • Conducted an extensive review of literature. And construct a table associating known anticholinergic drugs with serum anticholinergic activity • A pharmacologist, physician and biologist examined each participants records and classified anticholinergic burden from 0-3 (0=no anticholinergic drugs used; 1=drugs used with no likely effect; 2=drugs used with low effect; 3=drugs used with high effect)
Outcomes measures	Cognitive function – computerised neuropsychiatric examination- assessing primary memory, verbal and visuospatial , secondary memory, language skills, reaction time, reasoning, attention, primary memory, secondary verbal and spatial memory, implicit memory , visuospatial ability)
Authors conclusion	Elderly people taking anticholinergic drugs had significant deficits in cognitive functioning

Bibliographic reference	Boustani M, Campbell N, Munger S, Maidment I, Fox C (2008) Impact of anticholinergics on the aging brain: a review and practical application, Aging Health, 4 (3) 311-320
Study type	Cross sectional
Aim	To review the literature regarding the prevalence of anticholinergics and relationship between anticholinergic exposure and cognitive impairment. To offer a practical guide for the use of anticholinergics, to enhance the safety and quality of prescribing these medications for older adults
Population characteristics	N=3013; mean age=73.4 years; 66% female
Inclusion/ exclusion criteria	Cohort of older adults attending primary care clinics in Indianapolis
Assessment scales and method	• Searched Medline database from 1966 to 2007 for any study measuring anticholinergic activities of drugs and evaluated association between anticholinergic activities and cognitive function in older adults • Extracted the methods from each study, methods used to determine anticholinergic activity and list of medications with anticholinergic activity associated with negative cognitive effects • List presented to an interdisciplinary team of experts (geriatricians, geriatric pharmacists, geriatric psychiatrists, general physicians, aging brain researchers)

Bibliographic reference	Boustani M, Campbell N, Munger S, Maidment I, Fox C (2008) Impact of anticholinergics on the aging brain: a review and practical application, Aging Health, 4 (3) 311-320

	• The interdisciplinary team categorised medications into three classes (mild, moderate and severe negative anticholinergic effects)
	• The team established a scoring system:
	  ○ Drugs with possible anticholinergic effect (as identified by SAA or in vitro affinity) but with no clinically relevant cognitive effects - score=1;
	  ○ Drugs with established and clinically relevant cognitive anticholinergic effects – score 2 or 3 (based on blood brain barrier permeability and association with delirium)
	• Total added score of different drugs taken by the patient determined the accumulative anticholinergic burden scale

Outcomes measures	Quality of life
Authors conclusion	More studies are needed to validate the anticholinergic cognitive burden scale

Bibliographic reference	Carnahan RM, Lund BC, Perry PJ, Pollock BG, Culp KR (2006) The Anticholinergic Drug Scale as a measure of drug-related anticholinergic burden: Associations with Serum Anticholinergic Activity, Journal of Clinical Pharmacology, 46: 1481-1486
Study type	Cross sectional
Aim	To ascertain if Anticholinergic Drug Scale (ADS) scores are associated with serum anticholinergic activity (SAA) and if the ADS could be modified to more accurately predict SAA
Population characteristics	Initial analysis n=201 mean age 86 years 77% female Modification analysis n=297 mean age 86 years 78% female
Inclusion/ exclusion criteria	Inclusion: • People admitted to a long term care facility for at least 30 days • Ability to read, speak and write English Exclusion: • Presence of implanted defibrillator • Surgical alteration of urinary tract or bladder • Diagnosis of psychosis, head trauma, conditions resulting in increased cranial pressure, toxin related neurological disorders at screening visit • Delirium upon initial assessment
Measure of anticholinergic load	Measure of SAA:

Bibliographic reference	Carnahan RM, Lund BC, Perry PJ, Pollock BG, Culp KR (2006) The Anticholinergic Drug Scale as a measure of drug-related anticholinergic burden: Associations with Serum Anticholinergic Activity, Journal of Clinical Pharmacology, 46: 1481-1486
	• Serum drawn and stored at -20c and assayed using radioreceptor assay ADS scores: • Based on a pilot study originally reported in Han (2002) and applied a modified criteria in current assessment Original method-development of original scale: • Data on medications taken from hospital records of medications received at time of enrolment • Information included route, frequency, dates of dose and frequency changes • Used to calculate 3 measures of medication exposure (Summers Drug Risk Number- based on 62 medications 3=highest ACH potency • Incorporation of CrAS (list of 340 new medications- based on literature and expert opinion) to incorporate newer drug classifications; • Number of anticholinergic medications based on the count of all medications with clinician rated score > 0 • Number of non-anticholinergic medications was count of all medications with a clinician rated score=0 Modified method: • Medication lists determined based on participants medication on the day of SAA blood draw • Anticholinergic potency of each medication was rated using ADS (0=no known anticholinergic properties; 1=potentially anticholinergic as evidenced by receptor binding; 2=anticholinergic adverse events sometimes noted; 3=markedly anticholinergic
Outcomes measures	• SAA
Authors conclusion	This study replicated findings of association of ADS with SAA

Bibliographic reference	Ehrt U, Broich K, Larssen JP, Ballard C, Aarsland D (2010) Use of drugs with anticholinergic effect and impact on cognition in Parkinson's disease: a cohort study, BMJ, 81, 160-65
Study type	Prospective longitudinal cohort
Aim	To assess the use and impact of drugs with anticholinergic activities in people with PD to ascertain if avoiding drugs which accelerate cognitive decline may be a key part of optimal therapy
Population characteristics	Total N=235 PD patients receiving agents with anticholinergic activity N=102 mean age=75.28 years; 53.9% female PD patients not receiving agents with anticholinergic activity N=133 mean age=74.2 years; 49.6% female
Inclusion/ exclusion	Inclusion:

Bibliographic reference	Ehrt U, Broich K, Larssen JP, Ballard C, Aarsland D (2010) Use of drugs with anticholinergic effect and impact on cognition in Parkinson's disease: a cohort study, BMJ, 81, 160-65
criteria	• People with PD drawn from a longitudinal prevalence study • People with dementia according to DSM IIIR if dementia occurred at least 1 year after onset of PD
Assessment scales and method	• Anticholinergic activity of 107 medications commonly prescribed to older adults detected using an in vivo radioreceptor assay and grade from no AA (0); no or minimal AA (0/+); low AA (+); moderate AA (++); high AA (+++) • Data was transformed into 0-4 point categorical scores • AA scores for drugs which were not included in the study were specified independently by two authors using available evidence from the literature • Scores from each patient were summed up and the sum score was considered the total AA load at each assessment point • A total AA load for the 8 year observation period a was calculated by adding together the A load at baseline plus 2 follow up assessments
Outcomes measures	Cognitive function (MMSE)
Authors conclusion	Findings suggest an association between anticholinergic drug use and cognitive decline in PD

Bibliographic reference	Han L, Agostini JV, Allore HG (2008) Cumulative Anticholinergic Exposure Is Associated with Poor Memory and Executive Function in Older Men, Journal of the American Geriatric Society, 56 (12) 2203-2210
Study type	Prospective cohort
Aim	To assess the cumulative exposure to anticholinergic medications and executive function in older men To evaluate the specificity of a clinician s' consensus based measure of total anticholinergic burden in predicting deficits in memory and executive function beyond effects of concomitant medication
Population characteristics	N=544; mean age=74.4 years
Inclusion/ exclusion criteria	Men aged 65 years or older with diagnosed hypertension
Assessment scales and method	• Clinicians rated anticholinergic score • Two authors reviewed a complete list of the generic medications used in the study cohort • An existing anticholinergic score based on the original anticholinergic drug list was assigned to each medication • Therapeutic classifications were reviewed based on the American Hospital Formulary Service system for medications without an available score

Bibliographic reference	Han L, Agostini JV, Allore HG (2008) Cumulative Anticholinergic Exposure Is Associated with Poor Memory and Executive Function in Older Men, Journal of the American Geriatric Society, 56 (12) 2203-2210
	• Classes of unrated medication judged to have no anticholinergic activity were assigned a score of 0 • Three geriatricians conducted an independent rating on the remaining unrated medications and the median value was adopted as the final anticholinergic score for each medication
Outcomes measures	Cognitive function (verbal recall test) Functional assessment (IADL)
Authors conclusion	Cumulative anticholinergic exposure was associated with poorer performance on short term verbal memory and executive function

Bibliographic reference	Rudolph JL, Salow MJ, Angelini MC, McGlinchy RE (2008) The anticholinergic risk scale and anticholinergic adverse effects in older persons, American Medical Association, 168 (5) 518-513
Study type	Retrospective and prospective cohort
Aim	To validate the anticholinergic risk scale (ARS) against clinical symptoms of anticholinergic reactions in a retrospective evaluation and a prospective assessment of an older age primary care population
Population characteristics	Retrospective cohort GEM clinic n=132 mean age=78.7 years (97.7% male) Prospective cohort Primary care n=117 mean age=71.5 years (100% male)
Inclusion/ exclusion criteria	Inclusion: • Aged 65 years or over attending Geriatric Evaluation and Management clinic or primary care Exclusion: • Not reported
Assessment scales and method	• Independent review of the 500 most prescribed medications in the Veterans Affairs Boston Healthcare system by 1 geriatrician and 2 geropharmacists to identify medications with known potential to cause adverse events • Medicines were entered into the drug screening program database, input into an evidence based review of all Food and Drug Administration prescribed medications, to determine rates of anticholinergic adverse effects compared to placebo; performed a MEDLINE search to ascertain what literature was available regarding anticholinergic adverse effects • Panel members ranked the resulting information on a 0-3 point scale according to anticholinergic potential (0=limited or none; 1=moderate; 2=strong; 3=very strong) • Individuals ARS score was calculated as the sum of ARS rankings assigned for each medication the patient was taking
Outcomes measures	• Anticholinergic adverse effects (central and peripheral adverse effects)

Bibliographic reference	Rudolph JL, Salow MJ, Angelini MC, McGlinchy RE (2008) The anticholinergic risk scale and anticholinergic adverse effects in older persons, American Medical Association, 168 (5) 518-513
Authors conclusion	Higher ARS scores are associated with significantly increased risk of anticholinergic adverse effects in older patients

Bibliographic reference	Sitirronarit G, Ames D, Bush AL, Faux N, et al (2010) Effects of anticholinergic drugs on cognitive function in older Australians: Results from the AIBL study, Dementia and Geriatric Cognitive Disorders, 31 173-178
Study type	Cross sectional
Aim	To examine the relationship between anticholinergic load of medications and cognition in people with mild cognitive impairment Alzheimer's disease and healthy controls
Population characteristics	AD n=211 mean age 78.0 years 62% female MCI n=133 mean age 75.7 years 56% female Healthy controls n=768 mean age=70.0 years 57|% female
Inclusion/ exclusion criteria	Inclusion: • Aged 60 years or over • Fluent English • Stable medications • People with AD defined by NINCDS–ADRDA • MCI categorised by reduced cognitive capacity Exclusion: • Non AD dementia, schizophrenia, bipolar, significant current depression, Parkinson's disease, cancer in last 2 years, symptomatic stroke • Regular alcohol use (exceeding 2 standard drinks per day for women or 4 drinks per day for men)
Measure of anticholinergic load	• Medication exposure assessed by interview • Medications listed and assigned scores based on anticholinergic load (ACL) scale • ACL scale developed based on serum anticholinergic activity (SAA) and clinician rated anticholinergic scores • For published data scores were transformed to an ordinal scale (0=no effect to 3=strong effect) • A loading value (0-3) based on independent ratings by a geriatrician, 2 psychiatrists and clinical pharmacologist were applied for medications not previously classified by studies of anticholinergic medications. The median ranking was used if there was any discordance

Bibliographic reference	Sitirronarit G, Ames D, Bush AL, Faux N, et al (2010) Effects of anticholinergic drugs on cognitive function in older Australians: Results from the AIBL study, Dementia and Geriatric Cognitive Disorders, 31 173-178
Outcomes measures	• Assessment of cognitive performance (California verbal learning test; CogState; MMSE; Boston Naming test; Rey Complex figure; Stroop; Deis Kaplan Executive Function) • Assessment of mood measures
Authors conclusion	Findings demonstrated a modest negative impact of drugs with anticholinergic load for healthy controls

E.9 Non-pharmacological interventions for dementia

E.9.1 Non-pharmacological interventions for people living with dementia

- What are the most effective non-pharmacological interventions for supporting cognitive functioning in people living with dementia?
- What are the most effective non-pharmacological interventions for supporting functional ability in people living with dementia?
- What are the most effective non-pharmacological interventions to support wellbeing in people living with dementia?
- What are the most effective methods of supporting people living with dementia to reduce harm and stay independent?

E.9.1.1 Cognitive stimulation therapy

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Alves (2014)	N=17 (13F, 4M) Global Deterioration Scale (GDS) of between 3 and 5 Mean age=78.82 (SD 10.39) Mean MMSE=17.94 (SD 4.56)	Cognitive stimulation (group)	Usual care	Cognition: MMSE Depression: Geriatric Depression Scale Quality of life: QoL-AD Carer burden: Zarit Burden Interview	Post-intervention: 6 weeks	Low
Alves (2014)	N=17 (13F, 4M) Global Deterioration Scale (GDS) of between 3 and 5 Mean age=78.82 (SD 10.39) Mean MMSE=17.94 (SD 4.56)	Cognitive stimulation (group)	Usual care	Cognition: MMSE Depression: Geriatric Depression Scale Quality of life: QoL-AD Carer burden: Zarit Burden Interview	Post-intervention: 6 weeks	Low
Baldelli (1993)	N=23 (23F, 0M) Alzheimer's (SDAT) Mean MMSE 20.6 (SD 4.9) Mean age 84.5 (range 75-94)	Reality orientation (group)	Usual care	Cognition: MMSE Depression: GDS-30 ADL: Stewart ADL scale	Post-intervention: 4 weeks Long-term follow-up: 3 months	Moderate: No details on randomisation method or assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	All resident in institution					
Baldelli (2002)	N=87 (61F, 26M) 'Degenerative senile dementia of the Alzheimer's type (SDAT)' (N=46) and "vascular multi-infarct dementia" (N=41) Mean MMSE 20.7 (SD 3.0) Mean age 80.0 (range 65-97) Resident in sub-acute care nursing home	Reality orientation + physical therapy programme (group)	Physical therapy programme	Cognition: MMSE Depression: Geriatric Depression Scale (GDS 30) ADL: Barthel Index	Post-intervention: 1 month Long-term follow-up: 3 months	Moderate: No details on randomisation method or assessor blinding reported
Bottino (2005)	N=13 (9F, 4M) 'Mildly impaired probable Alzheimer's diagnosis' All participants taking rivastigmine 6-12mg/day for 2 months Mean MMSE 22.31 (SD 3.61; range 16-28) Age 73.7 (range 62-83) Out-patients	Cognitive stimulation (group)	Usual care	Cognition: MMSE ADL: IADL	Post-intervention: 5 months	Low
Breuil (1994)	N=61 (37F, 24M) Diagnosis of dementia (DSM-III) (90% have Alzheimer's Disease) Age 77.1 (range 61-93) Mean MMSE 21.5 (range 9-29) Out-patients	Cognitive stimulation (group)	Usual care	Cognition: MMSE	Post-intervention: 5 weeks	Moderate: No details on randomisation method reported
Buschert	N=15 (mild Alzheimer's	Multi-component cognitive	Usual care	Cognition: MMSE	Post-intervention:	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
(2011)	disease) 8F, 7M Mean MMSE 24.9 (SD 1.6; range 22-27) All on stable doses of AChEIs or memantine Age 75.9 (SD 8.1) Out-patients	intervention - emphasis on cognitive stimulation (group)		Quality of life: QoL-AD Depression: Montgomery Asberg Depression Rating Scale	6 months	
Camargo (2015)	N=14 (5F, 9M) Mild to moderate Alzheimer's disease, on stable doses of donepezil Mean MMSE 22.43 (SD 2.91) Mean age 80.15 (SD 6.18)	Reality orientation + donepezil (individual)	Donepezil only	Cognition: MMSE	Post-intervention: 6 months	High: Patients assigned to groups based on their order of entry in to the trial
Capotosto (2017)	N=39 (27F, 12M) Diagnosis of mild or moderate dementia (Alzheimer's, vascular or mixed) Mean CDR: 2 (SD 0.67) for control and 2 (SD 0.68) for intervention Mean age: 86.52 (SD 5.55) for control and 88.25 (SD 5.15) for intervention Two residential homes	Cognitive stimulation (group)	Active control group	Cognition: MMSE Quality of life: QoL-AD Depression: Cornell Scale for Depression in Dementia ADL: Disability Assessment for Dementia	Post-intervention: 7 weeks	High: No details on randomisation or blinding methods reported; unclear post-intervention time
Chapman (2004)	N=54 (29F, 25M) Probable AD, on stable dose of donepezil for at least 3 months Mean MMSE 20.87 (SD	Cognitive stimulation + donepezil (group)	Donepezil only	Cognition: MMSE ADL: Texas Functional Living Scale BPSD: NPI - Irritability and Apathy	Long-term follow-up: 10 months	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	3.55, range 12-28) Mean age 76.4 (range 54-91) Living at home			Quality of Life: QoL-AD		
Coen (2011)	N=27 (14F, 13M) Dementia - MMSE 10-23 Mean MMSE: 16.9 (SD 5.0) Mean age: 79.8 (SD 5.6) Groups ran in 2 long term care facilities and a private nursing home	Cognitive stimulation (group)	Usual care	Cognition: MMSE Quality of life: QoL-AD Depression: CAPE	Post-intervention: 7 weeks	Moderate: No details on randomisation method or assessor blinding reported
Cove (2014)	N=47 (22F, 25M) DSM-IV diagnosis of dementia, MMSE of 18-30 Mean MMSE: 22.8 (SD 3.38) Mean age: 77.3 (SD 7.0) Living in the community	Cognitive stimulation (group)	Usual care	Cognition: MMSE Quality of life: QoL-AD	Post-intervention: 14 weeks	Moderate: No details on assessor blinding reported
Ferrario (1991)	N=19 (8F, 11M) Elderly patients with cognitive disturbances MMSE range 18-25 Age 82.5 (SD 5.2) Resident in institution	Reality orientation (group)	Usual care	Cognition: CAPE I/O ADL: MOSES self-care functioning BPSD: MOSES - irritable, withdrawn Depression: MOSES	Post-intervention: 21 weeks	Moderate: No details on randomisation method or assessor blinding reported
Kim (2016)	N=53 (37F, 16M) NINCDS-ADRDA criteria for probable Alzheimer's disease Mean MMSE: 18.04 (SD	Multidomain cognitive stimulation (group)	Usual care	Cognition: MMSE Quality of life: QoL-AD Depression: Geriatric Depression Scale Clinical dementia rating	Post-intervention: 6 months	Moderate: No details on randomisation method or assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	5.58) Mean age: 78.47 (SD 1.27)			scale		
Mapelli (2013)	N=20 CDR 1-2, MMSE 14-24 Mean MMSE: 19.5 (SD 3.5 Mean age: 83.7 (SD 4.64)	Cognitive stimulation (group)	Usual care	Cognition: MMSE BPSD: Behave-AD Clinical dementia rating scale	Post-intervention: 8 weeks	Moderate: No details on randomisation method or assessor blinding reported
Onder (2005)	N=156 (113F, 43M) Probable Alzheimer's Disease, on donepezil for at least 3 months Mean MMSE 20.1 (SD 3.1) Mean age 75.8 (SD 7.1) Living at home	Reality orientation + donepezil (individual)	Donepezil only	Cognition: MMSE ADL: Barthel Index BPSD: NPI Carer burden: Carer Burden Inventory	Post-intervention: 25 weeks	Low
Orgeta (2015)	N=356 (165F, 191M) DSM-IV diagnosis of dementia, MMSE>10 Mean MMSE: 21.2 (SD 4.3) Mean age: 78.2 (SD 7.5) Living in the community	Cognitive stimulation (individual)	Usual care	Cognition: MMSE BPSD: NPI ADL: BADLS Quality of life: QoL-AD Depression: HADS Carer burden: NPI (distress)	Post-intervention: 13 weeks Long-term follow-up: 26 weeks	Low
Orrell (2014)	N=236 (150F, 86M) DSM-IV diagnosis of dementia Mean MMSE: 17.8 (SD 5.5) Mean age: 83.1 (SD 7.6) 43% living in care homes	Maintenance cognitive stimulation (group - after cognitive stimulation)	Usual care (after cognitive stimulation)	Cognition: MMSE BPSD: NPI ADL: ADCS-ADL Quality of life: QoL-AD	Post-intervention: 6 months	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Paddick (2017)	N=34 (29F, 5M) DSM-IV diagnosis of mild or moderate dementia Median age: 80.0 (IQR 76.5, 85.3) CDR 1 (35.3%) and 2 (64.7%) Living at home	Cognitive stimulation – immediate start (group)	Cognitive stimulation – delayed start (group)	Cognition: Alzheimer's Disease Assessment Scale – Cognitive	Post-intervention: week 10-11 Only T2 was taken to make sure that the 'delayed start' group had not received the intervention	High: Evidence of selective reporting of outcome measures
Requena (2006)	N=86 (61F, 25M) Alzheimer-type dementia (severe dementia excluded) MMSE 21.3 Age 77 (SD 7.5) Attending day-care centre	Cognitive stimulation + donepezil (group)	Donepezil only	Cognition: MMSE Depression: GDS-30	Post-intervention: 24 months	Moderate: No details on randomisation method reported
Spector (2001)	N=35 Diagnosis of dementia according to DSM-IV criteria MMSE 13.1 (SD 4.4) Age 85.7 (SD 6.7) Living at home: 12; living in residential home: 23	Cognitive stimulation (group)	Usual care	Cognition: MMSE Depression: Cornell Scale for Depression in Dementia BPSD: Behavioural Rating Scale (CAPE) Carer burden: Relatives Stress Scale	Post-intervention: 7 weeks	Low
Spector (2003)	N=201 (158F, 43M) Dementia (DSM-IV criteria) - MMSE 10-24 MMSE: 14.4 (SD 3.8) Age: 85.3 (SD 7.0) Groups ran in 18 residential homes; 5 day centres	Cognitive stimulation (group)	Usual care	Cognition: MMSE Depression: Cornell Scale for Depression in Dementia BPSD: Behavioural Rating Scale (CAPE) Quality of life: QoL-AD	Post-intervention: 7 weeks	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Wallis (1983)	N=31 'Demented / organic' Age 69.8 (range 38-95) All residents in long-stay psychiatric hospital	Reality orientation (group)	Usual care	Cognition: Royal College of Physicians mental test score	Post-intervention: 3 months Long-term follow-up: 4 months	Low
Woods (1979)	N=18 'disorientated', significant memory impairment Age 76.6 (range 61-90) All living in specialist residential homes for people with dementia	Reality orientation (group)	Usual care	Cognition: Wechsler Memory Scale; composite Information & Orientation test	Post-intervention: 20 weeks	Low
Yamanaka (2013)	N=56 (44F, 12M) Diagnosis of dementia, MMSE>10 Mean MMSE: 16.94 (SD 0.8) Mean age: 83.9 (SD 6.0)	Cognitive stimulation (group)	Usual care	Cognition: MMSE Quality of life: QoL-AD, EQ-5D	Post-intervention: 7 weeks	Low

E.9.1.2 Cognitive training

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Amieva (2016)	653 people with Alzheimer's disease. Mean age of 78.7 (SD 6.7 at baseline), and mean MMSE of 21.5 (SD 3.1)	Cognitive training consisting of a structured program of a set of standard tasks designed to involve various cognitive functions (group)	Usual care	Cognition: ADAS-cog Quality of life: QoL-AD ADL: DAD BPSD: NPI Depression: MADRS Carer burden: Zarit Burden Interview	Post-intervention: 3 months Long-term follow-up: 2 years	Low
Bergamaschi (2013)	32 people with Alzheimer's disease (NINCDS-ADRDA).	Cognitive training (group)	Usual care	Cognition: MMSE ADL: Katz Index	Post-intervention: 12 months	Moderate: No details on randomisation method or assessor blinding

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Mean age of 77.96 (SD 5.3), and mean MMSE of 21.10 (2.48)			Depression: CSDD		reported
Cahn-Weiner (2003)	34 participants with mild probable AD and a mean MMSE score of 25.1 (SD 1.7) for control, and 24.3 (SD 2.2) for intervention	Memory training programme of six weeks' duration to improve word-list recall and recognition (group)	Usual care	Cognition: Everyday Memory Questionnaire ADL: Physical Self-Maintenance Scale	Post-intervention: 8 weeks Long-term follow-up: 16 weeks	Low
Davis (2001)	37 patients (16 men, 21 women) with probable AD and a mean MMSE score of 22.78 (SD 4.45) for control, and 21.84 (SD 4.03) for intervention	One hour of individual training weekly for five weeks on face-name associations and recall using spaced retrieval, plus home practice (0.5 hours/d for 6 days/week) on attention-training exercises (individual)	'Mock' intervention consisting of one-hour clinic visit weekly for unstructured conversation and questioning with examiner and viewing of health-related videos	Cognition: MMSE Depression: Geriatric Depression Scale	Post-intervention: 6 weeks	Moderate: No details on randomisation method or assessor blinding reported
De Luca (2016)	20 people with mild to moderate dementia. Mean age of 77.9 (SD 5.2), and mean MMSE of 25.2	Web-based cognitive training (individual)	Usual care	Cognition: MMSE ADL Depression: Geriatric Depression Scale	Post-intervention: 6 weeks	High: Patients assigned to groups based on their order of entry in to the trial
De Vreese (1999)	24 people with mild to moderate AD (Clinical Dementia Rating score 1 to 2) according to NINCDS-ADRDA criteria. Mean MMSE of 17.2 (SD 3.3)	Cognitive training in twice-weekly sessions lasting 45 minutes and targeting memory, language and executive function, with home practice facilitated by carer, for 3 months	Usual care	Cognition: MMSE ADL: IADL scale	Post-intervention: 26 weeks	Moderate: No details on randomisation method or assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
		(individual)				
Galante (2007)	12 participants who met criteria for mild AD (according to NINCDS-ADRDA criteria, with MMSE 19 to 26 or MODA 70 to 90) and who were treated with AChE-I for at least 3 months	Computerised cognitive training (n=7): 12 individual 60-minute sessions, 3 times per week, for 4 weeks. 15 computer tasks delivered using TNP software at a fixed order for all participants (individual)	12 individual 60-minute sessions, 3 times per week, for 4 weeks. Participants attended a semi-structured interview on current affairs and relevant events of their own life history	Cognition: MMSE ADL: BADLS Depression: Geriatric Depression Scale	Post-intervention: 5 weeks Long-term follow-up: 6 months	High: No details on randomisation method or assessor blinding reported. Post-hoc exclusion of participant for 'poor compliance'
Heiss (1993)	80 patients meeting NINCDS-ADRDA criteria for probable AD of mild to moderate severity (MMSE 14 to 25). Mean MMSE of 20.4 (SD 4.3)	Computerised cognitive training covering memory and perceptual and motor tasks in twice-weekly sessions (individual)	Social support only	Cognition: MMSE	Post-intervention: 25 weeks	High: No details on randomisation method or assessor blinding reported. High dropout rate during study
Huntley (2016)	30 participants with mild Alzheimer's disease based on NINCDS-ADRDA criteria. MMSE >22 Intervention (mean age 80.13 years; mean MMSE 25.93) Control (mean age 79.4 years; mean MMSE 26)	18 sessions of training over 8 week period covering digit span sequence training	18 sessions of an active control covering a fixed non-adaptive unstructured three digit span	Cognition: MMSE	Post-intervention 8 weeks	Moderate: Limited reporting of methods, randomisation details not reported
Koltai (2001)	24 participants (22 completed the study) with mild/moderate dementia (scoring 0.5 to	Memory and coping programme in individual or group sessions	Usual care	Cognition: MMSE Depression: Geriatric Depression Scale	Post-intervention: 7 weeks	Moderate: No details on randomisation method or assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	1.0 on the Clinical Dementia Rating)	(group/individual)				
Lee (2013)	13 participants with early Alzheimer's disease. Mean MMSE 16.5 (SD 3.7) and mean age 77.7 (SD 6.1)	Learning-based memory training programs (individual)	Usual care	Cognition: MMSE ADL: Barthel Index Depression: Geriatric Depression Scale	Post-intervention: 3 months	Moderate: No details on randomisation method or assessor blinding reported
Loewenstein (2004)	44 participants meeting NINCDS-ADRDA criteria for dementia and on stable dose of an AChE-I and with a mean baseline MMSE score of 24.5 (SD 4.5) for control and 23.4 (SD 2.9) for intervention	Cognitive rehabilitation training (individual)	Usual care	Cognition: Informant Questionnaire of the Cognitive Decline in the Elderly Scale ADL: Bayer Activities of Daily Living Scale Depression: Centre for Epidemiological Studies - Depression Scale Carer burden: RMBPC (reaction)	Post-intervention: 16 weeks Long-term follow-up: 28 weeks	Moderate: No details on randomisation method or assessor blinding reported
Quayhagen (1995)	79 community-dwelling persons with mild to moderate AD (scoring at least 90 on the Mattis Dementia Rating Scale) and their family carers	One hour daily of cognitive training facilitated by carer, using tasks covering memory, problem-solving and conversational fluency, and weekly home visits by therapist (individual)	Usual care	Cognition: Mattis Dementia Rating Scale	Post-intervention: 13 weeks Long-term follow-up: 38 weeks	High: No details on randomisation method or assessor blinding reported. Evidence of selective reporting of outcome measures
Quayhagen (2000)	103 people (65 men, 38 women) with dementia (AD, vascular dementia or Parkinson's dementia) in the mild or moderate stage (scoring	Training on memory, problem-solving and conversational fluency for one hour daily, 5 days a	Usual care	Carer burden: RMBPC (reaction)	Post-intervention: 12 weeks	Moderate: No details on assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	over 100 on the Mattis Dementia Rating Scale)	week, facilitated by spouse, with support from therapist (individual)				

E.9.1.3 Cognitive rehabilitation

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Amieva (2016)	653 people with Alzheimer's disease. Mean age of 78.7 (SD 6.7 at baseline), and mean MMSE of 21.5 (SD 3.1)	Cognitive rehabilitation (individual)	Usual care	Cognition: ADAS-cog Quality of life: QoL-AD ADL: DAD BPSD: NPI Depression: MADRS Carer burden: Zarit Burden Interview	Post-intervention: 3 months Long-term follow-up: 2 years	Low
Clare (2010)	69 people (28 men, 41 women) with mild AD (MMSE > 18). Mean age 77.8 (SD 6.3)	Cognitive rehabilitation: eight weekly individualised CR sessions focusing on patient-derived personal goals. Sessions supported by components addressing practical aids and strategies, techniques for learning new information, practice in maintaining attention and techniques for stress management (individual)	Usual care	ADL: COPM performance rating Depression: HADS Quality of life: QoL-AD Carer burden: Relatives' Stress Scale	Post-intervention: 9 weeks Long-term follow-up: 6 months	Low
Clare (2017)	475 people with a diagnosis of Alzheimer's disease, vascular	Cognitive rehabilitation aimed at managing or reducing functional disability and	Usual care	ADL: Bangor Goal-Setting Interview Quality of life:	Post-intervention: 3 months Long-term follow-	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	or mixed dementia (MMSE≥18)	maximising engagement and social participation		DEMQOL Depression: HADS Carer burden: RSS	up: 9 months	
Seyun (2015)	43 people with a diagnosis of Alzheimer's disease and an MMSE>18	Cognitive rehabilitation to improve performance of a chosen IADL (individual)	Usual care	Cognition: MMSE ADL: Barthel Index Quality of life: QoL-AD	Post-intervention: 8 weeks	Moderate: No details on randomisation method or assessor blinding reported
Thivierge (2014) Additional data reported in Brunelle-Hamann (2015)	20 people with mild to moderate Alzheimer's disease. Mean age 80.0 (SD 5.6) and mean MMSE 21.8 (SD 2.4)	Cognitive rehabilitation involving the use of memory techniques to re-learn an IADL chosen by the participant and their carers (individual)	Usual care	Quality of life: DQoL BPSD: NPI Carer burden: Zarit Burden Interview	Post-intervention: 5 weeks Long-term follow-up: 13 weeks	Low

E.9.1.4 Self-management groups

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Laakonen (2016)	People diagnosed with dementia (based on national recommended diagnostic procedures) recruited from memory clinic Intervention (n=67; mean age =77.3 years; MMSE = 19.9) Usual care (n=69; mean age = 76.6 years; MMSE=21.7)	8 weekly sessions of self-management group rehabilitation lasting 4 hours in groups of 10 participants including people with dementia/ carers	Usual care	Quality of life: 15D Cognition: (CDR-SB; VF; CDT)	Post-intervention: 9 months	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Logsdon (2010)	Individual/carer dyads of people diagnosed with dementia (MMSE ≥ 18; physician diagnosis confirmation) ESML group (n=96; mean age = 77.1 years; MMSE= 23.2) Wait list (n=46; mean age = 70.4 years; MMSE= 24)	9 weekly sessions of early stage memory loss support groups, 90 min duration	Wait list control received educational materials about dementia and AD	Quality of life: QoL-AD Depression: Geriatric Depression Scale	Post-intervention: 9 weeks	Moderate: Outcome assessors not blinded
Quinn (2016)	People diagnosed with Alzheimer's disease, Vascular dementia or mixed dementia (ICD10) MMSE≥ 20 and carers Intervention (n=13; mean age =75.2 years; MMSE= 23.5) Treatment as usual (n=11; mean age =76.1 years; MMSE=23.8)	8 weekly self-management intervention (2 groups) lasting 90 minutes	Treatment as usual	Quality of life: EQ-5D Depression: HADS Anxiety: HADS	Post-intervention: 3 months Long-term follow-up: 6 months	Low

E.9.1.5 Reminiscence therapy

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Individual reminiscence therapy						
Eritz (2015)	Residents showing symptoms consistent with a diagnosis of	Life history intervention involving semi structured interviews with people	Control group (usual care)	Agitation: CMAI Quality of life: ADRQL	Post-intervention: 20 days	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	dementia (Based on Cognitive Performance Scale) Mean age = 85.98 years; mean CPS score = 4.17- moderate to severe dementia Life story intervention (n=38) Medical history (n=35)	living with dementia and/ or a proxy family carer or relative regarding residents' childhood, friends, personality & life events. Photographs from past/ artefacts. 5 staff members from place of residential care were also involved and completed a questionnaire on staff empathy. Intervention lasted for period it took to complete life history book (average 38.63 days)			Long-term follow-up: 46 days	
Lopes (2016)	Residents with cognitive impairment (MoCA 26 to 9) Intervention (n= 20; mean age = 83.85 years; MoCA = 14.35 – mild dementia) Control (n= 21; mean age = 83.62 years; MoCA= 13.62- mild dementia)	Individual reminiscence programme 5 weekly unstructured sessions, lasting 30-40 minutes using narrative reminiscence functions, to identify events most important in individuals' life facilitated by same therapist at each session	Control group (usual care)	Cognition: MoCA Depression: CSDD	Post-intervention: 5 weeks	Low
Subramaniam (2014)	Care home residents with a formal diagnosis of mild to moderate dementia (CDR) Life review (n= 11; mean age = 84.5 years; Mean CDR not reported) Control (n= 12; mean	Reminiscence therapy (life review) involving one hour session over 12 week period) an interactive session involving both person living with dementia/ therapist to produce a book of memories	Control (gift book) Therapist worked with carer only to produce a memory book gifted to person living with dementia	Quality of life: QoL-AD Depression: Geriatric Depression Scale	Post-intervention: 12 weeks	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	age = 88.3 years; mean CDR not reported		at end of study period.			
Van Bogaert (2013)	People with probable Alzheimer's disease (NINCDS-ADRDA) Intervention (n=41; mean age=83 years; MMSE not reported) Control (n=41; mean age = 85 years; MMSE not reported)	Individual reminiscence therapy based on SOICos model (structured reminiscence) delivered by 1 research nurse. 4 weekly sessions lasting 45 minutes (reminiscence section lasting 30 minutes)	Control (description not reported)	Cognition: MMSE Depression: GDS-30 BPSD: NPI	Post-intervention: 8 weeks	High: Participants sequential allocated to groups, outcome assessors not blinded
Joint reminiscence groups (person living with dementia & carer)						
Charlesworth (2016)	Community dwelling people diagnosed with dementia (CDR 0.5-3) and their carers Intervention 1 (n= 97; mean age = 79.8 years; MMSE= 16.3) Intervention 2 (n= 48; mean age = 79.8 years; MMSE = 16.3) Intervention 3 (n=97; mean age 79.3 years; MMSE = 17.5) Control (n= 47; mean age = 79.5 years; MMSE = 19.7)	Intervention 1 (Group reminiscence therapy-followed a structured programme (remembering yesterday caring today) involving 12 weekly sessions lasting up to 2 hours in community settings followed by covering themes across the lifespan) Intervention 2 No reminiscence therapy	Control group (usual care)	Quality of life: EQ-5D, QoL-AD Depression: HADS BPSD: NPI ADL: ADCS-ADL Carer burden: NPI-D	Post-intervention: 12 months	Low
Woods (2016)	Community residing people living with mild to moderate dementia (DSM-IV) plus their relative or other informal carer.	Remembering Yesterday Caring Today (RYCT) group sessions focusing on active and passive reminiscence by both carers and people living	Control group (usual care)	Quality of life: EQ-5D, QoL-AD ADL: Bristol Activities of daily living scale Depression: CSDD	Post-intervention: 3 months Long-term follow-up: 10 months	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
		with dementia. Weekly 2 hour sessions for 12 weeks followed by 7 monthly maintenance sessions				
Group reminiscence therapy						
Amieva (2016)	653 people with Alzheimer's disease. Mean age of 78.7 (SD 6.7 at baseline), and mean MMSE of 21.5 (SD 3.1)	Group reminiscence therapy	Usual care	Cognition: ADAS-cog ADL: DAD Quality of life: QoL-AD BPSD: NPI Depression: MADRS Carer burden: Zarit Burden Interview	Post-intervention: 3 months Long-term follow-up: 2 years	Low
Hsiesh (2010)	People diagnosed with mild to moderate dementia (CDR) Intervention (n=29; mean age = 77.9 years; MMSE not reported) Control (n=32; mean age = 77.25 years; MMSE not reported)	Group reminiscence therapy 12 sessions lasting 40-50 minutes per week	Control group (usual care)	Depression: GDS	Post-intervention: 3 months	Moderate: No details of randomisation method or assessor blinding reported
Ito (2007)	People diagnosed with vascular dementia Group reminiscence;(n=18; mean age = 82.9 years; MMSE= 15.8) Social contact (n=16; mean age = 81.9 years; MMSE= 16.6) Control (n=17; mean age = 82.1 years;	Group reminiscence approach (GRA) (RA conducted in a 1 hour session once a week for 3 months based on a structured program) Facilitated by 3 fixed specialists (chosen from either 3 occupational therapists; 3 medical social workers; psychologist; 2 speech	Control group (usual care)	Cognition: MMSE BPSD: MOSES	Post-intervention: 3 months	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	MMSE = 15.4)	therapists or a nurse)				
Tadaka (2007)	People with a diagnosis of Alzheimer's disease or vascular dementia (DSM IV; CDR 1 or 2) AD n=24 (intervention n=12; mean age =82.5 years; control n= 12; mean age =81.2 years) VaD n=36; (intervention n=18; mean age =85.3 years; control n= 18; mean age = 83.2 years)	Reminiscence therapy group session lasting 60-90 minutes once a week over 8 weeks Each group included 6 people with dementia;1 care worker; 2 specialists (trained public health nurse or clinical psychologist)	Control group (usual care)	Cognition: MMSE	Post-intervention: 8 weeks Long-term follow-up: 6 months	Moderate: No details of randomisation method or assessor blinding reported
Wang (2007)	People with a medical diagnosis of dementia (mild to severe CDR 1-3) Intervention (n=51; mean age = 79.6 years; CDR 1.39) Control ((n=51; mean age = 78.92 years; CDR 1.44)	8 group sessions once weekly lasting 60 minutes based on themes; 6 consecutive sessions of 8 – 10 people Led by one lead facilitator and one co facilitator	Control group (details not reported)	Cognition: MMSE Depression: CSDD	Post-intervention: 8 weeks	Moderate: No details of randomisation method reported
Individual and group reminiscence therapy						
Tanaka 2017	People in one geriatric health service facility with MMSE score of 15 to 16. Group therapy n =	Group therapy: 24 sessions conducted over 12 weeks, twice a week and composed of: reality orientation for 15 minutes, reminiscence for 35	Control group: usual care (daily living assistance and personal rehabilitation	Depression: GDS-5 Cognition: MMSE	Post-intervention: 12 weeks	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	20, mean age = 84.9, F/M=16/4. Individual therapy n = 20, mean age = 86.0, F/M= 19/1 Control n = 20, mean age = 86.9, F/M = 19/1.	minutes and physical activities for 10 minutes. Each group included 1 staff member and 3 to 5 participants. Individual therapy: 1 staff member per participant conducted session. Included reality orientation for 3 minutes, reminiscence therapy for 12 minutes and physical activity for 5 minutes. The intervention was modified to be meaningful for the participant.	for 20 minutes twice a week).			
Spiritual reminiscence programme						
Wu (2015)	People aged 65 years with mild (MMSE 21-24) to moderate (13-20) dementia	Spiritual reminiscence involved 6 weekly sessions lasting 1 hour. Content based on spiritual model of dementia. Groups comprised 3-6 people	Control group (details not reported)	Cognition: MMSE	Post-intervention: 8 weeks	Moderate: No details of randomisation method or assessor blinding reported

E.9.1.6 Occupational therapy

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Graff (2007)	People aged 65 years or over diagnosed with mild to moderate dementia (DSMIV; BCRS) and had a primary carer	10 sessions of occupational therapy at home over 5 weeks	Usual care	Quality of life: DQoL Depression: CSDD	Post-intervention: 6 weeks Long-term follow-up: 12 weeks	Low
Gitlin (2008)	People diagnosed with dementia	Tailored activity program (TAP)	Wait list control	Quality of life: QoL-AD Depression: CSDD	Post-intervention: 4 months	Moderate: No details of

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	(physician diagnosis and/or MMSE <24) and their carers Experimental (n=30; mean age = 80.8 years; MMSE= 12.2) Control (n=30; mean age = 78.0 years; MMSE= 11)	8 sessions, 6 home visits each lasting 90 minutes; 2 telephone conversations with OT lasting 15 minutes over 4 months		Carer burden: ZBI		randomisation method or assessor blinding reported
Gitlin (2010)	People diagnosed with dementia (NINCDS-ADRDA; MMSE ≤24) and their carers	Care of persons with dementia in their environment (COPE) Program. 10 sessions over 4 months with Occupational therapists. 1 face to face session and 1 telephone session with ban advance practice nurse	Telephone calls and educational information Up to three 20 minute phone calls from trained research staff-using scripts to ask about care challenges	ADL: Functional Independence measure Quality of life: QoL-AD Agitation: Agitated behaviour in Dementia	Post-intervention: 4 months	Low
Voigt-Radloff (2011)	Community dwelling people diagnosed with mild to moderate dementia (MMSE14-24) diagnosed with Alzheimer's disease or mixed type dementia (ICD-10)	Community occupational therapy in Alzheimer's disease (COTiD). 10 sessions of 1 hour duration over 5 weeks	1 hour of community occupational therapy semi structured consultation at home	Activities of daily living: Interview for Deterioration in Daily Living Activities in Dementia Depression: CSDD Quality of life: DQOL	Post-intervention: 6 weeks Long-term follow-up: 52 weeks	Low

E.9.1.7 Psychotherapy

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Burns (2005)	People with mild Alzheimer's disease (NINCDS-ADRDA; CDR 1; MMSE≥15)	Six sessions of psychodynamic interpersonal therapy delivered in individual's	Standard care (general advice regarding diagnosis and	Cognition: MMSE ADL: BADLS Depression: CSDD	Post-intervention: 6 weeks Long-term follow-	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Intervention group (n=20; mean age = 73.9 years; MMSE = 24.4) Control group (n=20; mean age = 77.7 years; MMSE= 21.5)	home, designed to identify interpersonal conflicts	treatment of dementia)		up: 3 months	
Marshall (2014)	People diagnosed with Alzheimer's disease (NINCDS-ADRDA) or vascular dementia (NINCDS-AIREN) MMSE ≥18) Intervention (n=28; mean age = 74.6 years; mean MMSE not reported) Wait list control (n=30; mean age = 76.6 years;	Living well with dementia group intervention based on a psychotherapy and a psychoeducational framework. Seven sessions once weekly	Control (wait list initially receiving usual care until after study was completed)	Cognition: MMSE Depression: CSDD Quality of life: QoL-AD	Post-intervention: 12 weeks Long-term follow-up: 20 weeks	Low
Tappen (2009)	People diagnosed with probable Alzheimer's disease (NINCDS-ADRDA; MMSE≤ 25)	30 minutes of modified counselling (based on Peplau's theory of interpersonal relations). Sessions occurred three times per week for 16 weeks	Control (usual care)	Depression: MADRS	Post-intervention: 16 weeks	Low

E.9.1.8 Exercise

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Multimodal exercise combinations						
Burgener (2008)	People living with dementia Intervention (n=24;	Multimodal intervention-Tai chi, cognitive behavioural	Delayed treatment (after 20 weeks)	Cognition: MMSE Depression: Geriatric Depression Scale	Post-intervention: 20 weeks	Moderate: No details of randomisation

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	mean age = 77.9 years; CDR= 1.15) Control (n=19; mean age = 76.0 years; CDR= 1.22)	therapy and support group participation (tai chi - one hour class 3 x weekly; CBT individual and small group 90 minutes, twice weekly; support group 90 minutes, twice weekly)				method or assessor blinding reported
Christofoletti (2007)	Residents living with dementia (ICD-10; MMSE; Katz ADL) Interdisciplinary intervention (n=11; mean age = 70 years; MMSE = 18.7) Physiotherapy (n=12; mean age = 72.9 years; MMSE=12.7) Control (n=14; mean age = 79.4 years; MMSE = 14.6)	Interdisciplinary motor intervention (physiotherapy-strength and balance exercises; occupational therapy – arts and craft activities involving motor co-ordination; physical education-in groups involving walking, upper and lower limb exercise, aerobic endurance - 2 hrs 5 x per week)	Usual care	Cognition: MMSE	Post-intervention: 6 months	Low
Luttenberger (2012)	Residents living with primary degenerative dementia (ICD-10) MMSE score <24 MAKS (n=71; mean age = 84.6 years; MMSE= 15.9) Control (n=68; mean age = 84.9 years; MMSE=14.4)	Multicomponent intervention (MAKS) daily sessions lasting 80 mins comprising 10 min introduction and spiritual element; 30 mins motor stimulation (balancing a ball and passing to neighbour; bowling; croquet); 40 minutes activities of daily living (preparing a snack; creative tasks such as wood or craft;	Usual care	Global assessment: NOSGER ADL: Barthel index	Post-intervention: 6 months	High: Only per-protocol results available for analysis

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
		gardening) and cognition (paper and pencil exercises; completing puzzles)				
Souto Barreto (2017)	People living with dementia in nursing homes Exercise group (n=44; mean age = 88.3 years; MMSE=11.4) Control (n=47; mean age = 86.9 years; MMSE =10.8)	Multicomponent group base exercises lasting 60 minutes, twice per week for 24 weeks. Sessions included 10-15 mins muscle strengthening; 20 mins aerobic (walking) exercises; 5-10 minutes of cooling down	Social activity group, based on group based activities	Cognition (MMSE) ADL (ADCS-ADL)	Ollow up 24 weeks	Low
Tai chi						
Cheng (2014)	People living with dementia (MMSE 10-24; CDR 0.5 or more) Tai Chi (n=39; mean age=81.8 yrs; MMSE=18.7) Control n=35 (mean age=80.9 years; MMSE=18.9)	Tai Chi (three 60 minute sessions per week)	Simple handicrafts (Three 60 min sessions per week)	Cognition: MMSE	Long-term follow-up: 9 months	High: No details of randomisation method or assessor blinding reported. Results only reported for some time points in study
Dance therapy						
Hwang (2010)	People living with dementia aged 65 years or older in nursing homes (MMSE –KC standard scores) Dance (n=10; mean age = 81.3 yrs; MMSE= 11.6)	Dance therapy (24 sessions over 8 weeks; three 50 minute sessions per week)	Control group – specific details not specified	Cognition: MMSE	Post-intervention: 6 months	Moderate: No details of randomisation method or assessor blinding reported

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Control (n=8; mean age = 81.75 yrs; MMSE=13.88)					
Van de Winckel (2004)	People living with dementia (multiple infarct dementia; NINCDS-ADRDA) MMSE <24 Music based dance therapy (n=15; mean age = 81.33 years; MMSE= 12.87) Control group (n= 10; mean age = 81.90 years; MMSE=10.8)	Group based daily 30 minute exercise programme to music (folkloric accordion songs) Focusing on upper and lower body strength, balance, trunk movements, flexibility training	Daily one to one 30 minute conversation between participant and physiotherapist	Cognition: MMSE	Post-intervention: 3 months	Moderate: Assessors were not blinded to treatment allocation
Combined non aerobic/aerobic exercise						
Bossers (2016)	People living with dementia aged 65 years or over and MMSE score 9-23 and ability to complete timed up and go. Combined strength and aerobic exercise group (n=35; mean age = 85.7 years; MMSE = 15.9) Aerobic only (n= 35; mean age = 85.5 years; MMSE= 15.3) control (n=35; mean age = 85.7 years; MMSE = 15.9)	Strength exercises – lower limb strength exercises (seated knee extensions, plantar flexion, hip extension) 3 sets of 8 repetitions increasing to 10 and 12 repetitions with 0.5kg weight attached to ankle Aerobic training- Moderate to high intensity walking sessions. 30 minute sessions with varying distances	Social program – One to one 30 minute social visits	ADL: Katz Index	Post-intervention: 9 weeks	Low
Hoffmann 2015	People living with Alzheimer's disease (NINDS/ ADRDA;	Three weekly group exercises (2-5 participants) involving	Usual care	Cognition: MMSE Depression: Hamilton Depression Rating Scale	Post-intervention: 16 weeks	Low

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	MMSE>19) Exercise program (n=107; mean age= 69.8 years; MMSE= 23.8) Control (n= 93; mean age = 71.8 years; MMSE; 24.1)	4 weeks of strength training, followed by 8 weeks of aerobic activity		ADL: ADCS-ADL BPSD: NPI Quality of life: EQ-5D		
Kemoun (2010)	People with a DSM-IV diagnosis of dementia and an MMSE lower than 23. 38 participants (20 intervention group, 18 control group)	13 weeks of exercises based on walking, equilibrium and stamina (40 minutes per session)	Usual care	Cognition: ERFC	Post-intervention: 15 weeks	Moderate: No details of randomisation method or assessor blinding reported
Pitkälä (2013) Additional data reported in Ohman (2016)	210 people living with dementia n=140: exercise, mean age (SD) = 78.0 years (5.4). n=70 comparator: control group, mean age (SD) = 78.1 years (5.3)	Aerobic and balance exercise program – either group or home based (1 hour twice a week for 12 months)	Oral and written advice on nutrition and exercise methods	Cognition: MMSE ADL: Functional Independence Measure	Post-intervention: 12 months	Moderate: Assessors were not blinded to treatment allocation
Rolland (2007)	Residents with Alzheimer's disease and MMSE <25. Exercise group (n= 67; mean age = 82.8 years; MMSE= 9.7) Control group (n= 67; mean age = 83.1 years; MMSE= 7.9)	Twice weekly sessions lasting an hour walking to reach moderate breathlessness; strength training	Usual care	ADL: Katz Index BPSD: NPI Depression: MADRS	Post-intervention: 12 months	Low
Steinberg (2009)	People living with dementia (NINCDS-ADRDA; MMSE>10)	Daily exercise program (Aerobic fitness; strength training	Home safety assessment-identifying	Quality of life: ADQRL BPSD: NPI	Post-intervention: 12 weeks	Low

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Exercise group (n=14; mean age = 76.5 years; MMSE=20.1) Home group (n=13; mean age =74.0 years; MMSE=15.5)	targeted at major muscle groups; flexibility training	hazards, recommending interventions (2 home visits)	Depression: CSDD Carer burden: SCB		
Suttanon (2013)	Diagnosis of dementia and an MMSE>10 n=19 exercise group; mean age (SD)= 83.42 years (5.10) n=21 usual care; mean age (SD)= 80.52 years (6.01)	Individualized home-based exercise programme supervised by a physiotherapist. Includes standing balance and strengthening exercises and a graduated walking programme	Usual care	Quality of life: ADQRL Carer burden: ZBI	Post-intervention: 6 months	Low
Toots (2016)	DSM-IV diagnosis of dementia and an MMSE>10 n=93 exercise; mean age (SD)=84.4 years (6.2) n=93 usual care; mean age (SD)= 85.9 years (7.8)	High-intensity functional exercise program, which aims to improve lower limb strength, balance, and mobility. Five exercise sessions lasting approximately 45 minutes each were held per 2-week period	Usual care	ADL: Barthel Index	Post-intervention: 4 months	Low
Vreugdenhil (2012)	People living with Alzheimer's disease (DSM-IV; NINCDS-ADRDA) Exercise program (n=20; mean age = 73.5 years; MMSE= 22.9) Control group (n=20;	Daily home based exercise program involving at least 30 mins of brisk walking and 10 simple exercises focusing on balance, upper and lower body strength	Treatment as usual	Cognition: MMSE ADL: Barthel Index Depression: Geriatric Depression Scale Carer burden: ZBI	Post-intervention: 4 months	Low

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	mean age = 74.7 years; MMSE= 21.0)					
Non aerobic exercise						
Littbrand (2009)	Frail older people (aged 65 years or older) living in residential care with MMSE score of 10 or more Exercise (n=91; 52% = dementia; mean age = 85.3 years; MMSE=17.5) or control (n=100; 53% = dementia; mean age =84.2 years; MMSE= 18)	Exercise intervention (functional weight bearing positions- e.g., stand from sitting, step-ups, squats) performed in groups or nutritional intervention	Usual care	ADL: Barthel Index	Post-intervention: 3 months Long-term follow-up: 6 months	Moderate: Assessors were not blinded to treatment allocation
Telenius (2015)	Residents with dementia (CDR 1 or 2).	Twice weekly 50-60 min session for 12 weeks. High Intensity Functional exercise 5 minute warm ups, strengthening exercise. Balance exercise	Twice weekly 50-60 min session of activities led by occupational therapist. Mobility exercise, reading, playing games	Cognition: MMSE BPSD: NPI Depression: CSDD ADL: Barthel Index Quality of life: QUALID	Post-intervention: 12 weeks	Low
Aerobic exercise						
Arcoverde (2014)	People living with mild dementia (CDR1; NINCDS/ADRDA) Exercise group (n=10; 8 Alzheimer's disease; 2 mixed dementia; mean age = 79 years; MMSE= 19.9 Control group (n=10; Alzheimer's disease; 2 mixed dementia; mean	30 minute treadmill training sessions twice weekly plus 5 minutes stretching activities	Usual care	Cognition: MMSE	Post-intervention: 4 months	Moderate: Assessors were not blinded to treatment allocation

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	age = 78.5 years; MMSE= 20.4)					
Cancela (2016)	Residents with diagnosis of dementia (DSM-IV criteria) aged 65 years or over able to stand and walk for 30 minutes Exercise group (n=51; mean age = 80.63 years; MMSE= 15.16) Control (n=63; mean age = 82.90 years; MMSE= 14.95)	Exercise group (aerobic activity)	Control group (non-physical, recreational activities)	Cognition: MMSE BPSD: NPI ADL: Katz Index Depression: CSDD	Post-intervention: 15 months	Moderate: High dropout rate during study
Miu (2008)	People living with mild to moderate dementia (MMSE 10-26) Exercise group (n=36; mean age= 75 years ; median MMSE = 20) Control group (n=49; mean age =78; median MMSE= 20	1 hour twice weekly session of aerobic exercise training (treadmill bicycle & arm ergometry including 10 min flexibility training	Usual care	Cognition: MMSE	Post-intervention: 3 months Long-term follow-up: 12 months	High: Effect sizes not reported for all outcomes measured in study
Venturelli (2011)	Residents with Alzheimer's disease aged 65 years or older with maximum MMSE score 15. Walking group (n=12; mean age = 83 years; MMSE=15.5) Control group (n=12; mean age = 85 years; MMSE=12.3)	30 minutes of moderate simple aerobic walking exercise 4 times per week	Usual care	Cognition: MMSE ADL: Barthel Index	Post-intervention: 24 weeks	Low
Yang (2015)	Outpatients diagnosed with Alzheimer's	40 min cycling training including 5 min warm	AD related information plus	Cognition: MMSE BPSD: NPI	Post-intervention: 3 months	Moderate: No details of

	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	disease aged 65-80 years (MMSE≤24) Aerobic group (n=25; mean age = 72 years; MMSE = 21.33) Control group (n=25; mean age = 71.92 years; MMSE= 20.00)	up session; 30 min target session and 5 min warm down); 3 times per week	treatment as usual	Quality of life: QoL-AD		randomisation method or assessor blinding reported

E.9.1.9 Nutrition

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
Ginkgo biloba						
Herrschaft (2012)	410 individuals aged 50 years or older diagnosed with mild to moderate AD or VaD, and an NPI score of at least 6.	Ginkgo biloba 240 mg daily	Placebo	Cognition: SKT BPSD: NPI Global assessment: ADCS-CGIC ADL: ADL-IS Quality of life: DEMQOL	Post-intervention: 24 weeks	Low
Kanowski (2003)	205 individuals aged 54 years or older diagnosed with mild to moderate Alzheimer's disease or vascular dementia	Ginkgo biloba 240 mg daily	Placebo	Cognition: SKT ADL: ADL-IS	Post-intervention: 24 weeks	Low
Ihl (2012)	Individuals aged 50 years or older diagnosed with mild to moderate AD or VaD, and an NPI score of at least 5. Mean age: 65 years	Ginkgo biloba 240 mg daily	Placebo	Cognition: SKT BPSD: NPI Global assessment: ADCS-CGIC ADL: ADL-IS Quality of life: DEMQOL	Post-intervention: 24 weeks	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	333 people with AD 71 people with VaD					
Le Bars (1997)	236 individuals with a DSM-III diagnosis of AD and an MMSE score of 9-26 Mean MMSE 21.2 (SD 5.7) Mean age 68 (SD 10)	Ginkgo biloba 120 mg daily	Placebo	Cognition: ADAS-cog Global assessment: CGIC	Post-intervention: 52 weeks	Low
Maurer (1997)	20 individuals with mild to moderate Alzheimer's disease Mean age 64.6 (SD 7.4)	Ginkgo biloba 240 mg daily	Placebo	Cognition: ADAS-cog	Post-intervention: 12 weeks	Low
Mazza (2006)	76 individuals with mild to moderate (MMSE 13-25) Alzheimer's disease (DSM-IV) Mean age 68.5 (SD 5) Mean MMSE 18.71 (SD 3.51)	Ginkgo biloba 160 mg daily	Placebo	Cognition: MMSE	Post-intervention: 24 weeks	Low
Napryeyenko (2007)	395 individuals with probable Alzheimer's disease or vascular dementia, and an NPI score ≥3	Ginkgo biloba 240 mg daily	Placebo	Cognition: SKT BPSD: NPI ADL: GBS ADL subscale Global assessment: GBS total score	Post-intervention: 22 weeks	Moderate: No details of randomisation method or allocation concealment
Nikolova (2013)	408 individuals with probable Alzheimer's	Ginkgo biloba 240 mg daily	Placebo	Cognition: SKT BPSD: NPI ADL: GBS ADL	Post-intervention: 22 weeks	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	disease or vascular dementia, and an NPI score ≥5			subscale Global assessment: GBS total score		
Schneider (2005)	513 individuals with mild to moderate (MMSE 10-24) probable Alzheimer's disease (NINCDS-ADRDA)	Ginkgo biloba 240 mg daily	Placebo	Cognition: ADAS-cog Global assessment: CIBIC+	Post-intervention: 26 weeks	Low
Van Dongen (2000)	18 individuals aged 50-80 years, diagnosed with mild to moderate Alzheimer's disease (NINCDS-ADRDA)	Ginkgo biloba 160 mg or 240 mg daily	Placebo	Cognition: MMSE ADL: NAA	Post-intervention: 24 weeks	Moderate: No details of randomisation method
Huperzine A						
Dong (2012)	32 participants with a DSM-III diagnosis of dementia	Huperzine A 0.2 mg/day	No intervention	Cognition: MMSE ADL: Chinese ADL scale	Post-intervention: 12 weeks	High: study was not placebo controlled
Liu (1995)	28 participants with a DSM-III diagnosis of dementia	Huperzine A 0.4 mg/day	Placebo	Cognition: MMSE ADL: Chinese ADL scale	Post-intervention: 8 weeks	Moderate: No details of allocation concealment
Rafii (2011)	210 participants with mild to moderate Alzheimer's disease (NINCDS-ADRDA)	Huperzine A 0.2 or 0.4 mg/day	Placebo	Cognition: MMSE ADL: ADCS-ADL BPSD: NPI	Post-intervention: 16 weeks	Low
Xu (1997)	103 participants with a DSM-III diagnosis of dementia and an MMSE<23. People	Huperzine A 0.4 mg/day	Placebo	Cognition: MMSE ADL: Chinese ADL scale	Post-intervention: 8 weeks	Moderate: No details of randomisation method or allocation concealment

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	with non-AD dementia were excluded					
Yang (2003)	65 participants with a NINCDS-ADRDA diagnosis of Alzheimer's disease and an MMSE<26	Huperzine A 0.3 mg/day	Placebo	Cognition: MMSE Dementia severity: CDR ADL: Chinese ADL scale	Post-intervention: 16 weeks	High: Inadequate methods of randomisation and allocation concealment
Zhang (2002)	202 participants with a NINCDS-ADRDA diagnosis of Alzheimer's disease and an MMSE<26	Huperzine A 0.2, 0.3 or 0.4 mg/day	Placebo	Cognition: MMSE BPSD: ADAS non-cog ADL: Chinese ADL scale	Post-intervention: 12 weeks	Low
Zhou (2004)	26 participants with a DSM-IV diagnosis of dementia and an MMSE<20. People with non-AD dementia were excluded	Huperzine A 0.3 mg/day	Placebo	Cognition: MMSE ADL: Chinese ADL scale	Post-intervention: 36 weeks	High: Inadequate methods of randomisation and allocation concealment
Omega-3 fatty acids						
Freund-Levi (2006)	Individuals diagnosed with AD with an MMSE score between 15-30, patients should be living in their own home	1-g omega-3 fatty acids four times daily, each containing 430mg of DHA and 150 mg of EPA	Placebo	Cognition: MMSE Dementia severity: CDR	Post-intervention: 6 months	Low
Quinn (2010)	Individuals with probable Alzheimer disease, with an MMSE score between 14 and 26	Docosahexaenoic acid (DHA) administered as capsules, dosed as 1g twice per day for a total daily dose of 2g	Placebo capsules (made up of corn or soy oil)	Cognition: MMSE Dementia severity: CDR ADL: ADCS-ADL BPSD: NPI	Post-intervention: 18 months	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Intervention group = n=238, mean age = 76 (9.3), mean MMSE score = 20.9 (3.6) **Control group =** n=164, mean age = 76 (7.8), mean MMSE score = 20.3 (3.7)					
Shinto (2014)	Individual with a probable diagnosis of AD, MMSE score 15-26 and CDR scale score between 0.5-1.0.	Omega-3 only – given in the form of fish oil concentrate in the triglyceride form at 3g/day (containing a daily dose of 675mg DHA, 975mg EPA) – 2 capsules in the morning and 1 capsules in the afternoon with food; also took 1 placebo Lipoic Acid. Omega-3 (daily dose of 675mg DHA, 975mg EPA) – 2 capsules in the morning and 1 capsules in the afternoon with food and Lipoic acid (600mg/day)	Placebo	Cognition: MMSE ADL: OARS-ADL	Post-intervention: 12 months	Low
Souvenaid						
Scheltens (2010)	Outpatients with Alzheimer's disease, older than 50 years with an MMSE of 20-26	Souvenaid (125ml once daily)	Placebo (isocaloric milk drink)	Cognition: MMSE ADL: ADCS-ADL Quality of life: QoL-AD	Post-intervention: 12 weeks	Low
Scheltens (2012)	Outpatients with Alzheimer's	Souvenaid (125ml once daily)	Placebo (isocaloric milk	Cognition: NTB	Post-intervention: 24 weeks	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	disease, older than 50 years with an MMSE greater than 20		drink)			
Shah (2013)	Outpatients with Alzheimer's disease, older than 50 years with an MMSE of 14-24	Souvenaid (125ml once daily)	Placebo (isocaloric milk drink)	Cognition: ADAS-cog ADL: ADCS-ADL Dementia severity: CDR	Post-intervention: 24 weeks	Low
Tailored nutritional guidance						
Suominen (2015)	Home dwelling persons with Alzheimers Disease and their spouses. **Intervention group** – n= 40, mean age= 78.2 (±5.5), MMSE = 18.8(±6.4), CDR of 0.5-1 point =68%, Hrqol 15D Score – 0.76 (±0.11) **Control group** –n = 38 Mean age = 76.9(± 5.9), MMSE = 20.2(± 4.7), CDR of 0.5-1 point =55%, Hrqol 15D Score – 0.77 (±0.14)	Tailored nutritional guidance based on food diaries, weight measurements, home visits and discussions every 3 months	Normal community care as well as written guide about nutrition for older adults.	Quality of life: 15D	Post-intervention: 12 months	Moderate: unclear ITT analysis reported
Other nutritional interventions						
Aisen (2008)	Individuals with probable AD who were older than 50 years old, have a	5mg/d Folic Acid, 1mg/d vitamin B12, 25mg/d vitamin B6	Placebo tablet	Cognition: MMSE ADL: ADCS-ADL scale Dementia severity:	Post-intervention: 18 months	Low risk

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	MMSE score within the range of 14-26 **Intervention group –** n= 240 Mean age – 75.7(8.0) MMSE=20.98(3.4) CDR=5.61(2.7) ADCS-ADL=61.31(11.58) **Control group –** n=169 Mean age – 77.3(7.9) MMSE=20.91(3.7) CDR=5.85(2.9) ADCS-ADL=59.66(12.9)			CRD		
Chen (2016)	Participants with a new diagnosis of possible or probable AD of mild to moderate severity, defined as a Mini-Mental State Examination (MMSE) total score between 3 and 26 **Intervention group** – mean age: 68.1 (±8.50) MMSE: 18.56 (±6.23) ADL: 32.87 (±10.88)	1.25mg/d folic acid and donepezil (5mg then 10mg after 1 month) daily during or after a meal for 6 months	donepezil (5 mg then 10 mg after 1 month)	Cognition: MMSE ADL: measure not reported	Post-intervention: 6 months	Moderate – per protocol analysis reported only

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Control group – mean age=67.63 (± 7.92) MMSE = 17.63 (± 7.77) ADL = 33.97 (± 13.42)					
Connelly (2008)	Outpatient's referrals to a mixed urban and rural memory service. All subjects had probable AD. **Intervention group** (n=23)– mean age = 79.4, (6.9), MMSE = 23.48 (4.10) **Control group** (n=18) - mean age = 77.6, (6.89), MMSE = 23.5(2.75)	Folate (1 mg/day) and cholinesterase inhibitors (dose unknown)	Placebo and cholinesterase inhibitors	Cognition: MMSE ADL: IADL	Post-intervention: 6 months	Low
De Sousa (2012)	All patients admitted at Geriatric Unit of a Psychiatric hospital aged ≥60 years, recently diagnosed with probable mild AD, with a weight loss of ≥5% in the previous year. **Intervention group** (n=20)– mean age = 79.4, (6.9), MMSE = 17 (7) BI = 59.2(18.1)	High protein, energy dense, liquid nutritional oral supplement and standard (400kcal/day – 42.8g carbs, 17.4g fat and 18g protein) dietetic advice, folic acid and B12 supplementation	Standard dietetic advice, folic acid and B12 supplementation	Cognition: MMSE ADL: Barthel Index	Post-intervention: 21 days Long-term follow-up: 90 days	Low

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Control group (n=15) - mean age = 78.4, (5.2), MMSE = 18(5) BI = 56.6(10.6)					
Dysken (2014)	Veterans with a diagnosis of probable AD of mild to moderate severity, MMSE score between 12 and 26 inclusive. **Intervention group – vitamin E only** n=140 – mean age = 78.3(± 5.4), Mean MMSE score= 21.3 (± 3.3) **Vitamin E and memantine –** n- = 139, mean age = 78.3(7.0) Mean MMSE score – 20.8(3.8) **Control group – Placebo -** n=152, mean age = 79.4(± 7.0), mean MMSE score = 20.8 (3.8) **Memantine -** mean age = 78.8(± 7.2), mean MMSE score = 20.8 (±3.8)	Vitamin E Vitamin E and Memantine	Placebo Memantine	Cognition: MMSE ADL: ADCS-ADL	Post-intervention: 4 years	Low
Furukawa (2017)	Individuals diagnosed with probable AD aged between 55-84	Yokukansan (YKS) a traditional herbal medicine, administered three times a day (2.5g	Placebo	Cognition: MMSE BPSD: NPI	Post-intervention: 12 weeks	Moderate: No details on randomisation or assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	years **Intervention group** n=75 – mean age = 78.3(± 5.4), Mean MMSE score= 19.7 (± 3.9) **Control group** n=70), mean age = 78.5 (± 5.1), mean MMSE score = 19.0 (± 4.4)	each, 7.5g/day)				
Gu (2015)	Clinical diagnosis of Parkinson's Disease, ≥50 years with a cognitive decline meeting the DSM-IV criteria for dementia due to PD.	Combined therapy Di-Huang-Yi-Zhi (oral administration of 150ml twice a day) and donepezil (5mg then 10mg/day after a month)	Low concentration of DHYZ diluted by 20 times and Donepezil (5mg then 10mg/day after a month)	Cognition: MMSE ADL: Barthel Index	Post-intervention: 6 months	Low
Heo (2008)	Patients diagnosed with probable Alzheimers aged older than 50 years and baseline MMSE score of ≥10 and ≤26 **Intervention group – low dose group –** n= 15, mean age = 66.07(± 6.7) years; mean MMSE score = 22.07 ± 3.99 **High dose group –** n=15, mean age = 67.73(± 11.83) ;mean MMSE score	6 year root Korea Ginseng was administered at a dose of 4.5g/day or 9g/day	Placebo	Cognition: MMSE Dementia severity: CDR	Post-intervention: 12 weeks	Moderate: No details on randomisation or assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	= 21.43 (± 6.63) **Control group – n=31,** mean age =66.68(± 7.53); mean MMSE score = 21.45 (± 4.53)					
Heo (2012)	AD patients aged 50-90years who visited the outpatient clinic at Seoul National University Hospital. **Intervention group – low dose group –** mean age = 75.7(± 11.8) years; mean MMSE score = 12.1 ± 7.4 **Medium dose group –** mean age = 73.5 (± 9.9) ; mean MMSE score = 11.6 (± 6.0) **High dose group –** mean age = 70.4(± 7.5) ;mean MMSE score = 14.6 (± 6.8) **Control group –** mean age =72.1(± 8.5); mean MMSE score = 16.4 (± 3.5)	SG-135 (Sun Ginseng powder capsule) – Low dose SG (1.5g/day) Intermediate dose SG (3g/day) High dose SG (4.5g/day)	Placebo	Cognition: MMSE	Post-intervention: 24 weeks	Moderate: No details on randomisation or assessor blinding reported
Lee (2008)	Patients with probable AD, **Intervention group** – n= 58, mean age = 66.6 (±9.6), mean MMSE score =	Korean white ginseng powder 4.5g/day of 6 year old Panax ginseng root for 12 weeks	Placebo	Cognition: MMSE	Post-intervention: 24 weeks	Moderate: No details on randomisation or assessor blinding reported

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	21.5(±3.8) **Control Group –** n= 39, mean age = 65.6 (±8.7), Mean MMSE score = 22.0 (±3.9)	Additional 9 patients were administered with 9g/d				
Lauque (2004)	Ninety-one subjects with AD aged 65 and older and at risk of undernutrition. **Intervention group** (n=46)– mean age = 79.52, (±5.97), MMSE = 15.33 (±8.11) **Control group** (n=45) - mean age = 78.11, (±4.80), MMSE = 15.88(±8.46)	Receiving oral nutritional supplements - Clinutren ranging between 300 and 500 kcal/d in addition to the patients' spontaneous food intake. Clinutren Soup (200kcal, 10g protein per 201ml), Clinutren dessert (150kcal, 12g protein per 150ml) and Clinutren 1.5(300kca, 11g protein per 200ml) These were enriched with proteins, vitamins and minerals and contained high amounts of energy and nutrients in a small volume.	Not receiving nutritional supplements	Cognition: MMSE ADL: measure not reported	Post-intervention: 3 months Long-term follow-up: 6 months	Low
Remington (2015)	Individuals diagnosed with AD recruited from nursing homes, assisted living facilities, senior centre and private clinics; as well as community dwelling. **Intervention group –** n=62	Nutritional formulation – consisting of 400µg folic acid, 6µg B1, 30I.U. alpha-tocopherol,400g SAM (200mg active ion), 600mg NAC and 500mg ALCAR,- with 2 tablets/daily dose	Placebo tablets	BPSD: NPI ADL: ADCS-ADL	Post-intervention: 6 months	Moderate: High loss to follow-up during study

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	Mean age – 78.7(±7.9) mean MMSE score = 22.2(±5.5) **Control group** – n= 44, mean age 79.7(±8.6); mean MMSE score = 22.2(±6.0)					
Salas-Salvado (2004)	Individuals diagnosed with Alzheimer's disease (based on DSM-IV criteria) who Scored 3 and above on the Pfeiffer's cognitive questionnaire Need a semi solid or liquid diet and Present a weight loss of higher than 5% in the previous year **Intervention group** – n= 24 mean age = 85.6(± 6.6) Pfeiffer's test = 7.5 (±2.5) **Control group** - n=24, mean age = 83.9(±6.9) Pfeiffer = 7.8(± 1.7)	Complete diet based on natural lyophilised (dried) foods with liquid or semi-solid consistency. 3 packets/day – 450kcal/packet and snack/dessert items and dietetic advice on balanced diet recommendations and advice to increase energy intake using home-made foods	No nutritional supplements and same dietetic advice as the control group	Cognition: Pfeiffer's test	Post-intervention: 3 months	Moderate: No details on randomisation or assessor blinding reported
Sun (2007)	Patients aged >50 who had visited the	Mecobalamin (0.5 mg) + multivitamin	Mecobalamin and placebo	Cognition: MMSE ADL: Barthel Indeex	Post-intervention: 26 weeks	Moderate: No details on randomisation or

Paper	Population	Intervention	Comparator	Outcomes	Follow-up	Risk of bias
	neurologic Outpatient Department for the treatment for AD and had a history of cognitive decline with a gradual onset that was progressive over a period of >6 months; clinical diagnosis of mild to moderate AD, MMSE score of 10-26 and a score of 1 to 2 on the CDR scale	supplement, (folic acid, pyridoxine HCl, iron ferrous 60 mg, nicotinamide 10 mg, calcium carbonate 250 mg, riboflavin 2 mg, thiamine mononitrate 3 mg, calcium pantothenate 1 mg, ascorbic acid 100 microgram, iodine 100 microgram, copper 150 microgram, vitamin B12 3 microgram, vitamin A 4000 IU, and vitamin D3 400 IU.				assessor blinding reported
Zhang (2015)	Patients with mild AD **Intervention group** - mean age = 72.79(± 6.76), 20.49 (± 4.29) **Control group** - mean age = 72.97 (± 6.59), 19.82 (± 3.54)	100ml of Yishen Huazhuo (YHD) a Chinese herbal formula, decoction once a day half an hour after breakfast for 24 weeks and 5mg of donepezil each day before sleep	YHD- simulation 100 ml of the decoction half an hour after breakfast for 24 weeks and 5mg of donepezil each day before sleep	Cognition: MMSE ADL: measure not reported BPSD: NPI	Post-intervention: 48 weeks	Low

E.9.1.10 Music therapy

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Music therapy versus standard care						
Ceccato (2012)	People with mild/moderate dementia of unspecified aetiology, unspecified care setting N=51 (1 withdrawal)	Music therapy – active based on Sound Training for Attention and Memory Protocol	Standard care – activities participants would normally perform	Cognition: MMSE (change from baseline) Activities of daily living: Katz Index of Independence in	Post-intervention: 3 months	High: no information on allocation concealment method, participants and personnel not blinded, follow-up was

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
	(40F/10M in completer set) Mean age: STAM group (n=27) 85.5 (SD 5.9); standard care group (n=23) 87.2 (SD 7.1) Mean MMSE: STAM group (n=27) 16.93 (SD 3.66), standard care group (n=23) 16.39 (SD 3.9)	(STAM); 4 phase protocol; 1) stimulus-movement association, 2) reaction to acoustic stimuli, 3) shifting attention, 4) orderly and inverted repetition Group sessions 12 weeks – 2 session/week a 45 min		Activities of Daily Living (change from baseline) Depression: Geriatric Depression Scale (GDS) (change from baseline) Agitation: CMAI (change from baseline)		planned but not conducted due to funding, no information on calculation of pre versus post intervention
Chu (2014)	People with mild, moderate, or severe dementia of unspecified aetiology living in nursing home N=104 (4 withdrawals) (53F/51M) Mean MMSE: music therapy group (n=49) 12.8 (SD 6.15), standard care group (n=51) 13.76 (SD 5.36)	Music therapy – active including active and receptive elements (song choice, music-prompted reminiscence, singing, music listening, instrumental play) Group sessions 6 weeks – 2 sessions/week a 30 min	Standard care – including watching TV, afternoon tea, taking walks	Cognition: MMSE (mean SD) Depression: CSDD (mean SD)	Post-intervention: 6 weeks Follow-up: 10 weeks	Moderate: participants and personnel not blinded, no information on assessor blinding

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Guetin (2009)	People with mild to moderate AD and anxiety (Hamilton Anxiety Scale score of at least 12), living in nursing home N=30 (6 withdrawals) (22F/8M) Mean age: music therapy group (n=15) 85.2 (SD 6), standard care group (n=15) 86.9 (SD 5.2) Mean MMSE: music therapy group (n=15) 19.8 (SD 4.4), standard care group (n=15) 20.7 (SD 3.4)	Music therapy – receptive Individual sessions 16 weeks – 1 session/week a 20 min	Standard care – not further specified	Cognition: MMSE (mean SD)[6] Depression: Geriatric depression scale (GDS) (mean SD)	Post-intervention: 4 months Follow-up: 6 months	Moderate: no information on allocation concealment method, participants and personnel not blinded, not all outcomes reported at follow-up
Hong (2011)	People with AD, vascular dementia, or Parkinson of unspecified severity, living in nursing home N=30 (28F/2M) Mean age: 78.3 (SD 6.3) Mean MMSE: 14.8 (SD 3.0), music therapy group (n=15) 14.6 (SD 2.97), standard care group (n=15) 15.00 (SD 3.05)	Music therapy – active consisting of song writing activity Individualised sessions[1] 16 weeks – 1 session/week a 60 min	Standard care – not further specified	Cognition: MMSE (mean SD)	Post-intervention: 17 weeks	Moderate: no information on concealment allocation methods, participants and personnel not blinded
Lin (2011)	See Chu (2014)	See Chu (2014)	See Chu (2014)	Agitation: CMAI (mean SD)	See Chu (2014)	Moderate: no information on allocation concealment methods and assessor blinding,

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
						participants and personnel not blinded
Raglio (2015)	People with moderate to severe dementia (MMSE ≤18, unspecified aetiology) with non-cognitive symptoms such as depression, anxiety, agitation (NPI ≤18), living in nursing home N=120 (22 withdrawals) (94F/26M) Mean age: individualised listening group (n=40) 81.7 (SD 7.8), music therapy group (n=40) 81 (SD 7.6), standard care group (n=40) 82.4 (SD 6.8) Mean MMSE: individualised listening group (n=40) 11 (SD 6.2), music therapy group (n=40) 11.1 (SD 5.4), standard care group (n=40) 11.3 (SD 5.3)	Music therapy – 1) receptive listening, 2) active using musical instruments Individualised sessions 10 weeks – 2 sessions/week a 30 min	Standard care – included educational and occupational (for example reading the newspaper, playing cards, personal care) and physical (motor rehabilitation sessions) activities	Behavioural and psychological symptoms: NPI (mean SD) HRQoL: Cornell-Brown scale (CBS) for quality of life (mean SD)	Post-intervention: 10 weeks Follow-up: 18 weeks	Moderate: no information on randomisation method, participants and personnel not blinded
Ridder (2013)	People with dementia of unspecified aetiology and severity with symptoms of agitation residing in nursing home N=42 (1 withdrawal at crossover point) (29F/13M)	Music therapy – active including vocal or instrumental, dancing/moving, listening, other activities Individualised	Standard care – as administered in the nursing homes, sometimes including group music sessions	HRQoL: ADRQL (mean SD) Agitation: CMAI (mean SD)	Post-intervention: 7 weeks	High: no information on randomisation method, participants and personnel not blinded, incomplete baseline data, crossover study with first-period data available

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
	Mean age: music therapy group (n=21; 6 reported) 82.17 (SD 8.841), standard care group (n=21; 5 reported) 80.20 (SD 8.672) Mean MMSE: music therapy group (n=21; 19 reported) 9.84 (SD 5.97), standard care group (n=21; 20 reported) 5.25 (SD 4.83)	sessions 6 weeks – 2 sessions/week (length not reported)				
Sakamoto (2013)	People with severe AD of unspecified severity staying in specialised dementia hospital N=39 (32F/7M) Mean age: active music therapy group (n=13) 80.5 (SD 11.2), perceptive music therapy group (n=13) 80.4 (SD 7.5), standard care group (n=13) 81.5 (SD 8) Mean MMSE: active music therapy group (n=13) 4.7 (SD 4.8), perceptive music therapy group (n=13) 4.6 (SD 3.5), standard care group (n=13) 4.7 (SD 3.9)	Music therapy – 1) active including clapping, singing, dancing, 2) perceptive Individualised sessions 10 weeks (1 session/week a 30 min)	Standard care – spending time with carer	Carer burden: Global rating	Post-intervention: 10 weeks Follow-up: 13 weeks	Moderate: no information on randomisation and allocation concealment methodsn participants and personnel not blinded

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Sarkamo (2016)	People with dementia (such as AD, vascular dementia, or mixed-type dementia) of mild or moderate severity living at home or in nursing home N=89 (15 withdrawals) (55F/19M) Mean age: 78.3 (SD 10.5) Mean MMSE[2]: singing group (n=23) 19 (SD 5.6), listening group (n=28) 15.7 (SD 5.05), standard care group (n=23) 20 (SD 5.6)	Music therapy – 1) receptive listening 2) active singing Group sessions involving people with dementia and their carers 10 weeks – 1 session/week a 90 min	Standard care – not further specified	Cognition: MMSE (mean SD) HRQoL: QoL-AD (mean SD) Carer burden: ZBI (mean SD)	Post-intervention: 10 weeks Follow-up: 6 months	High: no information on randomisation and allocation concealment methods, participants and personnel were not blinded, not all outcomes reported
Sung (2006)	People with dementia of unspecified aetiology and severity exhibiting agitation residing in nursing home N=57 (F/M not reported) Mean age: Not reported Mean MMSE: Not reported	Music therapy – receptive listening Individualised sessions[3] 6 weeks – 2 sessions/week a 30 min	Standard care – not further specified	Agitation: CMAI (mean SD)	Post-intervention: 6 weeks	High: no information on randomisation, allocation concealment methods, and assessor blinding, participants and personnel not blinded, incomplete baseline data reported
Sung (2012)	People with dementia of unspecified aetiology and severity with presence of behavioural and psychological symptoms residing in care home N=60 (5 withdrawals) (36F/24M) Mean age: music	Music therapy – active using percussion instruments Group sessions 6 weeks – 2 sessions/week a 30 min	Standard care – including social activities such as TV watching, family visits, parties	Agitation: CMAI (mean SD)	Post-intervention: 6 weeks	Moderate: no information on allocation concealment method and assessor blinding, participants and personnel not blinded

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
	therapy group (n=27) 81.37 (SD 9.14), standard care group (n=28) 79.5 (SD 8.76) Mean MMSE: not reported					
Music therapy versus standard care and active control						
Remington (2002)	People with AD, multi-factorial dementia or senile dementia of mild, moderate or severe severity with agitation residing in nursing home N=68 (F/M not reported) Mean age: 82.4 (SD/SE not reported) Mean MMSE: not reported	Music therapy – receptive listening to calming music Individualised session 1 session a 10 min	Standard care – not further specified Hand massage Calming music and hand massage	Agitation: CMAI (mean SD)	Post-intervention: 10 min Follow-up: 1 hour	Moderate: participants and personnel not blinded
Music therapy versus active control						
Cooke (2010)	People with confirmed diagnosis of mild to moderate dementia including AD and documented history of agitation/aggression within last month residing in nursing home N=47 (33F/14M) Mean age: Mean MMSE: 16.51 (SD 6.737)	Music therapy – active including live music as well as recorded music and participants are encouraged to sing, play instruments, and move to music Group sessions 1 session a 40 min	Reading with activities (reading local news stories, short stories, telling jokes, undertaking quiz activities)	HRQoL: DQOL (mean 95% CI)[5] Depression: Geriatric Depression Scale (GDS) (mean 95% CI)[5]	Post-intervention: 8 weeks	Moderate: incomplete information on randomisation method, no information on concealment allocation, participants and personnel not blinded, crossover study with first-period data available

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Narme (2014)	Participants with moderate to severe AD or mixed dementia living in nursing home N=48 (11 withdrawals) (32F/5M) Mean age: music therapy group (n=18) 86.7 (SD 6.4), cooking group (n=19) 87.5 (SD 6) Mean MMSE: music therapy group (n=18) 9.6 (SD 5.3), cooking group (n=19) 5.1 (SD 4.6)	Music therapy – active including listening, singing and playing percussion instruments Group session 4 weeks – 2 sessions/ week a 1 hour	Cooking	Cognition: Severe Impairment Battery (SIB) (mean SD) Behavioural and psychological symptoms: NPI (mean SD) Agitation: CMAI Carer burden: NPI distress (mean SD)	Post-intervention: 4 weeks Follow-up: 8 weeks	Moderate: no information on randomisation and allocation concealment methods, participants and personnel not blinded, high dropout (20%) following randomisation but prior start of intervention
Thornley (2016)	People with AD, vascular dementia or dementia with Lewy Bodies of unspecified severity with agitation (CMAI ≥45) residing as inpatient in acute psychiatric unit N=16 (F/M not reported) Mean age: music therapy group (n=10) 83.5 (SD 7.7), active engagement group (n=6) 68.4 (SD 5.2) Mean MMSE: music therapy group (n=10) 7.3 (SD 6.3), active engagement group (n=6) 5.7 (SD 3.4)	Music therapy – active including singing and playing simple instruments Individualised sessions 4 weeks – 2 sessions/week a 1 hour	Engagement therapy	Cognition: MMSE[4] Behavioural and psychological symptoms: NPI[4] Agitation: CMAI	Post-intervention: 4 weeks	Moderate: participants and personnel not blinded, data not reported for all assessments (however, stated that there was no statistical difference between groups and from baseline)
Van de	People with AD or	Music therapy –	Conversation	Cognition: MMSE	Post-intervention:	Moderate: no

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Winckel (2004)	multiple infarct dementia of unspecified severity (unspecified care setting) N=25 (25F/0M) Mean age: music therapy group (n=15) 81.33 (SD 4.24), conversation group (n=10) 81.9 (SD 4.18) Mean MMSE: music therapy group (n=15) 12.87 (SD 5.01), conversation group (n=10) 10.80 (SD 5.01)	active including movement and dance Group sessions 3 months – 1 session/day a 30 min			3 months	information on allocation concealment; participants and personnel not blinded

1. Not explicit stated in the method section, however it is assumed that song writing is an individual activity
2. Mean and SD are calculated from subgroup data
3. Not explicit stated in the methods
4. Only reported at baseline
5. SD calculated from 95% confidence interval (CI)
6. Not reported at follow-up

AD: Alzheimer's disease; ADRQL: Alzheimer's Disease Related Quality of Life; CBS: Cornell-Brown scale; CI: confidence interval; CMAI: Cohen-Mansfield Agitation Inventory; DQOL: Dementia Quality of Life; CSDD: Cornell Scale for Depression in Dementia; F: female; GDS: Geriatric Depression Scale; HRQoL: health related quality of life; M: male; MMSE: Mini Mental State Examinations; N: participant number randomised; NPI: Neuropsychiatric inventory; QoL-AD: Quality of Life in Alzheimer's Disease; SD: standard deviation; SE: standard error; STAM: Sound Training for Attention and Memory Protocol; ZBI: Zarit Burden Interview

E.9.1.11 Aromatherapy

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Ballard (2002) UK	72 people with severe dementia and clinically significant agitation (occurring at least on a daily basis and causing moderate or severe management problem for care staff, as defined on the NPI)	Melissa oil 1ml twice daily (providing a total of 200mg oil) for 4 weeks	Plocabo	Agitation: CMAI	Post-intervention: 4 weeks	Low

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Burns (2011) UK	People with AD and agitation for a minimum of 4 weeks (CMAI >39) residing in a nursing home or NHS continuing care facility N=114 (81 completers) 56F/38M (at interim assessment) Mean age: aromatherapy group (n=32) 85.6 (SD not provided), active comparator (n=31) 84.6 (SD not provided), control group (n=31) 85.1 (SD not provided)	Melissa oil 1ml twice daily (providing a total of 200mg oil) for 12 weeks	Sun flower oil 1ml twice daily (providing a total of 200mg oil) Donezepil (not used in analysis)	Behavioural and psychological symptoms – NPI Activities of daily living – Barthel Index (change from baseline mean 95% CI) HRQoL – Blau QoL Agitation – PAS	Post-intervention: 12 weeks	Moderate: no information on concealment allocation, blinding of participants and personnel unclear, 28.9% of participants lost following randomisation, compliance
Yang (2016) Taiwan	People with mild to severe dementia of unspecified aetiology and agitation or depressive symptoms in the past 2 weeks residing in long-term care facilities N=59 (3 withdrawals) 36F/23M Mean age Aromatherapy (n=29) 83.34 (SD 6.41), Standard care (n=30) 80.67 (SD 7.44) Mean MMSE: 8.65 (SD 6.7)	Lavandula angustifolia (lavender) and orange mix applied for 30min once per week for 8 weeks	Standard care only consisting of regular activities such as group singing, watching movies	Depression – CSDD Agitation – CMAI	Post-intervention: week 9 (8 weeks of intervention)	Moderate: baseline characteristics were not balanced for CSDD outcome measure

AD: Alzheimer's disease; CI: confidence interval; CMAI: Cohen-Mansfield Agitation Inventory; CSDD: ; Cornell Scale for Depression in Dementia; HRQoL: Health Related Quality of Life; M: male; MMSE: Mini Mental State Examinations; NPI: Neuropsychiatric inventory; PAS: Pittsburgh agitation scale; QoL: Quality of life

E.9.1.12 Light therapy

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Burns (2009) UK	People with AD, vascular dementia, dementia with Lewy bodies or mixed dementia and presence of one or more agitated behaviours residing in nursing home N=48 32F/16M Mean age Bright light group (n=22) 84.5 (SEM 1.7) Control light group (n=26) 82.5 (SEM 1.5) Mean MMSE: Bright light group (n=22) 6.9 (SD 5.3), control light group (n=26) 5.1 (SD 5.6)	Bright light box 10,000lux 2 hours in the morning for 2 weeks	Standard fluorescent light 100lux	Cognition – MMSE (mean SD) Behavioural and psychological symptoms – MOUSEPAD (mean SD) Activities of daily living – CRBRS (mean SD) Depression – CSDD (mean SD)	Post-intervention: 1 week after treatment Follow-up: 5 weeks after treatment	Moderate: no information on participant and personnel blinding, high intensity light used which caused negative reactions in some participants, timing of light therapy not matched to participants activity pattern
Graf (2001) Austria	People with AD and vascular dementia (MMSE of =<23) with absence of a current depressive episode residing in nursing home N=23 (5 withdrawals) F/M (not reported) Mean age (not reported) Mean MMSE: bright light group (n=9) 15.2 (SD 4.8), dim light group (n=9) 17.1 (SD 7.1)	Bright light 3,00lux 2 hour light therapy in the evening for 10 days	Dim light 100lux	Cognition – MMSE (mean SD)	Post-intervention: 10 days	Moderate: no information on randomisation, concealment allocation, and assessor blinding methods, participants and personnel not blinded, >10% drop-out no data imputation

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Onega (2016) US	People with dementia of unspecified aetiology and severity residing in long-term care N=71 (11 withdrawals) 43F/17M Mean age: 82.6 (SD 9.6) Mean MMSE: 7.22 (SD 6.85) Bright light group (n=30) 6.07 (SD 6.43), low light group (n=30) 8.37 (SD 7.16)	Bright light 10,000lux 30min twice a day morning and afternoon, 5 days per week for 8 weeks	Dim light 250lux	Depression – CSDD (mean SD) Agitation – CMAI (mean SD)	Post-intervention: 8 weeks	Moderate: no information on randomisation, allocation concealment, and assessor blinding, baseline characteristics of outcomes not balanced between groups

AD: Alzheimer's disease; CMAI: Cohen-Mansfield Agitation Inventory; CSDD: ; Cornell Scale for Depression in Dementia; CRBRS: Crichton Royal Behavior Rating Scale; MMSE: Mini Mental State Examinations; MOUSEPAD: Manchester and Oxford Universities Scale for the Psychological Assessment of Dementia

Non-invasive brain stimulation

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
People with Alzheimer's disease (AD)						
Ahmed (2012)[8]	People with AD (mild/moderate and severe) N=45 (29F/16M) Mean age: 68.4 (SD not reported) Mean MMSE: 14.84 (SD 5.5)	Repetitive transcranial magnetic stimulation (rTMS) (1 Hz and 20 Hz) Multiple sessions	Sham	Cognition: MMSE (mean SD) Activities of daily living: Instrumental Activities of Daily Living (IADL) Scale (mean SD)[1] Depression: Geriatric Depression Scale (GDS) (mean SD)	Post-intervention: 5 days Follow-up: 3 months	High: no information on randomisation method; personnel not blinded, misreporting of IADL data
Cotelli (2011)[2]	People with AD (moderate) N=10 Mean age: rTMS group 71.2 (SE 6.1), sham rTMS group 74.4 (SE 3.8)	Repetitive transcranial magnetic stimulation (rTMS) over left DLPFC (20 Hz) Multiple sessions	Sham	Cognition: MMSE (mean SD) Activities of daily living: Activity of Daily Living (ADL) scale[3], Instrumental Activity of daily living (IADL)	Post-intervention: 2 weeks Follow-up[9]: 2 months	High: no information on randomisation and allocation concealment methods, personnel not blinded, inconsistent reporting – unclear whether SE has been

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
	Mean MMSE: rTMS group 16.2 (SE 2.7), sham rTMS group 16.0 (SE 2.0)					used throughout; crossover design with first-period data available
Cotelli (2014)[4]	People with AD (mild/moderate) N=36 (29F/7M) Mean age: anodal tDCS plus individualised computerised memory training group 76.6 (SD 4.6), sham tDCS plus individualised computerised memory training group 74.7 (SD 6.1), anodal tDCS plus motor training group 78.2 (SD 5.2) Mean MMSE: anodal tDCS plus individualised computerised memory training group 20.1 (SD 2.4), sham tDCS plus individualised computerised memory training group 20.8 (SD 2.1), anodal tDCS plus motor training group 22.1 (SD2.3)	Anodal transcranial direct current stimulation (tDCS) (2 mA) over left DLPFC plus individualised computerised memory training Multiple sessions	Sham plus individualised computerised memory training	Cognition: MMSE (mean SE) Activities of daily living: Activity of Daily living (ADL) scale[3], Instrumental Activities of Daily Living (IADL) (mean SE)	Post-intervention: 2 weeks Follow up: 6 months	Moderate: no information on randomisation and allocation concealment methods, personnel not blinded, unclear whether groups were balanced at baseline for some outcomes of interest
Lee (2016)	People with AD (mild/moderate) N=27 (15F/12M) (1 withdrawal) Mean age: 71.6 (SD 6.8) Mean MMSE: 22.5 (SD	Repetitive transcranial magnetic stimulation (rTMS) (10 Hz) plus cognitive training Multiple sessions	Sham	Cognition: MMSE (mean SD) Depression: Geriatric Depression Scale (GDS) (mean SD)	Post-intervention: 6 weeks Follow-up: 6 weeks	Moderate: no information on randomisation and allocation concealment methods, personnel not blinded, unclear whether groups were balanced at baseline for

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
	2.7)					some outcomes of interest
Rabey (2013)	People with AD (mild/moderate) N=15 (10F/5M) (1 lost to follow up LOCF, only week 6 assessment included) Mean age: TMS group 72.6 (SD 8.9) Sham group 75.4 (9.07)	Repetitive transcranial magnetic stimulation (rTMS) (10 Hz) Multiple sessions	Sham	Cognition: ADAS-cog (change from baseline SE) Behavioural and psychological symptoms: NPI[5] Global assessment: Clinical global impression of change scale (CGIG)[5]	Post-intervention: 6 weeks Follow-up: 4.5 months[6] (following maintenance phase)	High: no information on randomisation and allocation concealment methods, personnel not blinded, incomplete baseline data
People with non-AD dementia						
Andre (2016)	People with vascular dementia (mild – MMSE range 20 to 26) N=22 (1 withdrawal) Mean age: anodal tDCS group (n=13) 80.3 (SEM 5.8), sham tDCS group (n=8) 75.8 (SEM 7.4) Age range: 63 to 94 years Mean MMSE: anodal tDCS group (n=13) 24.5 (SEM 1.8), sham tDCS group (n=8) 22.4 (SEM 2.6)	Anodal transcranial direct current stimulation (tDCS) (2 mA) over left DLPFC Multiple sessions	Sham	Cognition: ADAS-cog (mean SE)[7]	Post-intervention: 4 days Follow-up: 18 days after treatment[6]	Moderate: no information on randomisation and allocation concealment methods and assessor blinding, personnel not blinded, unclear whether groups were balanced at baseline for some outcomes of interest

1. Values are misreported (values >8 are reported, IADL scale is 0–8), excluded from analysis
2. It was assumed that data are report as mean SE throughout the publication; crossover trial design with first-period data available; only first-period data used in analysis
3. Not used for analysis; IADL data are used for activities of daily living outcome as this is a well-defined scale
4. This was a three arm trial; anodal tDCS plus motor training arm was excluded from analysis as the training in this arm was different from the training (individualised computerised memory training) was different in the sham group and the other treatment group
5. Incomplete data reported (SD/SE and p-value missing), not included in analysis
6. No or incomplete data reported for outcome of interest at this time point
7. SD calculated for analysis
8. Study included two intervention arms, only data from 20 Hz intervention arm used for analysis, data from 1 Hz intervention arm not used, 1 Hz was very different from

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
what has been used in other publications 9. Data at this time point not used for analysis, follow-up happens after crossover AD: Alzheimer's disease; ADAS-cog: Alzheimer's Disease Assessment Scale-cognitive; ADL: Activity of Daily Living; CGIG: Clinical global impression of change scale; DLPFC: dorsolateral prefrontal cortex; F: female; GDS: Geriatric Depression Scale; IADL: Instrumental Activities of Daily Living; M: male; MMSE: Mini Mental State Examinations; N: number of randomised participants; NPI: Neuropsychiatric inventory; rTMS: transcranial magnetic stimulation SD: standard deviation; SE: standard error; tDCS: transcranial direct current stimulation						

Acupuncture

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Liu (2016) China	People with vascular dementia (MMSE score ≤ 23), life and social dysfunction, mild or moderate National Institutes of Health Stroke Scale (NIHSS) treated in hospitals Donezepil hydrochloride was used in all participants N=272 (104 withdrawals) 62F/106M Mean age: acupuncture group (n=84) 55 (SD 7) Control group (n=84) 56 (SD 9) Mean MMSE: acupuncture group (n=84) 7.98 (SD 2.8), control group (n=84) 8.11 (SD 2.54)	Acupuncture (on several acupuncture points): once daily, 14-days a course, for a total of 4 courses (total 8 weeks)	No treatment	Cognition – MMSE (mean SD)	Post-intervention: 8 weeks	High: no information on randomisation, allocation concealment, and blinding; no sham acupuncture was used, participants were recruited from acupuncture clinic therefore they would have expected to receive acupuncture
Wang (2014) China	People with mild to moderate AD, Hachiski ischemic scale score =<4 points, inpatients	Acupuncture (several points) 30min once a day, for two courses	No treatment	Cognition – MMSE (mean SD) Activities of daily living – Barthel index (mean SD)	Post-intervention 20 days	Moderate: Participants and personnel not blinded, no sham acupuncture was used

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
	and outpatients Donezepil hydrochloride was used in all participants N=55 28F/27M Mean age: acupuncture group (n=27) 70.3 (SD 8), control group (n=28) 70.7 (SD 9.1) Mean MMSE: acupuncture group (n=27) 18.4 (SD 2.9), control group (n=28) 16.3 (SD 2.7)	each course lasting 10 days (total 20 days)				
AD: Alzheimer's disease; MMSE: Mini Mental State Examinations						

E.9.1.13 Animal assisted therapy

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Olsen 2016	People with dementia or a MMSE score of < 25 N=51 32F/19M Mean age: animal assisted therapy (n= 25) 83 (SD 8.5) Control group (n=26) 84 (SD 6.7) Mean MMSE: 13.8 (SD 6.6)	Animal assisted activity twice weekly for 12 weeks in groups of 3 to 6 participants, assisted by a qualified dog handler. Activities included petting, feeding and throwing a toy at the dog.	Usual care – no new activities were offered and treatment continued as usual.	Depression – CSDD Agitation – BARS Quality of Life – QUALID (Norwegian version) Dementia severity – CDR	Post-intervention: 12 weeks Follow-up: 3 months	Moderate: diagnosis method of dementia not reported.

E.9.1.14 Robotic pet therapy

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Petersen	People diagnosed with	Treatment with	Standard care,	Depression – CSDD	Post-intervention:	Low risk

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
2017	mild to moderate dementia, inpatients in the living memory care unit N = 61 Mean age = 83.4 years Mean MMSE: not reported Global deterioration scale: 5.6 (intervention), 5.3 (standard care)	PARO (personal robot) robotic pet once a day for 3 days a week. Each session lasted 20 minutes, seating 6 participants at a round table and encouraging individual interaction.	including: physical activity, music and mental stimulation.	Anxiety - Rating for Anxiety in Dementia (RAID)	3 months	

E.9.1.15 Adapted mindfulness program

Paper	Population	Intervention	Comparator	Outcomes of interest	Follow-up	Risk of bias
Churcher-Clarke (2017)	People diagnosed with dementia (DSM-IV) MMSE 10-26 n= 31; mean age = 80.61 years; mean MMSE 15.35)	10 sessions over 5 week period covering focused attention training, mindful breathing and a mindful warm-up activity	Treatment as usual	Cognition –MMSE Quality of life –QOLAD Depression -CSDD		Single blind, randomisation reported but allocation concealment not reported

E.9.2 Pre, peri and post-diagnostic counselling and support for people living with dementia and their families

- How effective are pre, peri & post-diagnostic counselling and support on outcomes for people living with dementia and their families?

Bibliographic reference	**Koivisto Am, Hallikainen I, Välimäki T et al. (2016) Early psychosocial intervention does not delay institutionalization in persons with mild Alzheimer disease and has impact on neither disease progression nor caregivers' well-being: ALSOVA 3-year follow-up. International Journal of Geriatric Psychiatry 31(3):273-283**
Study type	A randomised controlled trial to evaluate the effect of early psychosocial intervention on delaying the institutionalisation of people with Alzheimer's disease Follow-up 36 months
Participants	Inclusion criteria: very mild (Clinical Dementia Rating global score [CDR]=0.5) or mild (CDR=1.0) Alzheimer's disease; ability to understand and speak Finnish; community-dwelling; free of comorbid conditions that could affect cognition at baseline; capable of performing the Consortium to Establish a Registry for Alzheimer's Disease Neuropsychological Battery (CERAD-NB); and the presence of a family caregiver. Exclusions: not reported
Sample characteristics	N=236 dyads n=84 intervention people with Alzheimer's disease: 50.0% male; mean age (SD) 75.8 years (7.13); mean MMSE (SD) 21.8 (3.5); time since Alzheimer's disease diagnosis average of 5 months caregivers: 35.7% male; mean age (SD) 65.3 years (13.1) n=152 control people with Alzheimer's disease: 48.0% male; mean age (SD) 75.5 years (6.19); mean MMSE (SD) 21.3 (3.4) caregivers: 32.2% male; mean age (SD) 65.8 years (11.2)
Intervention	Psychosocial intervention for both people with Alzheimer's disease and their caregivers provided as rehabilitation courses including 4 courses (16 days in total) during the first 2 years after diagnosis The intervention aimed to enhance knowledge, to reduce social isolation and caregivers distress, and to support functional ability and managing everyday life situations Intervention methods included individual assessments, individual counselling, education, and both individual support and support groups A maximum of 10 families were invited to each course The intervention was delivered by neurologists and social workers
Comparison	The control group was also followed up annually but did not receive the psychosocial intervention All participants received basic counselling about Alzheimer's disease by a memory nurse at the time of diagnosis
Outcome measures	People with Alzheimer's disease: quality of life; cognitive impairment; memory disorder severity; activities of daily living;

Bibliographic reference	Koivisto Am, Hallikainen I, Välimäki T et al. (2016) Early psychosocial intervention does not delay institutionalization in persons with mild Alzheimer disease and has impact on neither disease progression nor caregivers' well-being: ALSOVA 3-year follow-up. International Journal of Geriatric Psychiatry 31(3):273-283
	behavioural disturbances; nursing home placement; mortality Caregivers: quality of life; psychological distress during caregiving; orientation to life; depression
Study dates	Recruitment was between 2002 and 2006
Study location	Finland
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? No – only a study nurse and a psychologist who carried out annual follow-ups • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Adjusted sub-hazard ratio with confidence interval (CI); adjusted mean changes with CIs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	Laakkonen M L, Kautiainen H, Holtta E, et al. (2016) Effects of Self-Management Groups for People with Dementia and Their Spouses--Randomized Controlled Trial. Journal of the American Geriatrics Society 64(4):752-60
Study type	A randomised controlled trial to compare the effects of self-management group rehabilitation (against usual care) for people with dementia and their spouses after a dementia diagnosis Follow-up 9 months
Participants	Inclusion criteria: people with dementia and their spouses who were volunteers; had a dementia diagnosis; spoke Finnish; and the spouses lived in the same address Exclusion criteria: unable to walk by themselves; unable to hear regular speech; terminal disease
Sample characteristics	N=136 couples n=67 intervention people with dementia: 62.7% male; mean age (SD) 77.3 years (6.2); mean MMSE (SD) 19.9 (5.7) spouses: 35.8% male; mean age (SD) 75.9 years (5.7) n=69 control

Bibliographic reference	Laakkonen M L, Kautiainen H, Holtta E, et al. (2016) Effects of Self-Management Groups for People with Dementia and Their Spouses--Randomized Controlled Trial. Journal of the American Geriatrics Society 64(4):752-60
	people with dementia: 62.3% male; mean age (SD) 76.6 years (6.3); mean MMSE (SD) 21.7 (3.7) spouses: 39.1% male; mean age (SD) 73.8 years (7.4)
Intervention	The intervention was based on a psychosocial group rehabilitation model in which self-management capabilities as problem-solving skills, self-efficacy, and mastery were built gradually during the intervention The self-management group rehabilitation was provided in 4-hour group sessions in a day centre once a week for an 8-week period The intervention was delivered by 2 professionals trained as group facilitators
Comparison	The control group received usual care provided by the Finnish health and social services system, and the study nurses gave them oral and written advice on nutrition and exercise. Participants (people with dementia and their spouses) in the control group could participate in group activities
Outcome measures	People with dementia: health-related quality of life; cognitive function Spouses: health-related quality of life There were 2 outcomes without extractable data (spouses): sense of competence as caregiver; mastery
Study dates	September 2011 to March 2014
Study location	Finland
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Baseline moderate or severe dementia was significantly higher and verbal fluency was significantly lower in the intervention group compared to the control group (people with dementia). Baseline sense of competence and mental health-related quality of life were significantly higher in the intervention group compared to the control group (spouses) • Aside from the experimental intervention, were the groups treated equally? No, it seems that the control group received more than usual care • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Adjusted mean change with confidence intervals • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? MMSE (people with dementia) was not reported. Regarding spouses, 3 outcomes were reported as not significant without reporting any data: mental health component of health-related quality of life; sense of competence as caregiver; mastery (personal control beliefs) Overall risk of bias: Very low

Bibliographic reference	**Waldorff FB, Buss DV, Eckermann A, et al. (2012) Efficacy of psychosocial intervention in patients with mild Alzheimer's disease: the multicentre, rater blinded, randomised Danish Alzheimer Intervention Study (DAISY). BMJ;345:e4693.** **Phung Kieu T. T, Waldorff F B, Buss D V, et al. (2013) A three-year follow-up on the efficacy of psychosocial interventions for patients with mild dementia and their caregivers: the multicentre, rater-blinded, randomised Danish Alzheimer Intervention Study (DAISY). BMJ Open 3(11):e003584**
Study type	A randomised controlled trial to examine the long-term efficacy at the 36-month follow-up of an early psychosocial counselling and support program lasting 8-12 months for community-dwelling patients with mild Alzheimer's disease and their caregivers Follow-ups 12 months 36 months
Participants	Inclusion criteria: home-living patients diagnosed within the last 12 months with Alzheimer's disease, mixed Alzheimer's disease or Lewy body dementia (LBD); ≥50 years old; MMSE score ≥20; and having one participating primary caregiver Exclusion criteria: patients with severe somatic or psychiatric comorbidities (including impaired hearing or vision) that would significantly impair their compliance with the DAISY programme; patients already involved in other intervention programmes
Sample characteristics	N=330 patient-caregiver dyads n=163 intervention patients: 46.6% male; mean age (SD) 76.5 years (7.7); mean MMSE (SD) 24.0 (2.5); 68.7% pure Alzheimer's disease; 27.0% mixed Alzheimer's disease and vascular dementia; 4.3% LBD caregivers: 33.1% male; mean age (SD) 65.5 years (12.7) n=167 control patients: 44.9% male; mean age (SD) 75.9 years (6.6); mean MMSE (SD) 24.1 (2.7); 76.1% pure Alzheimer's disease; 22.8% mixed Alzheimer's disease and vascular dementia; 1.2% LBD caregivers: 33.5% male; mean age (SD) 66.5 years (12.7)
Intervention	A multifaceted and semi tailored psychosocial intervention programme to provide counselling, information and support to patients with mild dementia and their caregivers. The intervention included up to 7 counselling sessions: 2 sessions with both patient and caregiver; 2 sessions with the patient alone; 2 sessions with the caregiver alone; and an optional network session with the patient, caregiver, and family network. The intervention also included 2 parallel lines of 5 courses each targeted at patients and caregivers respectively (each course line was schedule for 12 participants per session lasting 2 hours and delivered by one counsellor and one invited teacher) Additionally, the study coordinator contacted the participants by telephone about 5 to 8 times at 3 or 4 weeks intervals The intervention programme lasted 8-12 months The intervention was delivered by an experienced nurse specialising in caring for people with dementia and having received special training in counselling for the study

Bibliographic reference	**Waldorff FB, Buss DV, Eckermann A, et al. (2012) Efficacy of psychosocial intervention in patients with mild Alzheimer's disease: the multicentre, rater blinded, randomised Danish Alzheimer Intervention Study (DAISY). BMJ;345:e4693.** **Phung Kieu T. T, Waldorff F B, Buss D V, et al. (2013) A three-year follow-up on the efficacy of psychosocial interventions for patients with mild dementia and their caregivers: the multicentre, rater-blinded, randomised Danish Alzheimer Intervention Study (DAISY). BMJ Open 3(11):e003584**
Comparison	The control group was provided with follow-up support at each follow-up visit 3, 6, 12, and 36 months. Participants (both intervention and control groups) were interviewed about current symptoms and daily-life issues, and informed about available support programme (if any) in their local communities
Outcome measures	Patients: quality of life; cognitive function; activities of daily living; behavioural disturbances; depression; nursing home placement; mortality Caregivers: quality of life; depression
Study dates	Not reported
Study location	Denmark
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Independent raters blind to group assignment carried out follow-up assessments • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Adjusted mean change with standard deviation • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

E.10 Managing non-cognitive symptoms

E.10.1 Interventions for treating illness emergent non-cognitive symptoms in people living with dementia

- What are the most effective pharmacological interventions for managing illness emergent non-cognitive symptoms, such as psychosis, depression, behavioural changes in people living with dementia?

- What are the most effective non-pharmacological interventions for managing illness emergent non-cognitive symptoms, such as psychosis, depression, behavioural changes in people living with dementia?

E.10.1.1 Anxiety, depression, antidepressants and antipsychotics

Systematic reviews

Bibliographic reference	Ing-Randolph AR, Phillips LR, Williams AB (2014) Group music interventions for dementia-associated anxiety: a -systematic review, International Journal of Nursing Studies, 37:1775-84
Study type	Systematic review
Aim	To examine group music interventions for reducing dementia-associated anxiety
Patient characteristics	5 RCTs and 3 non-comparative cohort studies Total of 361 participants across these studies
Inclusion/ exclusion criteria	Inclusion: • Studies evaluating group music interventions in dementia • Exclusion: • Age less than 65 • Individual music interventions
Intervention	Group music interventions
Comparison	• Other interventions for anxiety • Usual care
Length of follow up	5 weeks-6 months
Location	Review did not restrict to any specific locations
Outcomes measures	Anxiety
Authors conclusion	The small number of studies and the large variety in methods and definitions limits our ability to draw conclusions.
Source of funding	None declared The authors report they have no conflicts of interest
Risk of bias	• Was an ‘a priori’ design provided? Yes • Was there duplicate study selection and data extraction? No • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes

Bibliographic reference	Ing-Randolph AR, Phillips LR, Williams AB (2014) Group music interventions for dementia-associated anxiety: a -systematic review, International Journal of Nursing Studies, 37:1775-84
	• Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: Moderate

Bibliographic reference	Leong C (2014) Antidepressants for depression in patients with dementia: a review of the literature, American Society of Consultant Pharmacists, 29(4):254-63
Study type	Systematic review
Aim	To evaluate the literature investigating the efficacy and safety of antidepressants for treating depression in individuals with dementia
Patient characteristics	10 placebo-controlled RCTs Total of 1,515 participants across these RCTs
Inclusion/ exclusion criteria	Inclusion: Randomised controlled trials comparing an antidepressant with placebo for the treatment of depression in patients with dementia
Intervention	• Imipramine • Citalopram • Clomipramine • Maclobemide • Sertraline • Fluoxetine • Venlafaxine • Mirtazapine
Comparison	Placebo
Length of follow up	6-24 weeks
Location	Review did not restrict to any specific locations
Outcomes measures	Trial / N / Intervention / Duration (weeks) / Primary outcome / Trial result Reifler (1989) / 61 / Imipramine (83mg/day) / 8 / HDRS / Negative Nyth (1992)* / 149 / Citalopram (30mg/day) / 6 / HDRS / Positive

Bibliographic reference	Leong C (2014) Antidepressants for depression in patients with dementia: a review of the literature, American Society of Consultant Pharmacists, 29(4):254-63

Petracca (1996)	21	Clomipramine (100mg/day)	6	HDRS	Positive
Roth (1996)*	694	Maclobemide (400mg/day)	6	HDRS	Positive
Magai (2000)	31	Sertraline (100mg/day)	8	CSDD	Negative
Petracca (2001)	41	Fluoxetine (40mg/day)	6	HDRS	Negative
DIADS (2003)	44	Sertraline (95mg/day)	12	CSDD HDRS	Positive
Cunha (2007)	31	Venlafaxine (75mg/day)	6	MADRS	Negative
DIADS-2 (2010)	117	Sertraline (93mg/day)	24	mADCS-CGIC CSDD	Negative
HTA-SADD (2011)	326	Sertraline (95mg/day) Mirtazapine (30mg/day)	13	CSDD	Negative Negative

*Trial contained both people with and without dementia

HDRS: Hamilton Depression Rating Scale, CSDD: Cornell Scale for Depression in Dementia, MADRS: Montgomery-Asberg Depression Rating Scale, mADCS-CGIC: Modified Alzheimer's Disease Cooperative Study - Clinical Global Impression of Change

Authors conclusion	Depression in individuals with dementia remains a challenging condition for which an optimal approach to treatment has not been well established
Source of funding	No funding received for undertaking of review
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? No • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? No • Was the scientific quality of the included studies used appropriately in formulating conclusions? No • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: Low

Bibliographic reference	Ma H, Huang Y, Cong Z et al (2014) The efficacy and safety of atypical antipsychotics for the treatment of dementia: a meta-analysis of randomized placebo-controlled trials, Journal of Alzheimer's Disease, 42(3):915-37
Study type	Systematic review
Aim	To assess the efficacy, safety, and tolerability of SGAs for treatment of psychological and behavioural symptoms of dementia.
Patient characteristics	19 RCTs Total of 5,291 participants across these studies
Inclusion/ exclusion criteria	Inclusion: • Randomised controlled trials comparing atypical antipsychotics to placebo
Intervention	Atypical antipsychotics
Comparison	Placebo
Length of follow up	6 weeks-26 weeks
Location	Review did not restrict to any specific locations
Outcomes measures	• NPI • BPRS • CMAI • CGI-C • Adverse events • Mortality
Authors conclusion	The higher risks for AEs and mortality may offset the efficacy of atypical antipsychotics for treatment of dementia. Efficacy, safety, and tolerability thus should be carefully considered against clinical need.
Source of funding	Chinese Natural Science Foundation
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes

Bibliographic reference	Ma H, Huang Y, Cong Z et al (2014) The efficacy and safety of atypical antipsychotics for the treatment of dementia: a meta-analysis of randomized placebo-controlled trials, Journal of Alzheimer's Disease, 42(3):915-37
	• Was the likelihood of publication bias assessed? Yes • Was the conflict of interest included? Yes Overall quality: High

Bibliographic reference	Moulton CD, Hopkins CWP, Bevan-Jones WR (2014) Systematic review of pharmacological treatments for depressive symptoms in Huntington's disease, Movement disorders, 29(12):1556-61
Study type	Systematic review
Aim	To consolidate the available literature on pharmacological treatments for depressive symptoms in Huntington's disease
Patient characteristics	5 RCTs and 6 non-comparative cohort studies or case series Total of 190 participants across these studies
Inclusion/ exclusion criteria	Inclusion: • Studies using a pharmacological therapy recognised as a treatment for depression • Depressive symptoms measured before and after treatment
Intervention	• Antidepressants • Antipsychotics • Mood stabilisers (lithium) • Modafinil
Comparison	Placebo for RCTs
Length of follow up	4 weeks – 1 year
Location	Review did not restrict to any specific locations
Outcomes measures	

Trial	N	Design	Intervention	Primary outcome	Trial result
Beglinger (2014)	31	RCT	Citalopram	HRDS	Negative
Holl (2010)	26	Cohort	Venlafaxine	HRDS BDI	N/A
Como (1997)	30	RCT	Fluoxetine	HRDS	Negative
Beglinger (2009)	20	RCT	Atomoxetine	SCL-90-R	Negative
Duff (2008)	29	Retrospective	Risperidone	SCL-90-R	N/A
Brusa (2009)	6	RCT	Aripiprazole Tetrabenazine	HRDS	Negative

Bibliographic reference	Moulton CD, Hopkins CWP, Bevan-Jones WR (2014) Systematic review of pharmacological treatments for depressive symptoms in Huntington's disease, Movement disorders, 29(12):1556-61

Ciammola (2009)	3	Case series	Aripiprazole	BDI	N/A
Paleacu (2002)	9	Cohort	Olanzapine	UHDRS	N/A
Squitieri (2001)	11	Cohort	Olanzapine	UHDRS	N/A
Cao (2013)	5	Case series	Lithium	BPRS	N/A
Blackwell (2008)	20	RCT	Modafinil	PANAS	Negative

HRDS: Hamilton Depression Rating Scale, BDI: Beck Depression Inventory, UHDRS: Unified Huntington's Disease Rating Scale, BPRS: Brief Psychiatric Rating Scale, PANAS: Positive and Negative Affect Schedule

Authors conclusion	Inadequate evidence exists to guide antidepressant treatment in Huntington's disease. Further research is needed to assess antidepressant efficacy and to examine whether treatment of depression represents a modifiable target for the high suicide rate in Huntington's disease
Source of funding	Not reported
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? No • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? No • Was the scientific quality of the included studies used appropriately in formulating conclusions? No • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: Low

Bibliographic reference	Ortega V, Qazi A, Spector A et al (2015) Psychological treatments for depression and anxiety in dementia and mild cognitive impairment: systematic review and meta-analysis, British Journal of Psychiatry, 207:293-8
Study type	Systematic review
Aim	To evaluate the evidence of effectiveness of psychological treatments in treating depression and anxiety in people with dementia and MCI

<table>
<tr><th>Bibliographic reference</th><th>Ortega V, Qazi A, Spector A et al (2015) Psychological treatments for depression and anxiety in dementia and mild cognitive impairment: systematic review and meta-analysis, British Journal of Psychiatry, 207:293-8</th></tr>
<tr><td>Patient characteristics</td><td>6 RCTs
Total of 527 participants across these studies</td></tr>
<tr><td>Inclusion/ exclusion criteria</td><td>Inclusion:
• Diagnosis of dementia, Alzheimer’s disease, organic brain syndrome or mild cognitive impairment
• Symptoms of anxiety of depression
Exclusion:
• Passive music interventions (listening to music)
• Only participants with severe dementia</td></tr>
<tr><td>Intervention</td><td>Psychological therapy:
• CBT
• Relaxation training methods
• Psychodynamic therapies
• Interpersonal therapies
• Supportive/counselling therapies</td></tr>
<tr><td>Comparison</td><td>Usual care with no specific psychological intervention</td></tr>
<tr><td>Length of follow up</td><td>6 weeks – 1 year</td></tr>
<tr><td>Location</td><td>Review did not restrict to any specific locations</td></tr>
<tr><td>Outcomes measures</td><td>
<table>
<tr><th>Trial</th><th>N</th><th>Sample</th><th>Intervention</th><th>Outcomes</th><th>Follow-up</th></tr>
<tr><td>Burgener (2008)</td><td>43</td><td>• Diagnosis of dementia
• CDR <2</td><td>• Multimodal CBT
• Attention-control educational programme</td><td>• GDS
• MMSE</td><td>20 weeks</td></tr>
<tr><td>Burns (2005)</td><td>40</td><td>• Diagnosis of Alzheimer’s disease
• CDR of 1
• MMSE ≥15
• Living in own home with caregiver</td><td>• Psychodynamic interpersonal therapy
• Usual care</td><td>• CSDD
• BADLS
• MMSE</td><td>6 weeks</td></tr>
<tr><td>Spector (2012)</td><td>50</td><td>• Diagnosis of mild to moderate dementia
• CDR of 0.5-2</td><td>• CBT
• Usual care</td><td>• CSDD
• RAID
• QOL-AD</td><td>15 weeks</td></tr>
</table>
</td></tr>
</table>

Bibliographic reference	Ortega V, Qazi A, Spector A et al (2015) Psychological treatments for depression and anxiety in dementia and mild cognitive impairment: systematic review and meta-analysis, British Journal of Psychiatry, 207:293-8					
			• RAID ≥11 • Living in the community		• NPI • MMSE • HADS	
	Stanley (2012)	32	• Diagnosis of dementia • NPI-A ≥4 • CDR score of 0.5-2	• CBT • Diagnostic feedback	• GDS • RAID • NPI-A • GAI • QOL-AD • PHQ-9	6 months
	Tappen (2009)	32	• Diagnosis of probable Alzheimer's disease • MMSE ≤25	• Counselling • Usual care	• MADRS	16 weeks
	Waldorff (2012)	330	• Diagnosis of probable Alzheimer's disease or DLB • MMSE ≥20	• Multicomponent intervention (counselling, teaching, education, telephone support) • Information	• CSDD • QOL-AD • ADSC-ADL • NPI • MMSE • GDS	12 months
	CDR: Clinical Dementia Rating, MMSE: Mini Mental State Examination, RAID: Rating for Anxiety in Dementia, NPI: Neuropsychiatry Scale, GDS: Geriatric Depression Scale, CSDD: Cornell Scale for Depression in Dementia, BADLS: Bristol Activities of Daily Living Scale, QOL-AD: Quality of Life in Alzheimer's Disease, HADS: Hospital Anxiety and Depression Scale, GAI: Geriatric Anxiety Inventory, PHQ-9: Patient Health Questionnaire, MADRS: Montgomery-Asberg Depression Rating Scale, ADSC: Alzheimer's Disease Cooperative Study					
Authors conclusion	Psychological interventions are effective in reducing symptoms of depression and anxiety in people with dementia. There is a need for high-quality, multicentre trials including standardised well-defined interventions.					
Source of funding	Cochrane systematic review					
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes					

Bibliographic reference	Ortega V, Qazi A, Spector A et al (2015) Psychological treatments for depression and anxiety in dementia and mild cognitive impairment: systematic review and meta-analysis, British Journal of Psychiatry, 207:293-8
	• Was a list of studies (Included and excluded) provided? Yes • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: High

Bibliographic reference	Pan YJ, Wu CS, Gau SSF et al (2014) Antipsychotic discontinuation in patients with dementia: a systematic review and meta-analysis of published randomized controlled studies, Dementia and Geriatric Cognitive Disorders, 37:125-40
Study type	Systematic review
Aim	To evaluate the risks and benefits of antipsychotic discontinuation in dementia
Patient characteristics	10 RCTs Total of 643 participants across these studies
Inclusion/ exclusion criteria	Inclusion: • 50 years or older • Probable/possible dementia • Use of antipsychotics for behavioural and psychological symptoms of dementia
Intervention	Antipsychotic continuation
Comparison	Antipsychotic discontinuation
Length of follow up	4 weeks-54 months
Location	Review did not restrict to any specific locations
Outcomes measures	• Behavioural and psychological symptoms of dementia • Early study termination • Mortality
Authors conclusion	The equivocal nature of the evidence and the small number of RCTs indicated that more studies are needed to investigate the effect of dose and type of antipsychotics and the method of discontinuation
Source of funding	Department of Health, Taiwan

Bibliographic reference	Pan YJ, Wu CS, Gau SSF et al (2014) Antipsychotic discontinuation in patients with dementia: a systematic review and meta-analysis of published randomized controlled studies, Dementia and Geriatric Cognitive Disorders, 37:125-40
	The authors report they have no conflicts of interest
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: High

Bibliographic reference	Petrovsky D, Cacchione PZ, George M (2015) Review of the effect of music interventions on symptoms of anxiety and depression in older adults with mild dementia, American Society of Consultant Pharmacists, 29(4):254-63
Study type	Systematic review
Aim	To explore the efficacy of music interventions in this vulnerable population, identify limitations in the literature, and make recommendations for future research
Patient characteristics	3 RCTs and 7 non-comparative cohort studies Total of 378 participants across these studies
Inclusion/ exclusion criteria	Inclusion: • Adults (aged over 65 years) with dementia • Symptoms of anxiety of depression Exclusion: • Passive music interventions (listening to music) • Only participants with severe dementia
Intervention	An active music intervention that engaged the participants
Comparison	Usual care for RCTs

<table>
<tr><th>Bibliographic reference</th><th>Petrovsky D, Cacchione PZ, George M (2015) Review of the effect of music interventions on symptoms of anxiety and depression in older adults with mild dementia, American Society of Consultant Pharmacists, 29(4):254-63</th></tr>
<tr><td>Length of follow up</td><td><24 weeks</td></tr>
<tr><td>Location</td><td>Review did not restrict to any specific locations</td></tr>
<tr><td>Outcomes measures</td><td>
<table>
<tr><th>Trial</th><th>N</th><th>Design</th><th>Intervention</th><th>Primary outcome</th><th>Trial result</th></tr>
<tr><td>Ashida (2000)</td><td>20</td><td>Pre-post</td><td>Group reminiscence music therapy
Drumming</td><td>CSDD</td><td>Positive</td></tr>
<tr><td>Camic (2013)</td><td>10</td><td>Pre-post</td><td>Group singing
Percussion instruments</td><td>GDS</td><td>Negative</td></tr>
<tr><td>Ceccato (2012)</td><td>50</td><td>RCT</td><td>Sound training for attention
Sound training for memory</td><td>GDS</td><td>Negative</td></tr>
<tr><td>Choi (2009)</td><td>20</td><td>Pre-post</td><td>Singing songs
Playing instruments
Song drawing
Song writing</td><td>GDS
NPI-Q</td><td>Negative
Negative</td></tr>
<tr><td>Chu (2014)</td><td>100</td><td>RCT</td><td>Music listening
Music playing</td><td>CSDD</td><td>Positive*</td></tr>
<tr><td>Cooke (2010)</td><td>47</td><td>Cross-over</td><td>Live group music and singing</td><td>RAID
GDS</td><td>Negative
Positive</td></tr>
<tr><td>Han (2010)</td><td>28</td><td>Pre-post</td><td>Singing, music and movement
Drumming</td><td>RMBPC</td><td>Negative</td></tr>
<tr><td>Kang (2010)</td><td>38</td><td>Pre-post</td><td>Cognitive stimulation
Art therapy</td><td>GDS</td><td>Positive</td></tr>
<tr><td>Sung (2012)</td><td>55</td><td>RCT</td><td>Group singing
Percussion instruments</td><td>RAID</td><td>Positive**</td></tr>
<tr><td>Suzuki (2004)</td><td>10</td><td>Pre-post</td><td>Singing songs
Playing instruments</td><td>MOSES</td><td>Negative</td></tr>
</table>
CSDD: Cornell Scale for Depression in Dementia, GDS: Geriatric Depression Scale, NPI: Neuropsychiatry Scale, RAID: Rating for Anxiety in Dementia, RMBPC: Revised Memory and Behavioural Problems Checklist, MOSES: Multidimensional Observation Scale for Elderly Subjects, *Improvement in the intervention group, but not significantly more than in the usual therapy group. **Significantly lower anxiety in intervention group, but not significantly different change from baseline.
</td></tr>
<tr><td>Authors conclusion</td><td>There was inconclusive evidence as to whether music interventions are effective in alleviating symptoms of anxiety and depression in</td></tr>
</table>

Bibliographic reference	Petrovsky D, Cacchione PZ, George M (2015) Review of the effect of music interventions on symptoms of anxiety and depression in older adults with mild dementia, American Society of Consultant Pharmacists, 29(4):254-63
	older adults with mild dementia due to the poor methodological rigour of the studies conducted
Source of funding	Not reported
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? No • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? No • Was the scientific quality of the included studies used appropriately in formulating conclusions? No • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: Low

Bibliographic reference	Richter T, Meyer G, Möhler R et al (2012) Psychosocial interventions for reducing antipsychotic medication in care home residents, Cochrane Database of Systematic Reviews, 12:CD008634
Study type	Systematic review
Aim	To determine whether psychosocial interventions can reduce antipsychotic medication compared with no interventions or other interventions
Patient characteristics	4 RCTs Total of 72 care homes across these studies
Inclusion/ exclusion criteria	Inclusion: • All residents of included care homes
Intervention	Psychosocial interventions aiming to reduce antipsychotic medication use
Comparison	• Alternative interventions • Usual care
Length of follow up	30 days-12 months
Location	Review only included studies undertaken in care homes

Bibliographic reference	Richter T, Meyer G, Möhler R et al (2012) Psychosocial interventions for reducing antipsychotic medication in care home residents, Cochrane Database of Systematic Reviews, 12:CD008634
Outcomes measures	• Use of regularly prescribed antipsychotic medication • Antipsychotic medication prescribed 'as needed' • Prescription of regular psychotropic medication • Adverse events • Cognitive status • BPSD • Physical restraints • Costs
Authors conclusion	There is evidence to support the effectiveness of psychosocial interventions for reducing antipsychotic medication in care home residents. The most recent and methodologically most rigorous study showed the most pronounced effect.
Source of funding	Ministry of Education and Research, Germany The authors report they have no conflicts of interest
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Yes • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: High

Bibliographic reference	Schneider LS, Dagerman KS, Higgins JPT, et al (2011) Lack of evidence for the efficacy of memantine in mild Alzheimer's disease, Archives of Neurology, 68(8):991-8
Study type	Systematic review
Aim	To assess the efficacy of memantine in mild Alzheimer's disease

Bibliographic reference	Schneider LS, Dagerman KS, Higgins JPT, et al (2011) Lack of evidence for the efficacy of memantine in mild Alzheimer's disease, Archives of Neurology, 68(8):991-8
Patient characteristics	3 placebo-controlled RCTs (post-hoc subgroup analysis of mild Alzheimer's disease population) Total of 427 participants across these RCTs
Inclusion/ exclusion criteria	Inclusion: Randomised controlled trials comparing memantine with placebo in people with mild Alzheimer's disease
Intervention	Memantine
Comparison	Placebo
Length of follow up	24 weeks
Location	Review did not restrict to any specific locations
Outcomes measures	• ADAS-cog • CIBIS-plus • ADCS-ADL • NPI
Authors conclusion	Despite its frequent off-label use, evidence is lacking for a benefit of memantine in mild Alzheimer's disease
Source of funding	Government research funding
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? No • Was a comprehensive literature search performed? Unclear • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? No • Was the scientific quality of the included studies used appropriately in formulating conclusions? No • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: Low

Bibliographic reference	Seitz DP, Adunuri N, Gill SS et al (2011) Antidepressants for agitation and psychosis in dementia, Cochrane Database of Systematic Reviews, 2:CD008191

Bibliographic reference	Seitz DP, Adunuri N, Gill SS et al (2011) Antidepressants for agitation and psychosis in dementia, Cochrane Database of Systematic Reviews, 2:CD008191
Study type	Systematic review
Aim	To assess the safety and efficacy of antidepressant in treating psychosis and agitation in older adults with Alzheimer's disease, vascular dementia or mixed dementia
Patient characteristics	9 RCTs Total of 692 participants across these studies
Inclusion/ exclusion criteria	Inclusion: • Randomised controlled trials comparing antidepressant to either placebo or other psychotropic medications, where the primary outcome was treatment of psychosis or agitation
Intervention	Antidepressants
Comparison	• Psychotropic medication • Placebo
Length of follow up	4 weeks-12 weeks
Location	Review did not restrict to any specific locations
Outcomes measures	• Neuropsychiatric symptoms • Psychosis • Agitation • Cognitive impairment • Adverse events
Authors conclusion	Both SSRIs and trazodone appear to be tolerated reasonably well when compared to placebo, typical antipsychotics and atypical antipsychotics
Source of funding	Alzheimer's Society of Canada Canadian Institute of Health Research
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Yes • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes

Bibliographic reference	Seitz DP, Adunuri N, Gill SS et al (2011) Antidepressants for agitation and psychosis in dementia, Cochrane Database of Systematic Reviews, 2:CD008191
	• Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: High

Randomised controlled trials

Bibliographic reference	Ballard C, Lana MM, Theodoulou M et al (2008) A randomised, blinded, placebo-controlled trial in dementia patients continuing or stopping neuroleptics, Plos Medicine, 5(4):587-99
Study type	Randomised controlled trial
Aim	To determine the impact of long-term treatment with neuroleptic agents upon global cognitive decline and neuropsychiatric symptoms in patients with Alzheimer's disease
Patient characteristics	165 people with Alzheimer's disease • Mean age: 85 years • Sex: 37% male • Mean MMSE: 11 • Hallucinations: 12% at baseline • Delusions: 32% at baseline
Inclusion/ exclusion criteria	Inclusion: • Living in a nursing or residential home • Possible or probable Alzheimer's disease (NINCDS/ADRDA) • MMSE > 6 or SBI > 30 • Patient taking at least 10mg chlorpromazine equivalent of a typical neuroleptic or at least 0.5mg of risperidone Exclusion: • Unable to complete primary outcomes measures at baseline • Clinician responsible for care considered the person inappropriate for randomisation • Patient currently taking thioridazine and showing a prolonged QTc on electrocardiogram • Unable to take capsules
Intervention	Neuroleptic continuation
Comparison	Switch to placebo
Length of follow up	12 months

Bibliographic reference	Ballard C, Lana MM, Theodoulou M et al (2008) A randomised, blinded, placebo-controlled trial in dementia patients continuing or stopping neuroleptics, Plos Medicine, 5(4):587-99
Location	UK (5 areas)
Outcomes measures	• Severe Impairment Battery • NPI • MMSE • Modified UPDRS (only items independent of cognitive function) • Bristol Activities of Daily Living • Sheffield test for acquired language disorders • Functional Assessment Staging
Authors conclusion	For most patients with Alzheimer's disease, withdrawal of neuroleptics had no overall detrimental effect on functional and cognitive status and by some measures improved it. Neuroleptics may have some value in the maintenance treatment of more severe neuropsychiatric symptoms, but this possibility must be weighed against the unwanted effects of therapy.
Source of funding	Alzheimer's Research Trust Various study authors have received consultancy, speaker and research fees from manufacturers of relevant drugs
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Substantial dropout • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Ballard C, Hanney ML, Theodoulou M et al (2009) The dementia antipsychotic withdrawal trial (DART-AD): long-term follow-up of a randomised placebo-controlled trial, lancet Neurology, 8:151-57
Study type	Randomised controlled trial
Aim	To assess whether continued treatment with antipsychotics in people with Alzheimer's disease is associated with an increased risk of mortality
Patient characteristics	165 people with Alzheimer's disease • Mean age: 85 years • Sex: 37% male

Bibliographic reference	Ballard C, Hanney ML, Theodoulou M et al (2009) The dementia antipsychotic withdrawal trial (DART-AD): long-term follow-up of a randomised placebo-controlled trial, lancet Neurology, 8:151-57
	• Mean MMSE: 11 • Hallucinations: 12% at baseline • Delusions: 332% at baseline
Inclusion/ exclusion criteria	Inclusion: • Living in a nursing or residential home • Possible or probable Alzheimer's disease (NINCDS/ADRDA) • MMSE > 6 or SBI > 30 • Patient taking at least 10mg chlorpromazine equivalent of a typical neuroleptic or at least 0.5mg of risperidone Exclusion: • Unable to complete primary outcomes measures at baseline • Clinician responsible for care considered the person inappropriate for randomisation • Patient currently taking thioridazine and showing a prolonged QTc on electrocardiogram • Unable to take capsules
Intervention	Neuroleptic continuation
Comparison	Switch to placebo
Length of follow up	24-54 months
Location	UK (5 areas)
Outcomes measures	• Severe Impairment Battery • NPI • MMSE • Modified UPDRS (only items independent of cognitive function) • Bristol Activities of Daily Living • Sheffield test for acquired language disorders • Functional Assessment Staging
Authors conclusion	For most patients with Alzheimer's disease, withdrawal of neuroleptics had no overall detrimental effect on functional and cognitive status and by some measures improved it. Neuroleptics may have some value in the maintenance treatment of more severe neuropsychiatric symptoms, but this possibility must be weighed against the unwanted effects of therapy.
Source of funding	Alzheimer's Research Trust Various study authors have received consultancy, speaker and research fees from manufacturers of relevant drugs
Risk of bias	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	Ballard C, Hanney ML, Theodoulou M et al (2009) The dementia antipsychotic withdrawal trial (DART-AD): long-term follow-up of a randomised placebo-controlled trial, lancet Neurology, 8:151-57
	• Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Substantial dropout • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Ballard C, Thomas A, Gerry S et al (2015) A double-blind randomized placebo-controlled withdrawal trial comparing memantine and antipsychotics for the long-term treatment of function and neuropsychiatric symptoms in people with Alzheimer's disease (MAIN-AD), JAMDA, 16(4):316-22
Study type	Randomised controlled trial
Aim	To evaluate the efficacy of 24 weeks treatment with memantine compared with antipsychotics for the treatment of neuropsychiatric symptoms in patients with Alzheimer's disease already receiving antipsychotics for more than 3 months
Patient characteristics	199 people with probable Alzheimer's disease living in care homes already receiving an antipsychotic • Mean age: 83 years • Sex: 31% male • Mean MMSE: 8.5 • Mean NPI: 17.6
Inclusion/ exclusion criteria	Inclusion: • Residence in a care facility • Fulfil NINDS/ADRDA criteria for possible or probable Alzheimer's disease • Taking a minimum dose of antipsychotics for at least 3 months before study entry Exclusion: • Severe physical or mental health comorbidities
Intervention	Switch to memantine
Comparison	Continue with antipsychotics
Length of follow up	24 weeks
Location	UK (3 areas) and Norway (1 area)
Outcomes measures	• Bristol Activities of Daily Living

Bibliographic reference	Ballard C, Thomas A, Gerry S et al (2015) A double-blind randomized placebo-controlled withdrawal trial comparing memantine and antipsychotics for the long-term treatment of function and neuropsychiatric symptoms in people with Alzheimer's disease (MAIN-AD), JAMDA, 16(4):316-22
	• CMAI • NPI • MMSE • MUDRS • CGIC • Adverse events • Mortality
Authors conclusion	This study indicates no benefits for memantine in the long-term treatment and prophylaxis of clinically significant neuropsychiatric symptoms. The results did indicate some benefits for antipsychotic medications in reducing the relapse of neuropsychiatric symptoms, but this must be balanced against increased mortality risk.
Source of funding	Not stated
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Higher MMSE scores in antipsychotic group • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Substantial dropout • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Banerjee S, Hellier J, Dewey M et al (2011) Sertraline or mirtazapine for depression in dementia (HTA-SADD): a randomised, multicentre double-blind placebo-controlled trial, Lancet, 378:403-11
Study type	Randomised controlled trial
Aim	To assess the efficacy and safety of two of the most commonly prescribed drugs, sertraline and mirtazapine, compared with placebo
Patient characteristics	326 people with 413 carers • Mean age: 79 years • Sex: 32% male • Mean MMSE: 18.1 • Mean EQ-VAS: 52.6

Bibliographic reference	Banerjee S, Hellier J, Dewey M et al (2011) Sertraline or mirtazapine for depression in dementia (HTA-SADD): a randomised, multicentre double-blind placebo-controlled trial, Lancet, 378:403-11
	• Residence: 15% live in care homes • Paid carers: 22% of carers
Inclusion/ exclusion criteria	Inclusion: NINCDS criteria for probable or possible Alzheimer's disease Co-existing depression that was assessed as potentially needing antidepressants CSDD ≥8 Exclusion: • Clinically too critical for randomisation • Contraindications to trial drugs • Already taking antidepressants • No family or professional carer informant
Intervention	• Sertraline • Mirtazapine
Comparison	Placebo
Length of follow up	39 weeks
Location	UK (9 NHS clinical centres)
Outcomes measures	• Cornell Scale for Depression in Dementia • MMSE • Bristol Activities of Daily Living • NPI • DEMQOL (participant and proxy) • EQ-5D (participant and proxy) • Zarit carer burden index • Carer physical and mental health • Adverse events
Authors conclusion	Because of the absence of benefit compared with placebo and increased risk of adverse events, the present practice of use of these antidepressants, with usual care, for first-line treatment of depression in Alzheimer's disease should be reconsidered.
Source of funding	UK NIHR HTA Programme Various study authors have received consultancy, speaker and research fees from manufacturers of relevant drugs
Risk of bias	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	Banerjee S, Hellier J, Dewey M et al (2011) Sertraline or mirtazapine for depression in dementia (HTA-SADD): a randomised, multicentre double-blind placebo-controlled trial, Lancet, 378:403-11
	• Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Substantial dropout • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Boström G, Conradsson M, Hörnsten C et al (2015) Effects of a high-intensity functional exercise program on depressive symptoms among people with dementia in residential care: a randomised controlled trial, International Journal of Geriatric Psychiatry
Study type	Randomised controlled trial (cluster randomised)
Aim	To evaluate the effect of a high-intensity functional exercise program on depressive symptoms among older care facility residents with dementia
Patient characteristics	186 people with dementia • Mean age: 85 years • Sex: 24% male • Mean MMSE: 14.9 • Mean GDS: 3.8 • Antidepressants: 55% using at baseline • Analgesics: 60% using at baseline
Inclusion/ exclusion criteria	Inclusion: • DSM-IV diagnosis of dementia • Age ≥65 years • Dependency in activities of daily living (Katz Index) • Ability to stand up from an armchair with help from no more than one person • MMSE ≥10 • Ability to hear and understand Swedish
Intervention	High-Intensity Functional Exercise program: • Supervised by two physical therapists

Bibliographic reference	Boström G, Conradsson M, Hörnsten C et al (2015) Effects of a high-intensity functional exercise program on depressive symptoms among people with dementia in residential care: a randomised controlled trial, International Journal of Geriatric Psychiatry
	• 39 exercises, intended to be performed at high intensity and imitating daily functional movements
Comparison	Non-exercise activity program led by occupational therapist: • Conversation, singing, picture viewing, listening to readings or music
Length of follow up	7 months
Location	Sweden (16 residential care facilities)
Outcomes measures	Geriatric Depression Scale Montgomery-Asberg Depression Rating Scale
Authors conclusion	A 4-month high-intensity functional exercise program has no superior effect compared with a control activity on depressive symptoms among older people living in residential care facilities, irrespective of dementia type or depressive symptom level
Source of funding	Swedish Research Council, Swedish Research Council for Health, various charities and academic funding bodies The author reports they have no conflicts of interest
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Carer outcomes not reported

Bibliographic reference	Brodaty H, Draper BM, Millar J et al (2003) Randomised controlled trial of different models of care for nursing home residents with dementia complicated by depression or psychosis, Journal of Health Psychology, 15(5):765-76
Study type	Randomised controlled trial
Aim	To compare the outcomes of 3 interventions for the management of dementia complicated by depression or psychosis: psychogeriatric case management, general practitioners with specialist psychogeriatric consultation, and standard care for nursing home residents
Patient characteristics	86 people with dementia • Mean age: 83 years • Sex: 28% male • Depression alone: 34

Bibliographic reference	Brodaty H, Draper BM, Millar J et al (2003) Randomised controlled trial of different models of care for nursing home residents with dementia complicated by depression or psychosis, Journal of Health Psychology, 15(5):765-76
	• Psychosis alone: 19 • Depression and psychosis: 33
Inclusion/ exclusion criteria	Inclusion: • Nursing home resident for at least 1 month • Significant cognitive impairment (AMTS ≤ 7) • At least 3 depressive symptoms (EBAS-DEP) or defined psychotic symptoms (BEHAVE-AD)
Intervention	• Psychogeriatric case management • Psychogeriatric consultation
Comparison	Standard care
Length of follow up	12 weeks
Location	Australia (11 nursing homes)
Outcomes measures	• Hamilton rating Scale for Depression • Cornell Scale for Depression in Dementia • Geriatric Depression Scale • Neuropsychiatric Inventory • BEHAVE-AD • EBAS-DEP
Authors conclusion	The study's model of specialist mental health care provided directly or through consultation advice had no appreciable benefit over that evident in a control group
Source of funding	Charity and government funding Various study authors have received consultancy, speaker and research fees from manufacturers of relevant drugs
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Carer outcomes not reported

Bibliographic reference	Cooke M, Moyle W, Shum D et al (2010) A randomised controlled trial exploring the effect of music on quality of life and depression in older people with dementia, Journal of Health Psychology, 15(5):765-76
Study type	Randomised controlled trial (cluster randomised - crossover design)
Aim	To investigate the effect of a live music programme on quality of life and depression in older people with dementia
Patient characteristics	47 people with dementia • Age: 66% ≥ 85 years • Sex: 30% male • Antidepressants: 9% using at baseline • Analgesics: 63% using at baseline • Antipsychotics: 20% using at baseline
Inclusion/ exclusion criteria	Inclusion: • Care facility resident • Confirmed or probable diagnosis of dementia • Documented behavioural history of agitation/aggression within the last month
Intervention	Music group sessions • Live music delivered by two musicians for 40 minutes, 3 times a week
Comparison	Interactive reading sessions • Reading local news stories, short stories, telling jokes, quiz activities
Length of follow up	16 weeks
Location	Australia (2 nursing homes)
Outcomes measures	• Dementia Quality of Life • Geriatric Depression Scale
Authors conclusion	Participation in a 40-minute live music intervention, three times a week for eight weeks, did not significantly affect levels of depression and quality of life in older people with dementia
Source of funding	Australian National Health and Research Council The author reports they have no conflicts of interest
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear

Bibliographic reference	Cooke M, Moyle W, Shum D et al (2010) A randomised controlled trial exploring the effect of music on quality of life and depression in older people with dementia, Journal of Health Psychology, 15(5):765-76
	• Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Carer outcomes not reported

Bibliographic reference	Fossey J, Ballard C, Juszcak E et al (2006) Effect of enhanced psychosocial care on antipsychotic use in nursing home residents with severe dementia: cluster randomised trial, BMJ Online
Study type	Randomised controlled trial (cluster randomised)
Aim	To evaluate the effectiveness of a training and support intervention for nursing home staff in reducing the proportion of residents with dementia who are prescribed neuroleptics
Patient characteristics	12 nursing homes containing 249 residents • Median age: 82 years • Sex: 63% male • Neuroleptic use: 49% at baseline • Median dose of neuroleptics: 100 chlorpromazine equivalents • Other psychotropic use: 54% at baseline • Severe dementia (clinical dementia rating): 58% at baseline
Inclusion/ exclusion criteria	Inclusion: • Nursing homes needed to contain a minimum of 25% of residents who had dementia and were taking neuroleptic drugs
Intervention	Psychosocial care package (systematic consultation approach): • Environment • Care practice • Attitudinal issues • Skills training • Behavioural management techniques • Promoting involvement of family carers
Comparison	Usual care
Length of follow up	12 months
Location	UK (12 specialist nursing homes)
Outcomes measures	• Neuroleptic use

Bibliographic reference	Fossey J, Ballard C, Juszcak E et al (2006) Effect of enhanced psychosocial care on antipsychotic use in nursing home residents with severe dementia: cluster randomised trial, BMJ Online
	• Falls • Aggression • Wellbeing
Authors conclusion	An intervention offering supports with individualised psychological intervention as part of a programme promoting person centred care and good practice provides a viable alternative to neuroleptics for treating behavioural symptoms in patients with dementia
Source of funding	Alzheimer's Society Various study authors have received consultancy, speaker and research fees from manufacturers of relevant drugs
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Hickman SE, Barrick AL, Williams CS et al (2007) The effect of ambient bright light therapy on depressive symptoms in persons with dementia, Journal of the American Geriatrics Society, 55:1817-24
Study type	Randomised controlled trial (cluster randomised - crossover design)
Aim	To assess the effect of ambient bright light therapy on depressive symptoms in persons with dementia
Patient characteristics	66 older adults with dementia • Age: 48% ≥ 80 years • Sex: 53% male • Cognitive impairment: 69% severe or very severe • Antidepressants: 61% using at baseline • Anxiolytics: 56% using at baseline • Antipsychotics: 67% using at baseline
Inclusion/ exclusion criteria	Inclusion: • Resident in one of three dementia-specific geriatric/residential care units Exclusion:

Bibliographic reference	Hickman SE, Barrick AL, Williams CS et al (2007) The effect of ambient bright light therapy on depressive symptoms in persons with dementia, Journal of the American Geriatrics Society, 55:1817-24
	• Eye disease (moderate or severe macular degeneration, absence of a lens) • Bipolar disorder
Intervention	High-intensity, low-glare ambient lighting system (2,000-2,500 lux) in either the morning (4 hours), evening (4 hours) or all-day (13 hours) • Indirect lighting • Low-gloss, highly reflective paint • Non-reflective materials for furniture
Comparison	Standard lighting (500-600 lux)
Length of follow up	3 weeks
Location	USA (3 geriatric/residential care units)
Outcomes measures	Cornell Scale for Depression in Dementia
Authors conclusion	Ambient bright light therapy administered in the morning benefits some persons with dementia by decreasing depressive symptoms but may worsen symptoms in others
Source of funding	National Centre for Complementary and Alternative Medicine, National Institute on Aging The authors report they have no conflicts of interest
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Only depressive symptoms measured

Bibliographic reference	Holmes C, Wilkinson D, Dean C et al (2007) Risperidone and rivastigmine and agitated behaviour in severe Alzheimer's disease: a randomised double blind placebo controlled trial, International Journal of Geriatric Psychiatry, 22:380-1
Study type	Randomised controlled trial
Aim	To compare risperidone with a cholinesterase inhibitor for the treatment of agitation
Patient characteristics	27 people with Alzheimer's disease

Bibliographic reference	Holmes C, Wilkinson D, Dean C et al (2007) Risperidone and rivastigmine and agitated behaviour in severe Alzheimer's disease: a randomised double blind placebo controlled trial, International Journal of Geriatric Psychiatry, 22:380-1
	• Mean age: 86 years • Sex: 26% male • Mean MMSE: 8 • Mean CMAI: 69
Inclusion/ exclusion criteria	Inclusion: • Living in a nursing home • NINCDS-ADRDA criteria for Alzheimer's disease • Clinically significant agitation Exclusion: • Previous exposure to a cholinesterase inhibitor • Previous high doses of psychotropic drugs (equivalent of 20mg thioridazine)
Intervention	Risperidone
Comparison	Rivastigmine
Length of follow up	6 weeks
Location	UK
Outcomes measures	• CMAI • UPDRS
Authors conclusion	In the acute treatment of marked agitation in patients with severe Alzheimer's disease, risperidone has a greater efficacy than rivastigmine
Source of funding	Research donations from Novartis and Shire pharmaceuticals
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Unclear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Unclear • Were all clinically important outcomes considered? No

Bibliographic reference	Kiosses DN, Ravdin LD, Gross JJ et al (2015) Problem adaptation therapy (PATH) for older adults with major depression and cognitive impairment: a randomised clinical trial, JAMA Psychiatry, 72(1):22-30
Study type	Randomised controlled trial
Aim	To test the efficacy of PATH versus supportive therapy for cognitively impaired patients in reducing depression and disability
Patient characteristics	74 people with dementia • Mean age: 81 years • Sex: 26% male • Dementia: 52% • Antidepressants: 63% using at baseline
Inclusion/ exclusion criteria	Inclusion: • DSM-IV diagnosis of depression • MADRS score ≥17 • Cognitive defects • At least one impairment in activities of daily living • Limited mobility to attend weekly outpatient treatment Exclusion: • Other non-anxiety psychiatric disorder • Acute or severe medical illness • Drugs known to cause depression • Current involvement in psychotherapy • Advanced dementia • Aphasia or inability to speak English
Intervention	PATH: • Home delivered psychosocial intervention – 12 weekly sessions • Personalised strategies to regulate emotions and lessen the negative impact of emotions • Caregivers can participate in treatment
Comparison	Supportive Therapy for Cognitively Impaired Older Adults: • Home delivered psychotherapy intervention – 12 weekly sessions • Non-specific therapeutic factors such as facilitating expression of affect, conveying empathy and imparting optimism • Caregivers can participate in treatment
Length of follow up	12 weeks
Location	USA (1 geriatric psychiatry institute)

Bibliographic reference	Kiosses DN, Ravdin LD, Gross JJ et al (2015) Problem adaptation therapy (PATH) for older adults with major depression and cognitive impairment: a randomised clinical trial, JAMA Psychiatry, 72(1):22-30
Outcomes measures	• Montgomery-Asberg Depression Rating Scale • WHODAS II
Authors conclusion	PATH was efficacious in reducing depression in a group of older adults with cognitive impairment, but this observation needs to be confirmed in an adequately powered study
Source of funding	US National Institute for Mental Health Various study authors have received consultancy, speaker and research fees from manufacturers of relevant drugs
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Unclear • Were all clinically important outcomes considered? Carer outcomes not reported

Bibliographic reference	Leontjevas R, Gerritsen DL, Smalbrugge M et al (2013) A structural multidisciplinary approach to depression management in nursing-home residents: a multicentre, stepped-wedge cluster-randomised trial, Lancet, 381:2255-64
Study type	Randomised controlled trial (step-wedge trial)
Aim	To establish the effectiveness of a structural approach to depression management
Patient characteristics	403 residents of dementia units and 390 residents of somatic units Characteristics of dementia unit population: • Mean age: 83 years • Sex: 30% male • Mean MMSE: 9.2 • Mean EQ-VAS: 70.4 • Mean CSDD: 8.5
Inclusion/ exclusion criteria	Inclusion: • One dementia unit and one somatic unit allowed to be enrolled from each nursing home in the Organisations of the Nijmegen University Network
Intervention	Multidisciplinary care programme (Act in Case of Depression):

Bibliographic reference	Leontjevas R, Gerritsen DL, Smalbrugge M et al (2013) A structural multidisciplinary approach to depression management in nursing-home residents: a multicentre, stepped-wedge cluster-randomised trial, Lancet, 381:2255-64
	• Structured assessment (two-step screening and diagnostic procedure) • Multidisciplinary treatment • Monitoring of treatment effects
Comparison	Standard care with no structured depression assessment or management
Length of follow up	20 months
Location	Netherlands (16 dementia units and 17 somatic units)
Outcomes measures	• Cornell Scale for Depression in Dementia • Geriatric depression scale • EQ-VAS
Authors conclusion	A structural approach to depression management including systematic depression assessment can effectively reduce depression prevalence in somatic units of nursing homes and improve quality of life of residents of somatic units and dementia units
Source of funding	Netherlands Organisation for Health Research and Development The authors report they have no conflicts of interest
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Substantial dropout • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Carer outcomes not reported

Bibliographic reference	Lyketos CG, Del Campo LM, Steinberg M et al (2003) Treating depression in Alzheimer's disease. Efficacy and safety of sertraline therapy and the benefits of depression reduction: the DIADS, Archives of General Psychiatry, 60:737-46
Study type	Randomised controlled trial
Aim	To assess the efficacy and safety of sertraline hydrochloride for the treatment of major depression in Alzheimer's disease
Patient characteristics	44 people with dementia • Mean age: 78 years • Sex: 32% male

Bibliographic reference	Lyketos CG, Del Campo LM, Steinberg M et al (2003) Treating depression in Alzheimer's disease. Efficacy and safety of sertraline therapy and the benefits of depression reduction: the DIADS, Archives of General Psychiatry, 60:737-46
	• Mean MMSE: 17.0
Inclusion/ exclusion criteria	Inclusion: • NINCDS criteria for probable or possible Alzheimer's disease • MMSE ≥10 • Diagnosis of major depressive episode • Resident in a community setting • Caregiver willing to accompany person to study visits • Stable medical history and general health Exclusion: • Sertraline use contraindicated • Lifetime diagnosis of schizophrenia, bipolar disorder or pre-AD anxiety disorder • Current substance use disorder • Acute suicidal or requiring psychiatric hospitalisation
Intervention	Sertraline
Comparison	Placebo
Length of follow up	12 weeks
Location	USA (2 centres)
Outcomes measures	• Cornell Scale for Depression in Dementia • Hamilton Depression Rating Scale • MMSE • Psychogeriatric Dependency Rating Scale • NPI • Adverse events
Authors conclusion	Sertraline is superior to placebo for the treatment of major depression in Alzheimer's disease. Depression reduction is accompanied by lessened behaviour disturbance and improved activities of daily living, but not improved cognition
Source of funding	US National Institute of Mental Health Various study authors have received consultancy, advice and research fees from manufacturers of relevant drugs.
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes

Bibliographic reference	Lyketos CG, Del Campo LM, Steinberg M et al (2003) Treating depression in Alzheimer's disease. Efficacy and safety of sertraline therapy and the benefits of depression reduction: the DIADS, Archives of General Psychiatry, 60:737-46
	• Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Carer outcomes not reported

Bibliographic reference	Porsteinsson AP, Drye LT, Pollock BG et al (2014) Effct of citalopram on agitation in Alzheimer's disease, JAMA, 311(7):682-91
Study type	Randomised controlled trial
Aim	To evaluate the efficacy of citalopram for agitation in patients with Alzheimer's disease
Patient characteristics	186 people with Alzheimer's disease • Mean age: 78 years • Sex: 54% male • Mean MMSE: 15.7
Inclusion/ exclusion criteria	Inclusion: • NINDS criteria for probable Alzheimer's disease • MMSE score of between 5 and 28 Exclusion: • Antipsychotic treatment
Intervention	Citalopram plus a psychosocial intervention
Comparison	Placebo plus a psychosocial intervention
Length of follow up	9 weeks
Location	US and Canada
Outcomes measures	• Agitation • Anxiety • Activities of daily living • NPI • MMSE
Authors conclusion	Among patients with probable Alzheimer disease and agitation who were receiving psychosocial intervention, the addition of

Bibliographic reference	Porsteinsson AP, Drye LT, Pollock BG et al (2014) Effct of citalopram on agitation in Alzheimer's disease, JAMA, 311(7):682-91
	citalopram compared with placebo significantly reduced agitation and caregiver distress; however, cognitive and cardiac adverse effects of citalopram may limit its practical application at the dosage of 30 mg per day
Source of funding	Not stated
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? - Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? No • Can the results be applied to the population of interest ?Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Sung HC Change AM Lee WL (2010) A preferred music listening intervention to reduce anxiety in older adults with dementia in nursing homes, Journal of Clinical Nursing, 19:1056-64
Study type	Randomised controlled trial (cluster randomised)
Aim	To evaluate a preferred music listening intervention for reducing anxiety in older adults with dementia in nursing homes
Patient characteristics	52 people with dementia • Mean age: 80 years • Sex: 56% male • Severe dementia: 50%
Inclusion/ exclusion criteria	Inclusion: • Age ≥65 years • Diagnosis of dementia with moderate to severe cognitive impairment • Displaying symptoms of anxiety • Resident in a long-term care facility for at least 6 months Exclusion: • No hearing impairment • No obvious symptoms of acute pain
Intervention	Preferred music listening intervention • Listening to preferred music for 30 minutes in the mid-afternoon twice a week

Bibliographic reference	Sung HC Change AM Lee WL (2010) A preferred music listening intervention to reduce anxiety in older adults with dementia in nursing homes, Journal of Clinical Nursing, 19:1056-64
Comparison	Usual care
Length of follow up	6 weeks
Location	Taiwan (1 long-term care facility)
Outcomes measures	Rating Anxiety in Dementia tool
Authors conclusion	Preferred music listening can be a beneficial and accessible intervention for nursing staff to ameliorate the symptoms of anxiety in older adults with dementia in nursing homes
Source of funding	Not reported The author reports they have no conflicts of interest
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Unclear • Were all clinically important outcomes considered? Carer outcomes not reported

Bibliographic reference	Verhey FRJ, Verkaaik M, Lousberg R, et al (2006) Olanzapine versus haloperidol in the treatment of agitation in elderly patients with dementia: results of a randomized controlled double-blind trial, Dementia and Geriatric Cognitive Disorders, 21:1-8
Study type	Randomised controlled trial
Aim	To compare the efficacy and safety of olanzapine versus haloperidol in the treatment of agitation and aggression in patients with dementia
Patient characteristics	158 people with dementia and agitation • Mean age: 83 years • Sex: 43% male • Mean MMSE: 10
Inclusion/ exclusion criteria	Inclusion: • ≥60 years • DSM-IV diagnosis of dementia

Bibliographic reference	Verhey FRJ, Verkaaik M, Lousberg R, et al (2006) Olanzapine versus haloperidol in the treatment of agitation in elderly patients with dementia: results of a randomized controlled double-blind trial, Dementia and Geriatric Cognitive Disorders, 21:1-8
	• Agitation clinically judged to require antipsychotic treatment • CMAI≥45 Exclusion: • Delirium • Other causes of behavioural problems • Other neurological conditions
Intervention	Olanzapine
Comparison	Haloperidol
Length of follow up	5 weeks
Location	Netherlands (6 sites)
Outcomes measures	• CMAI • MMSE • NPI • CGI
Authors conclusion	The study could not demonstrate the superiority of olanzapine compared to haloperidol
Source of funding	Not stated
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Unclear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Substantial dropout • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Unclear

Bibliographic reference	Weintraub D, Rosenberg PB, Drye LT et al (2010) Sertraline for the treatment of depression in Alzheimer's disease: week-24 outcomes, American Journal of Geriatric Psychiatry, 18(4):332-40
Study type	Randomised controlled trial

Bibliographic reference	Weintraub D, Rosenberg PB, Drye LT et al (2010) Sertraline for the treatment of depression in Alzheimer's disease: week-24 outcomes, American Journal of Geriatric Psychiatry, 18(4):332-40
Aim	To assess the efficacy and safety of sertraline hydrochloride for the treatment of major depression in Alzheimer's disease
Patient characteristics	131 people with dementia • Mean age: 79 years • Sex: 46% male • Mean MMSE: 21.0
Inclusion/ exclusion criteria	Inclusion: • Diagnosis of Alzheimer's disease according to DSM-IV • MMSE score of 10-26 • Diagnosis of depression
Intervention	Sertraline
Comparison	Placebo
Length of follow up	24 weeks
Location	USA (5 centres)
Outcomes measures	• Cornell Scale for Depression in Dementia • MMSE • ADRQL • ADCS-ADL • NPI • Adverse events
Authors conclusion	Sertraline treatment is not associated with delayed improvement between 12 and 24 weeks of treatment and may not be indicated for the treatment of depression of Alzheimer's disease
Source of funding	US National Institute of Mental Health Various study authors have received consultancy, advice and research fees from manufacturers of relevant drugs.
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Only until 12 weeks • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes

Bibliographic reference	Weintraub D, Rosenberg PB, Drye LT et al (2010) Sertraline for the treatment of depression in Alzheimer's disease: week-24 outcomes, American Journal of Geriatric Psychiatry, 18(4):332-40
	• Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Carer outcomes not reported After 12 weeks, people rated as unchanged or worse had the option of discontinuing randomised treatment and utilising any open-label treatment

E.10.1.2 Sleep problems

Systematic reviews

Bibliographic reference	Forbes D, Culum I, Lischka AR, Morgan DG, Peacock S, Forbes J, Forbes S. (2009) Light-therapy for managing cognitive, sleep, functional behavioural or psychiatric disturbances in dementia. Cochrane Database of Systematic Reviews, 4: CD003946.
Study type	Systematic review
Aim	To assess the quality of studies that measure the effectiveness of light therapies in managing cognitive, sleep, functional, behavioural or psychiatric problems associated with dementia and to make recommendations to consumers, researchers and physicians based on these findings.
Patient characteristics	Patients with a confirmed diagnosis of dementia (Alzheimer's disease, Dementia with Lewy Bodies, Vascular Dementia or other causes of dementia) according to accepted criteria. Severity of dementia assessed using MMSE or equivalent method.
Inclusion/ exclusion criteria	Inclusion: RCTs with light therapy of any intensity and duration compared to a control group for the management of cognitive, sleep, functional, behavioural or psychiatric problems associated with dementia. Exclusion: Studies not meeting above inclusion criteria, patient characteristics or outcome of interest
Intervention	Bright light
Comparison	Placebo group
Length of follow up	5 days – 2 years
Location	Review did not restrict to any specific locations
Outcomes measures	Measures that assessed: changes in cognition; incidence or frequency of sleep-wake disturbances; changes in functional decline; changes in incidence, frequency or severity of behavioural or psychiatric problems; impacts on cost of care and changes in rate of institutionalisation
Authors conclusion	There was insufficient evidence to assess the value of light therapy for people with dementia. More research is required, in part because the quality of existing studies is so poor.
Source of funding	Cochrane Review
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Yes

Bibliographic reference	Forbes D, Culum I, Lischka AR, Morgan DG, Peacock S, Forbes J, Forbes S. (2009) Light-therapy for managing cognitive, sleep, functional behavioural or psychiatric disturbances in dementia. Cochrane Database of Systematic Reviews, 4: CD003946.
	• Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? Unclear • Was the conflict of interest included? Yes Overall quality: High

Bibliographic reference	McCleery J, Cohen DA, Sharpley AL (2016) Pharmacotherapies for sleep disturbances in Alzheimer's disease (Review), Cochrane Database of Systematic Reviews, 3:CD009178
Study type	Systematic review
Aim	To assess the effects of drug treatments versus placebo for sleep disorders in people with Alzheimer's disease through identification and analysis of all relevant RCTs.
Patient characteristics	AD patients diagnosed with a sleep disorder
Inclusion/ exclusion criteria	Inclusion: • RCTs comparing a drug with placebo to improve sleep in AD patients with a sleep disorder at baseline. • Adults (aged over 65 years) with dementia Exclusion: • Studies where fewer than 80% study participants had AD • Patients with sleep apnoea
Intervention	Pharmacological interventions intended to improve patients' sleep - including melatonin and trazadone. Non-pharmacological interventions were allowed if both placebo and drug groups were equally exposed to them.
Comparison	Placebo
Length of follow up	2-11 weeks
Location	Review did not restrict to any specific locations
Outcomes measures	• Total night-time sleep time (NTST) • Night-time waking after sleep onset • Night-time number of awakenings

Bibliographic reference	McCleery J, Cohen DA, Sharpley AL (2016) Pharmacotherapies for sleep disturbances in Alzheimer's disease (Review), Cochrane Database of Systematic Reviews, 3:CD009178
	• Total daytime sleep • Time awake after sleep onset until final awakening (WASO) • Ratio of total daytime sleep time/NTST • Number of daytime naps • Night-time % sleep (sleep efficiency)
Authors conclusion	The studies identified provided no evidence that melatonin is beneficial to AD patients with mild-moderate dementia and sleep problems. The use of a low dose of trazodone was supported by the evidence, but a larger trial was suggested to allow a better examination of the risks and benefits of this treatment.
Source of funding	Cochrane Review
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Yes • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? • Was the conflict of interest included? Yes Overall quality: High

Randomised controlled trials

Bibliographic reference	Alessi CA, Martin JL, Webber AP, et al (2005) Randomized, controlled trial of a nonpharmacological intervention to improve abnormal sleep/wake patterns in nursing home residents. JAGS, 53(8):803-10
Study type	Randomised controlled trial
Aim	To test a multidimensional, nonpharmacological intervention to improve abnormal sleep/wake patterns in nursing home residents
Patient characteristics	People living in a nursing home with at least one episode of daytime sleepiness and night-time wakefulness (mean MMSE of 11.3)
Inclusion/ exclusion	Inclusion: People living in a nursing home with at least one episode of daytime sleepiness and night-time wakefulness

Bibliographic reference	Alessi CA, Martin JL, Webber AP, et al (2005) Randomized, controlled trial of a nonpharmacological intervention to improve abnormal sleep/wake patterns in nursing home residents. JAGS, 53(8):803-10
criteria	Exclusion: Acute illness, bed-bound
Intervention	Multicomponent (5 consecutive days in 6 person groups): • Sunlight exposure • Exercise • Environmental modification
Comparison	Usual care
Length of follow up	Average of 24 days
Location	USA
Outcomes measures	• Actigraphy • Staff observation
Authors conclusion	Nonpharmacological intervention should be considered in the management of abnormal sleep/wake patters in nursing home residents
Source of funding	US National Institute on Aging
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Unclear (higher MMSE in control group) • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? No

Bibliographic reference	Chong MS, Ayalon L, Marler M, Loredo JS, Corey-Bloom J, Palmer BW, Liu L, Anconi-Israel S. (2006) Continuous positive airway pressure reduces subjective daytime sleepiness in patients with mild to moderate Alzheimer's disease with sleep disordered breathing. Journal of American Geriatric Society, 54: 777-781.
Study type	Randomised controlled trial
Aim	To assess the effect of continuous positive air pressure treatment on day time sleepiness in patients with Alzheimer's disease (AD).
Patient characteristics	Community-dwelling elderly with mild-moderate probable AD and sleep-disordered breathing (SDB).
Inclusion/ exclusion	Inclusion: mild to moderate AD diagnosis, MMSE score >17, 10 or more respiratory events per hour of sleep, stable health and

Bibliographic reference	Chong MS, Ayalon L, Marler M, Loredo JS, Corey-Bloom J, Palmer BW, Liu L, Anconi-Israel S. (2006) Continuous positive airway pressure reduces subjective daytime sleepiness in patients with mild to moderate Alzheimer's disease with sleep disordered breathing. Journal of American Geriatric Society, 54: 777-781.
criteria	medication, English speaking and with reliable care-givers. Exclusion: current treatment for sleep apnea, having central sleep apnea, narcolepsy or other sleep disorders, symptomatic chronic obstructive pulmonary disease or bronchospasm, symptomatic coronary or cerebrovascular disease, history of life-threatening arrhythmias or cardiomyopathy, history of psychosis or current alcohol or drug abuse, having an uncontrolled seizure disorder.
Intervention	6 weeks of continuous positive air pressure treatment
Comparison	3 weeks sham treatment, then 3 weeks continuous positive air pressure treatment
Length of follow up	6 weeks
Location	USA
Outcomes measures	• Epworth Sleepiness Scale
Authors conclusion	Data provides evidence of the effectiveness of CPAP in reducing subjective daytime sleepiness in patients with AD and SDB.
Source of funding	UCSD GCRC (MO1-RR00827) and UCSD ADRC (P50 AG05131)
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes, where possible - there was a sham mask for the control group and non-blinded people were not involved in collecting ESS data. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? No

Bibliographic reference	Harris M, Richards KC, Grando VT. (2012) The effects of slow-stroke back massage on minutes of night-time sleep in persons with dementia and sleep disturbances in the nursing home: A pilot study. Journal of Holistic Nursing, 30: 255-263.
Study type	Randomised controlled trial
Aim	To study the effects of a 3 minute- slow-stroke back massage on total minutes of night-time sleep in patients with dementia and sleep disturbances.
Patient characteristics	People ≥ 65 years in a nursing home with both dementia and sleep problems
Inclusion/ exclusion	Inclusion:

Bibliographic reference	Harris M, Richards KC, Grando VT. (2012) The effects of slow-stroke back massage on minutes of night-time sleep in persons with dementia and sleep disturbances in the nursing home: A pilot study. Journal of Holistic Nursing, 30: 255-263.
criteria	• English speaking • ≥ 65 years • People with a diagnosis of dementia • Resident at the facility for > 90 days • People with sleep disturbances (< 420 minutes of night-time sleep) Exclusion: • Unstable medical conditions • An integumentary condition that would interfere with the massage • Vertebral fracture or recent fall
Intervention	3 minute- slow-stroke back massage (SSBM)
Comparison	Usual care
Length of follow up	2 days
Location	4 nursing homes in rural Southeastern US.
Outcomes measures	• Total minutes of night-time sleep • Sleep latency (minutes) • Sleep efficiency (%) • Wake after sleep onset (minutes) • Daytime inactivity (minutes)
Authors conclusion	Study findings suggest that SSBM may be an effective nursing home intervention for patients with dementia and sleep problems, but further research is required to confirm the pilot study results.
Source of funding	Not stated
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Larsson V, Aarsland D, Ballard C, Mintho L, Londos E (2010) The effect of memantine on sleep behaviour in dementia with Ley bodies and Parkinson's disease dementia. Int. J. Geriatr. Psychiatry, 25:1030-1038
Study type	Randomised controlled trial – analysis of a secondary outcome from a bigger trial
Aim	To determine whether memantine has an effect on sleep disturbances in dementia with Lewy bodies and Parkinson's disease (PD) dementia patients
Patient characteristics	Patients with PD dementia (PDD) or dementia with Lewy bodies (DLB).
Inclusion/ exclusion criteria	Inclusion: PD patients that met the UK PD society brain bank clinical diagnostic criteria for PD and subsequently diagnosed with dementia at least one year after the onset of motor symptoms. The DLB patients needed to meet the consensus criteria for DLB and have MMSE ≥ 12 points (mild-moderate DLB). Exclusion: patients with other brain diseases, recent large changes in health, major depression, moderate-to severe renal impairment, heart disease, pulmonary disease, hepatic impairment or allergy to memantine.
Intervention	5mg memantine in the morning, gradually increased to 20mg from week 4 (10mg morning, 10mg at night).
Comparison	Placebo
Length of follow up	24 weeks
Location	UK, Sweden and Norway
Outcomes measures	• Stavanger Sleep Questionnaire (only used with patients in Sweden and Norway) - to assess probable REM sleep behaviour disorder • Epworth Sleepiness Scale
Authors conclusion	Memantine decreases probable REM sleep behaviour in patients with PDD and
Source of funding	Not stated
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Unclear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? No

Bibliographic reference	McCurry SM, Gibbons LE, Logsdon RG, et al (2005) Night-time insomnia treatment and education for Alzheimer's disease: a randomized, controlled trial. JAGS, 53:609-18
Study type	Randomised controlled trial
Aim	To evaluate whether a comprehensive sleep education program (NITE-AD) could improve sleep in dementia patients living at home with their family caregivers
Patient characteristics	Community-dwelling patients with Alzheimer's disease and their caregivers
Inclusion/ exclusion criteria	Inclusion: Possible or probable Alzheimer's disease and living in the community with sleep problems
Intervention	NITE-AD (6 sessions with a geropsychologist): • Sleep hygiene • Daily walking • Light exposure
Comparison	Usual care
Length of follow up	6 weeks
Location	USA
Outcomes measures	• Actigraphy • Caregiver reported outcomes
Authors conclusion	Patients with Alzheimer's disease who are experiencing sleep problems can benefit from behavioural techniques that are known to improve sleep in non-demented, institutionalised older adults.
Source of funding	Not stated
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Unclear (higher MMSE in control group) • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? No

Bibliographic reference	McCurry SM, Gibbons LE, Logsdon RG, et al (2011) Increasing walking and bright light exposure to improve sleep in community-dwelling persons with Alzheimer's disease: results of a randomized, controlled trial. JAGS, 59(8):1393-1402
Study type	Randomised controlled trial
Aim	To test the effects of walking, light exposure and a combination intervention on the sleep of persons with Alzheimer's disease
Patient characteristics	Community-dwelling patients with Alzheimer's disease and their caregivers
Inclusion/ exclusion criteria	Inclusion: Possible or probable Alzheimer's disease and living in the community and 2 or more sleep problems occurring per week, as measured by the Sleep Disorders Inventory Exclusion: Previously diagnosed primary sleep disorder, significant visual impairment
Intervention	NITE-AD (6 sessions with a geropsychologist): • Sleep hygiene • Daily walking • Light exposure The trial also included arms for only the light exposure part of the intervention, and only the walking part of the intervention. However, these were both less effective than the combined intervention and therefore no further data on these were extracted as part of the guideline.
Comparison	Usual care
Length of follow up	6 weeks
Location	USA
Outcomes measures	• Actigraphy • Caregiver reported outcomes
Authors conclusion	Walking, light exposure and the combination are potentially effective treatments for improving sleep in community-dwelling person with Alzheimer's disease, but consistent adherence to treatment recommendations is required
Source of funding	US National Institute of Mental Health
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Unclear (higher MMSE in control group) • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? No

Bibliographic reference	Richards KC, Beck C, O'Sullivan PS, Shue VM. (2005) Effect of Individualised social activity on sleep in nursing home residents with dementia. Journal American Geriatric Society, 53: 1510-1517.
Study type	Randomised controlled trial
Aim	To test the efficacy and determine the cost of an individualised social care activity intervention (ISAI) on sleep/wake pattern disturbance.
Patient characteristics	People with dementia and a sleep/wake pattern disturbance
Inclusion/ exclusion criteria	Inclusion: ≥ 55 years old Baseline actigraph with < 85% sleep efficiency and at least 30 min daytime sleep At least 1 month residence in the nursing home MMSE ≤ 24 indicating dementia (mean score 8.7 ±7.1) Exclusion: Not stated
Intervention	• Choice of more than 100 activities with different patient ability requirements • Individualised based in patient interests, cognition, functional status and napping patterns. • 1-2hrs a day in 15-30 minute sessions for 21 consecutive days
Comparison	Usual care
Length of follow up	21 days
Location	USA
Outcomes measures	• Daytime sleep minutes • Night-time sleep onset • Night-time minutes slept • Night-time minutes awake • Night-time sleep efficiency • Day/night sleep ratio
Authors conclusion	ISAI provides an alternative to medications, without side effects.
Source of funding	Department of Veterans Affairs, Veteran's Health Administration, National Institute of Nursing, National Institute of Health/National Centre for Research Resources
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes initially, but secondary analyses were carried out on a subgroup with sleep efficiency of <50% (inadequate baseline night-time sleep)

Bibliographic reference	Richards KC, Beck C, O'Sullivan PS, Shue VM. (2005) Effect of Individualised social activity on sleep in nursing home residents with dementia. Journal American Geriatric Society, 53: 1510-1517.
	• Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes, based on subgroup analyses • Were all clinically important outcomes considered? Yes

E.10.1.3 Agitation, aggression and apathy

Systematic reviews

Bibliographic reference	Brown R, Howards R, Candy B, Sampson EL (2015) Opioids for agitation in dementia (review), Cochrane database of Systematic Reviews, 5: Art. No, CD009705
Study type	Systematic review
Aim	Determine the efficacy and safety of opioids for agitation in people living with dementia
Population characteristics	0 RCTs included in final review
Inclusion/ exclusion criteria	Inclusion: • RCTs of opioids compared to placebo for agitation in people living with dementia • Opioids was taken to include synthetic and opiate narcotics and included agonists or partial agonists Exclusion: • Antagonists
Intervention	Opioids
Comparison	Placebo
Length of follow up	N/A
Location	Review did not restrict to any specific locations
Outcomes measures	• Agitation (reduction in agitation -Cohen Mansfield Agitation Inventory CMAI or neuropsychiatric index NPI) • Quality of life • Cognition • Other measures of Behavioural and Psychological Symptoms of dementia
Authors conclusion	Authors found no completed randomised controlled trials. Insufficient evidence to determine effectiveness of opioids for agitation in

Bibliographic reference	Brown R, Howards R, Candy B, Sampson EL (2015) Opioids for agitation in dementia (review), Cochrane database of Systematic Reviews, 5: Art. No, CD009705
	people living with dementia
Source of funding	Not reported
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? No • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes - accessed non-English language papers • Was a list of studies (Included and excluded) provided? Yes • Were the characteristic of the included studies provided? Not applicable - no studies found • Was the scientific quality of the included studies assessed and documented? Not applicable • Was the scientific quality of the included studies used appropriately in formulating conclusions? Not applicable • Were the methods used to combine the findings of studies appropriate? Not applicable • Was the likelihood of publication bias assessed? Not applicable • Was the conflict of interest included? Not applicable Overall quality: Moderate

Bibliographic reference	Forrester LT, Maayan N, Orrell M, Spector AE, Buchan LD, Soares-Weiser K (2014) Aromatherapy for dementia, Cochrane database of systematic reviews, 2: CD003150
Study type	Systematic review
Aim	To assess the efficacy of aromatherapy as an intervention for dementia
Population characteristics	7 papers identified as eligible
Inclusion/ exclusion criteria	Inclusion: • Randomised controlled trials using fragrance from plants in aromatherapy for people with dementia • All doses. Frequencies and fragrances Exclusion: • Not reported
Intervention	• Aromatherapy
Comparison	• Placebo aromatherapy

Bibliographic reference	Forrester LT, Maayan N, Orrell M, Spector AE, Buchan LD, Soares-Weiser K (2014) Aromatherapy for dementia, Cochrane database of systematic reviews, 2: CD003150
Length of follow up	Not reported
Location	Review did not restrict to any specific locations
Outcomes measures	• CMAI • NPI • Blau Quality of life • Barthel scale of Activities of Daily Living • Adverse events
Authors conclusion	The 7 trials included in the review showed equivocal evidence of aromatherapy on agitation, behavioural symptoms and quality of life
Source of funding	Not reported
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Yes • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? No Overall quality: High

Bibliographic reference	Jutkowitz E, Brasure M, Fuchs E, Shippee T et al (2016) Care delivery interventions to manage agitation and aggression in dementia nursing home and assisted living residents: A systematic review and meta analysis, JAGS, 64: 477-488
Study type	Systematic review
Aim	To evaluate the efficacy of nonpharmacological care-delivery interventions to reduce and manage agitation in nursing home and assisted living residents with dementia
Population characteristics	19 papers identified as eligible

Bibliographic reference	Jutkowitz E, Brasure M, Fuchs E, Shippee T et al (2016) Care delivery interventions to manage agitation and aggression in dementia nursing home and assisted living residents: A systematic review and meta analysis, JAGS, 64: 477-488
Inclusion/ exclusion criteria	Inclusion: • English language randomised controlled trials enrolling community dwelling or institutionalised people with dementia • Evaluated efficacy of nonpharmacological interventions for agitation or aggression • Restricted to care delivery interventions for nursing home and assisted living facility residents with dementia Exclusion: • Not reported
Intervention	• Nonpharmacological interventions for agitation • Identified 5 types of intervention: o Dementia care mapping (n=3) o Person centred care (n=3) o Protocols to reduce antipsychotic use (n=3) o Emotion oriented care (n=2) o Mutually distinct types of staff training (n=11)
Comparison	Usual care
Length of follow up	Not reported
Location	Review did not restrict to any specific locations
Outcomes measures	• Agitation (any measure of agitation. Pooled data was standardised using SMD) • Aggression (any measure of aggression. Pooled data was standardised using SMD)
Authors conclusion	Only sensory interventions showed a moderate effect in reducing agitation for people with dementia
Source of funding	Not reported
Risk of bias	• Was an ‘a priori’ design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? No • Were the characteristic of the included studies provided? In a summary table • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No

Bibliographic reference	Jutkowitz E, Brasure M, Fuchs E, Shippee T et al (2016) Care delivery interventions to manage agitation and aggression in dementia nursing home and assisted living residents: A systematic review and meta analysis, JAGS, 64: 477-488
	• Was the conflict of interest included? Yes Overall quality: Moderate

Bibliographic reference	Kong, EH, Evans, L , Guevara, J (2009) Nonpharmacological intervention for agitation in dementia: a systematic review and meta-analysis, Aging and Mental Health, 13: 512-520
Study type	Systematic review
Aim	To systematically review the literature regarding nonpharmacological interventions in older adults with dementia
Population characteristics	14 papers identified as eligible (7 randomised controlled parallel group; 7 randomised crossover)
Inclusion/ exclusion criteria	Inclusion: • Randomised controlled parallel group or randomised crossover design of people with dementia • Included nonpharmacological interventions for agitation • Published in English or Korean • Included a published scale measuring agitation as an outcome • Included sufficient information to determine the effect of nonpharmacological interventions Exclusion: • Not reported
Intervention	• Nonpharmacological interventions for agitation • Identified 7 types of intervention: ○ Sensory interventions (Aromatherapy; thermal bath; calming music and hand massage) ○ Social contact (simulated presence) ○ Activity based interventions (Rocking chair therapy; therapeutic recreational activities) ○ Environmental modifications (morning light therapy) ○ Caregiver training (Behaviour management techniques; abilities focused program of morning care) ○ Behavioural interventions (Activities of daily living intervention; way finding intervention)
Comparison	Usual care
Length of follow up	Not reported
Location	Review did not restrict to any specific locations
Outcomes measures	Agitation (any measure of agitation. Pooled data was standardised into SMD)

Bibliographic reference	Kong, EH, Evans, L , Guevara, J (2009) Nonpharmacological intervention for agitation in dementia: a systematic review and meta-analysis, Aging and Mental Health, 13: 512-520
Authors conclusion	Only sensory interventions showed a moderate effect in reducing agitation for people with dementia
Source of funding	Not reported
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? Yes • Was a list of studies (Included and excluded) provided? Yes • Were the characteristic of the included studies provided? - in summary table • Was the scientific quality of the included studies assessed and documented? No • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? No Overall quality: Moderate

Bibliographic reference	Von Gunten A, Schlaefe S, Uberla K (2015) Efficacy of Gingko Biloba extract EGb 761 in dementia with behavioural and psychological symptoms: A systematic review, The World Journal of Biological Psychiatry, 2: 1-12
Study type	Systematic review
Aim	To review current evidence of the efficacy of Gingko Biloba extract EGb 761 in people living with dementia and behavioural and psychological symptoms
Population characteristics	4 papers identified as eligible
Inclusion/ exclusion criteria	Inclusion: • Randomised placebo- controlled double blind trials assessing effects of an oral dosage of EGb 761 extract in people with a diagnosis of AD, VaD or mixed dementia • At least 22 weeks study duration • Diagnosed with dementia according to DSM-III R and DSM-IV; ICD-10 & NINCDS- ADRDA or NINDS-AIREN • Had clinically significant BPSD(minimal scores on NPI) Exclusion: • Not reported

Bibliographic reference	Von Gunten A, Schlaefe S, Uberla K (2015) Efficacy of Gingko Biloba extract EGb 761 in dementia with behavioural and psychological symptoms: A systematic review, The World Journal of Biological Psychiatry, 2: 1-12
Intervention	EGb 761 extract
Comparison	Placebo
Length of follow up	Treatment period had to last for at least 22 weeks
Location	Review did not restrict to any specific locations
Outcomes measures	• NPI • ADL • DEMQOL PROXY • SKT (cognition)
Authors conclusion	Overall, the pooled analysis demonstrates that Gingko Biloba is both safe and moderately effective in treatment of patients with dementia and mild to moderate behavioural and psychological symptoms
Source of funding	Not reported
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? No • Was a list of studies (Included and excluded) provided? No • Were the characteristic of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: Moderate

Bibliographic reference	Xiao H, Su Y, Cao X, Sun S, Liang Z (2010) A meta analysis of mood stabilisers for Alzheimer's disease, Journal of Science and Technology, 5, 652-658
Study type	Systematic review
Aim	To examine the effect of mood stabilisers as an adjunct treatment for agitation in people with Alzheimer's disease
Patient	5 RCTs – valproate divalproex n=3; lithium n=1; carbamazepine n=1

Bibliographic reference	Xiao H, Su Y, Cao X, Sun S, Liang Z (2010) A meta analysis of mood stabilisers for Alzheimer's disease, Journal of Science and Technology, 5, 652-658
characteristics	Total of 125 participants across these studies
Inclusion/ exclusion criteria	Inclusion: • RCTs where people with Alzheimer's disease were treated with a mood stabiliser Exclusion: • Studies on dementia other than Alzheimer's disease • Non placebo controlled trials
Intervention	Mood stabilisers
Comparison	• Placebo
Length of follow up	No restriction
Location	Review did not restrict to any specific locations
Outcomes measures	Agitation Functional Ability Neuropsychiatric profile Cognition Adverse events
Authors conclusion	Based on the existing evidence mood stabilisers are ineffective or even harmful as a treatment for Alzheimer's disease
Source of funding	None declared
Risk of bias	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (e.g. grey literature) used as an inclusion criterion? No • Was a list of studies (Included and excluded) provided? Included only • Were the characteristic of the included studies provided? No • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? No • Was the conflict of interest included? Yes Overall quality: Moderate

Randomised controlled trials

Bibliographic reference	Burns A, Allen H, Tomensen B, Duigan D, Byrne J (2009) Bright light therapy for agitation in dementia: a randomized controlled trial, International Psychogeriatrics, 21, 711-721
Study type	Randomised controlled trial
Aim	To assess the effects of bright light therapy on agitation in patients with dementia
Patient characteristics	48 people with dementia Baseline characteristics: • Treatment group n= 22; mean age = 84.5 years; female = 73%; mean MMSE = 5.1; Mean CMAI total score= 62.0 • Control group n= 26; mean age = 82.5 years; female = 62%; mean MMSE = 6.9; Mean CMAI total score= 57.5
Inclusion/ exclusion criteria	Inclusion: • People with a diagnosis of dementia (WHO) • Sleep disruption at least two nights a week • Presence of one or more agitated behaviours Exclusion: • Failure to satisfy inclusion criteria • Cataracts
Intervention	Bright light therapy
Comparison	Normal light
Length of follow up	3 weeks
Location	UK
Outcomes measures	• Agitation (CMAI) • MMSE • Cornell scale for depression • Behavioural psychopathology (MOUSEPAD)
Authors conclusion	There was limited evidence of reduced agitation in people receiving bright light treatment
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? List randomisation followed by stratification by MMSE score at baseline high to low (0-9/ 10-30)

Bibliographic reference	Burns A, Allen H, Tomensen B, Duigan D, Byrne J (2009) Bright light therapy for agitation in dementia: a randomized controlled trial, International Psychogeriatrics, 21, 711-721
	• Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes- • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Cohen Mansfield J, Libin A, Marx MS (2007) Nonpharmacological treatment of agitation: A controlled trial of systematic individualised Intervention Journal of Gerentology, 8, 908-916
Study type	Randomised controlled trial
Aim	To examine the efficacy of a systematic algorithm for individualised nonpharmacological interventions to reduce agitated behaviours in people diagnosed with dementia resident in a nursing home
Patient characteristics	Baseline characteristics: • N=167 • Intervention n=89 Mean age = 88 years; 84.3% female; MMSE = 7.26 • Control n=78 Mean age =85 years 75.6% female MMSE = 6.88
Inclusion/ exclusion criteria	Inclusion: • Not reported Exclusion: • No dementia diagnosis • Resident < 3 weeks • Exhibit agitation fewer than several times a day • Judged to have a life expectancy of < 2 months • Accompanying schizophrenia or psychotic disorder
Intervention	Treatment Routes for Exploring Agitation (TREA) approach – to uncover reasons for possible behaviours to prompt interventions for possible resolution of symptoms
Comparison	Usual care
Length of follow up	Interventions provided for 10 days during the 4 hours of greatest observed agitation behaviour
Location	USA (11 nursing homes)

Bibliographic reference	Cohen Mansfield J, Libin A, Marx MS (2007) Nonpharmacological treatment of agitation: A controlled trial of systematic individualised Intervention Journal of Gerentology, 8, 908-916
Outcomes measures	Overall agitation (ABMI)
Authors conclusion	Implementation of the intervention resulted in a significant increase in pleasure and interest outcomes
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? States yes but method not reported • Were patients, health workers and study personnel blinded? Not clear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

Bibliographic reference	Cohen-Mansfield J, Thein K, Marx MS et al (2012) , Efficacy of nonpharmacological interventions for agitation in advanced dementia: A randomised placebo controlled trial, Focus on Alzheimers's disease and Related Disorders, 25, 564-575
Study type	Randomised controlled trial
Aim	To follow up on the earlier study to determine the efficacy of nonpharmacological interventions individualised to address unmet needs in reducing agitation in people with dementia
Patient characteristics	Baseline characteristics Intervention N= 89 Mean age = 85.9 years; 73.0% female; Mean MMSE 7.62 ; Mean ABMI 8.76 Control N= 36 Mean age = 85.3 years; 77.8% female; Mean MMSE 9.38 ; Mean ABMI 7.16
Inclusion/ exclusion criteria	Inclusion: • Resident in one of contributing residential centres for ≥3 weeks • Agitated at least several times a day • Aged 60 years or over • Diagnosis of dementia Exclusion: • Life expectancy < 3 months • Diagnosis of bipolar, schizophrenia or mental retardation

Bibliographic reference	Cohen-Mansfield J, Thein K, Marx MS et al (2012) , Efficacy of nonpharmacological interventions for agitation in advanced dementia: A randomised placebo controlled trial, Focus on Alzheimers's disease and Related Disorders, 25, 564-575
	• Expected to leave nursing home in 4 months • MMSE score ≥ 25 • Participation in previous TREA trial
Intervention	TREA intervention for unmet needs (potential reasons for agitation)
Comparison	Usual care
Length of follow up	2 weeks
Location	USA (11 Residential care settings)
Outcomes measures	• Agitation ABMI • Behaviour LMBS
Authors conclusion	TREA interventions for unmet needs produced statistically significant decline in total physical nonaggressive and verbal agitation
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes random numbers 1.5:1 • Were patients, health workers and study personnel blinded? Not clear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes • Overall risk of bias: Low

Bibliographic reference	Cummings JL, Lykestos CG, Peskind ER, Porsteinsson AP et al (2015) Effect of dextromethorphan quinodine on agitation in people with alzheimer's disease dementia: a randomised controlled trial, JAMA,314:1242-1254
Study type	Randomised controlled trial
Aim	To determine the efficacy, safety and tolerability of dextromethorphan- quinidine upon agitation in patients with Alzheimer's disease
Patient characteristics	194 people with Alzheimer's disease Baseline characteristics: • Treatment group n= 93; mean age = 77.8 years; female = 55%; mean MMSE = 17.4; Mean NPI total score= 17.9 • Control group n= 127; mean age = 77.8 years; female = 58.3%; mean MMSE = 17.2; Mean NPI total score= 17.0

Bibliographic reference	Cummings JL, Lykestos CG, Peskind ER, Porsteinsson AP et al (2015) Effect of dextromethorphan quinodine on agitation in people with alzheimer's disease dementia: a randomised controlled trial, JAMA,314:1242-1254
Inclusion/ exclusion criteria	Inclusion: • Aged 50-90 years with possible or probable Alzheimer's disease (NINCDS/ADRDA) and clinically significant agitation • A score of 4 or more on CIGIC • MMSE = 8 to 28 • Behavioural symptoms interfering with current routine • Stable doses of AD medications and short acting psychotic medications (medication doses to remain stable throughout study duration) Exclusion: • Non Alzheimer's disease • Agitation not secondary to Alzheimer's disease • Hospitalisations for mental health care facility • Significant depression (Cornell scale for Depression ≥ 10)
Intervention	Oral administration of dextromethorphan-quinidine
Comparison	Switch to placebo
Length of follow up	10 weeks
Location	US (42 sites)
Outcomes measures	• NPI Agitation/ Aggression domain • NPI total score • MMSE • Cornell scale for depression • CGIC • Safety – adverse events
Authors conclusion	The combination of dextromethorphan- quinidine demonstrated clinically relevant efficacy for agitation and was generally well tolerated
Source of funding	Avanir pharmaceuticals
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Partly blocked randomisation in stage 2: Stage 1– stratified by MMSE score at baseline <15/>15 • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes

Bibliographic reference	Cummings JL, Lykestos CG, Peskind ER, Porsteinsson AP et al (2015) Effect of dextromethorphan quinodine on agitation in people with alzheimer's disease dementia: a randomised controlled trial, JAMA,314:1242-1254
	• Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Deudon A, Maubourguet N, Gervais X, Leone E, Brocker P et al (2009) Non pharmacological management of behavioural symptoms in nursing homes, Journal of Geriatric Psychiatry , 24, 1386-1395
Study type	Randomised controlled trial
Aim	To evaluate the effectiveness of a staff education intervention to manage BPSD in older people diagnosed with dementia
Patient characteristics	Baseline characteristics • Intervention n= 174; Mean age = 86.5 years; 77% female; mean MMSE= 9.2 • Control: n= 132; Mean age = 86.0 years; 78.8% female; mean MMSE= 12.1
Inclusion/ exclusion criteria	Inclusion: • Diagnosis of dementia (ICD 10) • MMSE ≤24 • Presenting with at least one BPSD once a week – opposition, denial of care, aberrant motor behaviour, agitation, delusions, hallucinations or screaming Exclusion: • Not reported
Intervention	Staff training programme
Comparison	Usual care
Length of follow up	8 weeks programme- follow up 12 weeks and 20 weeks
Location	France (16 nursing homes)
Outcomes measures	• CMAI total • NPI psychotic • NPI hyperactivity • Quality of life
Authors conclusion	The intervention reduced BPSD in people with severe dementia living in a nursing home. Effect was present 3 months after programme completion

Bibliographic reference	Deudon A, Maubourguet N, Gervais X, Leone E, Brocker P et al (2009) Non pharmacological management of behavioural symptoms in nursing homes, Journal of Geriatric Psychiatry , 24, 1386-1395
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes – randomly selected and divided according to type of administrative organisation • Were patients, health workers and study personnel blinded? Not clear • Were the groups similar at the start of the trial? Not reported – Yes- except MMSE in intervention group was significantly lower than control • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes • Overall risk of bias: Moderate

Bibliographic reference	Fox C, Crugel M, Maidment I, Austad H et al (2012) Efficacy of memantine for agitation in Alzheimer's disease: a randomised double-blind placebo controlled trial : Plos One,7: e35185
Study type	Randomised controlled trial
Aim	To determine if memantine is superior to placebo for clinically significant agitation in people with moderate to severe Alzheimer's disease
Patient characteristics	153 people with Alzheimer's disease (NINCDS-ADRDA) Baseline characteristics: • Treatment group n= 72; mean age = 84.9 years; 72.2% female; mean CMAI = 62.5; mean MMSE = 6.2; • Control group n= 77; mean age = 84.4 years; 75.3% female; mean CMAI = 68.3; mean MMSE = 7.3;
Inclusion/ exclusion criteria	Inclusion: • Diagnosed with probable Alzheimer's disease (NINCDS/ADRDA) • Aged ≥45 years • SMMSE score ≤19 • CMAI ≥ 45 Exclusion: • Memantine use in 4 weeks prior to trial commencing • Severe renal impairment, epilepsy, history of convulsions, seizure or receiving anti-epileptic treatment • Any anti- psychotic, anti-depressant, , benzodiazepine, lithium or hypnotic use, anti-Pakinsonian medication • Hypersensitivity to memantine • Use of NMDA receptor agonists • Recent myocardial infarction, congestive heart failure, uncontrolled hypertension, severe, unstable or poorly controlled illness or any disability interfering with participants ability to complete study
Intervention	Memantine
Comparison	Matched placebo
Length of follow up	12 weeks
Location	UK
Outcomes measures	• CMAI • NPI • MMSE • CIGIC • Adverse events
Authors conclusion	Memantine did not significantly improve agitation in people with mild to moderate AD

Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes but method not reported • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes. • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	**Frakey LL, Dalloway S Buelow M, Mallo A (2012) A randomized, double-blind, placebo controlled trial of modafinil for the treatment of apathy in individuals for mild-to- moderate Alzheimer's disease patients with agitation and aggression, Journal of Clinical Psychiatry, 73: 796-801**
Study type	Randomised controlled trial
Aim	To examine the effects of modafinil in apathetic symptoms in people with Alzheimer's disease
Patient characteristics	22 people with mild to moderate probable Alzheimer's disease (NINCDS-ADRDA) Baseline characteristics: • Treatment group n= 11; mean age = 75.27 years • Control group n= 11; mean age = 79.36 years
Inclusion/ exclusion criteria	Inclusion: • Diagnosed with Alzheimer's disease (NINCDS/ADRDA) • Been on stable dose of a cholinesterase inhibitor for 30 days • Showed clinically elevated symptoms of apathy (FrBS ≥65) Exclusion • Diagnosis of major depression • Focal brain lesions • History of head trauma
Intervention	Modafinil
Comparison	Matched placebo
Length of follow up	8 weeks
Location	USA

Bibliographic reference	Frakey LL, Dalloway S Buelow M, Mallo A (2012) A randomized, double-blind, placebo controlled trial of modafinil for the treatment of apathy in individuals for mild-to- moderate Alzheimer's disease patients with agitation and aggression, Journal of Clinical Psychiatry, 73: 796-801
Outcomes measures	• FrSBe Apathy • ADLQ • DAFS
Authors conclusion	Adding modafinil to standard treatment with a cholinesterase inhibitor did not result in additional symptoms of apathy although reductions in reported apathy were noted
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes Urn randomisation • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Only age differences reported • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Holmes C, Wilkinson D, Dean C, (2004) The efficacy of donepezil in the treatment of neuropsychiatric symptoms in Alzheimer's disease, Neurology, 2, 214-219
Study type	Randomised controlled trial
Aim	To determine the effect of treatment with donepezil on neuropsychiatric symptoms in people with mild to moderate Alzheimer's disease
Patient characteristics	134 people with Alzheimer's disease (NINCDS-ADRDA) Baseline characteristics: • Treatment group n = 41; mean age = 78.6 years; 54.0% female; mean CMAI = 62.5; mean standardised MMSE = 8.1; mean NPI= 15.1 • Control group n = 55; mean age = 78.8 years; 67.0% female; mean CMAI = 60.7; mean MMSE = 20.8; mean NPI= 14.3
Inclusion/ exclusion criteria	Inclusion: • Diagnosed with probable Alzheimer's disease (NINCDS/ADRDA) • Aged 55 years or greater • Total NPI score ≥ 11

Bibliographic reference	Holmes C, Wilkinson D, Dean C, (2004) The efficacy of donepezil in the treatment of neuropsychiatric symptoms in Alzheimer's disease, Neurology, 2, 214-219
	Exclusion: • MMSE score below 10 or greater than 27 • Previous exposure to cholinesterase inhibitor • Clinically relevant disease that might contraindicate use • Severe, unstable or uncontrolled medical conditions
Intervention	10mg Donepezil
Comparison	Matched placebo
Length of follow up	24 weeks
Location	UK (16 centres)
Outcomes measures	• NPI • NPI distress scale • Adverse events
Authors conclusion	Donepezil was significantly efficacious in treating neuropsychiatric symptoms in people with mild to moderate Alzheimer's disease
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Open label run in phase followed by number randomisation performed by independent pharmacist • Were patients, health workers and study personnel blinded? Partly – see above • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes. • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Howard RJ, Juszczak E, Ballard CG, Bentham P, Brown RG et al (2007) Donepezil for the treatment of agitation in Alzheimer's disease, New England Journal of Medicine, 357: 1382-1392
Study type	Randomised controlled trial
Aim	To determine the effect of treatment with donepezil on clinically significant agitation in people with Alzheimer's disease

Bibliographic reference	Howard RJ, Juszczak E, Ballard CG, Bentham P, Brown RG et al (2007) Donepezil for the treatment of agitation in Alzheimer's disease, New England Journal of Medicine, 357: 1382-1392
Patient characteristics	249 people with Alzheimer's disease (NINCDS-ADRDA) Baseline characteristics: • Treatment group n= 128; mean age = 84.9 years; 82.0% female; mean CMAI = 62.5; mean standardised MMSE = 8.1; mean SIB= 53.8 • Control group n= 26; mean age = 84.4 years; 87.0% female; mean CMAI = 60.7; mean standardised MMSE = 8.2; mean SIB= 55.9
Inclusion/ exclusion criteria	Inclusion: • Diagnosed with Alzheimer's disease (NINCDS/ADRDA) • Clinical agitation CMAI ≥ 39 and moderate management problems • Lived in residential care facility • Caregiver living in the community • Not receiving neuroleptics or cholinesterase inhibitors at time of enrolment • Capacity and willing to consent to participate Exclusion: • Known sensitivity to donepezil • Severe, unstable or uncontrolled medical conditions • Delirium • Dementia with Lewy bodies • Evidence of poor compliance with prescribed medication
Intervention	Donepezil
Comparison	Matched placebo
Length of follow up	12 weeks
Location	UK (8 centres)
Outcomes measures	• CMAI • NPI • MMSE • CIGIC • Adverse events
Authors conclusion	No significant difference between donepezil compared to placebo for agitation at end point or on NPI or on CGIC. Adverse events were similar in both treatment and control groups
Source of funding	Medical Research Council grant

Bibliographic reference	Howard RJ, Juszczak E, Ballard CG, Bentham P, Brown RG et al (2007) Donepezil for the treatment of agitation in Alzheimer's disease, New England Journal of Medicine, 357: 1382-1392
	Alzheimer's society grant
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes telephone randomisation performed centrally • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes. Recruited as showing NP symptoms but baseline differences between treatment groups not stated • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Lin Y, Chu H, Yang CY, Chen CH et al (2011) Effectiveness of group music intervention against agitated behaviour in elderly people with dementia, International Journal of Geriatric Psychiatry 7: 670-678
Study type	Randomised controlled trial
Aim	To examine the effects of group music as an intervention to alleviate agitated behaviour in people with dementia
Patient characteristics	100 people with dementia Baseline characteristics: • Treatment group n= 49; 53.06% female; mean age = 81.46 years; mean MMSE 12.80 • Control group n= 51; 52.94% female; mean age = 82.15 years; mean MMSE 13.80
Inclusion/ exclusion criteria	Inclusion: • Age 65 years or over • Diagnosed with dementia (DSM-IV) • Moderate to severe dementia (3-6 on GDS) • Spoke Mandarin and/or Taiwanese Exclusion: • Not reported
Intervention	Group music
Comparison	Usual care

Bibliographic reference	Lin Y, Chu H, Yang CY, Chen CH et al (2011) Effectiveness of group music intervention against agitated behaviour in elderly people with dementia, International Journal of Geriatric Psychiatry 7: 670-678
Length of follow up	6 weeks (12 sessions)
Location	Taiwan (3 facilities)
Outcomes measures	• Chinese CMAI
Authors conclusion	After group music the intervention group presented fewer agitated behaviours compared to usual care
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes permuted block randomisation • Were patients, health workers and study personnel blinded? Unclear Not stated • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Mahlberg R, Walther S, Eichman U, Tracik F, Kunz D (2007) Effects of rivastigmine on actigraphically monitored motor activity in severe agitation related to Alzheimer's disease, Srchives of gerontology and geriatrics, 1: 19-26
Study type	Randomised controlled trial
Aim	To examine whether rivastigmine can reduce motor activity among inpatients with severe agitation and Alzheimer's disease
Patient characteristics	20 people with probable Alzheimer's disease (NINCDS-ADRDA) Baseline characteristics: • Treatment group n= 10; mean age = 82.6 years; 70% female; mean FAS = 5.5; mean MMSE = 9.0 • Control group n= 10; mean age = 78.2 years; 60% female; mean FAS = 5.4; mean MMSE = 13.2
Inclusion/ exclusion criteria	Inclusion: • Diagnosed with Alzheimer's disease (NINCDS/ADRDA) • Agitated behaviour • Stable clinical state • Written informed consent Exclusion:

Bibliographic reference	Mahlberg R, Walther S, Eichman U, Tracik F, Kunz D (2007) Effects of rivastigmine on actigraphically monitored motor activity in severe agitation related to Alzheimer's disease, Srchives of gerontology and geriatrics, 1: 19-26
	• Delirium • Major depressive episode • Suicidal tendencies • Substance dependence • Epilepsy • Urinary retention • Asthma • Bradycardia • Prior use of study medication
Intervention	Rivastigmine 3mg
Comparison	Matched placebo
Length of follow up	2 weeks
Location	Germany
Outcomes measures	• NOSGER • NPI • NPI agitation
Authors conclusion	Rivastigmine reduced agitation on NPI agitation scale but not NOSGER with actigraphic data only showing a tendency to reduced motor activity
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes but randomisation only stated as according to protocol • Were patients, health workers and study personnel blinded? No. Single blind • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes. • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

Bibliographic reference	McCabe MP, Bird M, Davison TE, Mellor D et al (2015) An RCT to evaluate the utility of a clinical protocol for staff in the management of behavioural and psychological symptoms of dementia in residential aged care settings, Aging and Mental Health, 9, 799-807
Study type	Randomised controlled trial
Aim	To evaluate the efficacy of a training program to assist staff to manage BPSD in residential care
Patient characteristics	Baseline characteristics: • N = 187 Mean age = 83.03 years; 72% female; Mean baseline CDR 2.73
Inclusion/ exclusion criteria	Inclusion: • Identified as having dementia (MMSE <26 • Significant challenging behaviour Exclusion: • Not reported
Intervention	• Staff workshop on BPSD and person-centred care • Training and clinical support session on the protocol • Staff workshop and clinical support from a mental health professional experienced in working with BPSD • Staff training in implementing the protocol
Comparison	Usual care
Length of follow up	Implementation covering 12 weeks
Location	Australia (16 Residential care settings)
Outcomes measures	CMAI
Authors conclusion	Improvements in challenging behaviour observed for training/support condition but not maintained when clinical support was removed
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? States yes but method not reported • Were patients, health workers and study personnel blinded? Not clear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

Bibliographic reference	Porsteinsson AP, Tariot PN, Erb R, Cox, C Smith E et al (2001) Placebo=controlled study of divalproex sodium for agitation in dementia, Journal of Geriatric Psychiatry, 9, 58-66
Study type	Randomised controlled trial
Aim	To assess the efficacy, tolerability and safety of divalproex sodium for the treatment of agitation in patients with dementia
Patient characteristics	56 people with dementia Baseline characteristics • Treatment group n= 28; mean age = 85.3 years; female = 62%; • Control group n= 26; mean age = 84.7 years; female = 79%;
Inclusion/ exclusion criteria	Inclusion: • Probable or possible Alzheimer's disease (DSM-IV; NINDS/ADRDA), vascular dementia (DSMIV); mixed dementia (DSMIV) • >60 years • Exhibit agitation for at least two weeks (BPRS score 3 or more) • Free of acute medical illness Exclusion: • Not reported
Intervention	Divalproex sodium
Comparison	Placebo
Length of follow up	6 weeks
Location	USA 7 sites
Outcomes measures	• Overt aggression scale • BPRS • CGI • MMSE
Authors conclusion	The evidence suggests possible short term efficacy, tolerability and safety of divalproex sodium for agitation in dementia
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes but method not reported • Were patients, health workers and study personnel blinded? No – patients only • Were the groups similar at the start of the trial? Yes- • Aside from the experimental intervention, were the groups treated equally? Yes

Bibliographic reference	Porsteinsson AP, Tariot PN, Erb R, Cox, C Smith E et al (2001) Placebo=controlled study of divalproex sodium for agitation in dementia, Journal of Geriatric Psychiatry, 9, 58-66
	• Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes • Overall risk of bias- moderate

Bibliographic reference	Rapp MA, Mell T, Majic T, Treusch Y et al (2013) Agitation in nursing home residents with dementia (VIDEANT trial): effects of a cluster randomised controlled, guideline intervention trial, International Journal of the American Medical Directors, 9: 690-695
Study type	Randomised controlled trial
Aim	To examine the effects of complex guideline based intervention on agitation in people with dementia
Patient characteristics	304 people with dementia Baseline characteristics: • Treatment group n=163; 75% female; mean age = 81.34 years; mean MMSE 9.22 • Control group n= 141; 69% female; mean age = 81.91 years; mean MMSE 8.56
Inclusion/ exclusion criteria	Inclusion: Comparability of nursing home not participant inclusion criteria • Good standing with local nursing home authorities • Nursing home size between 100 and 200 residents • Ratio of 50% to 70% of residents with dementia Exclusion: • Not reported
Intervention	Training support of nursing home staff and activity therapy
Comparison	Usual care
Length of follow up	10 months
Location	Germany (18 centres)
Outcomes measures	• CMAI • Number of psychotropic drugs prescribed
Authors conclusion	Complex guideline based interventions are effective at reducing agitated behaviours in nursing home residents with dementia
Source of funding	Not reported

Bibliographic reference	Rapp MA, Mell T, Majic T, Treusch Y et al (2013) Agitation in nursing home residents with dementia (VIDEANT trial): effects of a cluster randomised controlled, guideline intervention trial, International Journal of the American Medical Directors, 9: 690-695
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes simple random number • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Rea R, Carotenuto A, Traini E, Fasanaro AM, Manzo V, Amenta F (2015) Apathy treatment in Alzheimer's disease: Interim results of ASVCOMALVA trial, Journal of Alzheimer's disease, 48: 377-383
Study type	Randomised controlled trial
Aim	To examine the efficacy of donepezil plus a cholinergic precursor (choline alphoscerate) on apathy in people with Alzheimer's disease
Patient characteristics	113 people with mild to moderate Alzheimer's disease (NINCDS-ADRDA) Baseline characteristics: • Treatment group n= 57; mean age = 76 years; mean MMSE = 19.9 • Control group n= 56; mean age = 78 years; mean MMSE = 20.3
Inclusion/ exclusion criteria	Inclusion: • Sub sample of people included in ASCOMALVA trial diagnosed with Alzheimer's disease (NINCDS/ADRDA) and showing signs of apathy • Showed MRI lesions ≥2 in at least one subfield of age related white matter changes • MMSE between 14 and 24 at baseline Exclusion: • Not reported
Intervention	Donepezil plus choline alphoscerate
Comparison	Donepezil only
Length of follow up	2 years

Bibliographic reference	Rea R, Carotenuto A, Traini E, Fasanaro AM, Manzo V, Amenta F (2015) Apathy treatment in Alzheimer's disease: Interim results of ASVCOMALVA trial, Journal of Alzheimer's disease, 48: 377-383
Location	Italy
Outcomes measures	• Apathy • NPI • FAB
Authors conclusion	Apathy scores were lower in people treated with donepezil plus choline alphoscerate compared to those receiving donepezil monotherapy
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes but method not reported here • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Ridder, HMO, Stige B, Qvale LG, Gold C (2013) Individual music therapy for agitation in dementia: an exploratory randomised controlled trial, Aging and Mental Health, 17, 667-678
Study type	Randomised controlled trial
Aim	To examine the effect of individual music therapy on agitation in people with moderate to severe dementia living in nursing homes
Patient characteristics	Baseline characteristics • Standard care first n= 21; Mean age = 80.2 years; mean MMSE = 5.25; Mean CMAI frequency = 30.98 • Music therapy first n= 21; Mean age = 82.17 years; mean MMSE = 9.84; Mean CMAI frequency = 30.21
Inclusion/ exclusion criteria	Inclusion: • Nursing home resident with moderate to severe dementia • Diagnosis of dementia based on medical journal • Referred to music therapy based on established referral procedures • Symptoms of agitation

Bibliographic reference	Ridder, HMO, Stige B, Qvale LG, Gold C (2013) Individual music therapy for agitation in dementia: an exploratory randomised controlled trial, Aging and Mental Health, 17, 667-678
	• Completed consent procedures Exclusion: • Not reported
Intervention	Music therapy bi weekly over 6 weeks (12 sessions)
Comparison	Usual care
Length of follow up	6 weeks
Location	Netherlands (17 care homes)
Outcomes measures	• CMAI • ADRQL
Authors conclusion	6 weeks of music therapy reduces agitation
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes participants were paired using a coding system • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Not reported – Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Sung H, Chang SM, Lee W, Lee M (2006) The effects of group music with movement intervention on agitated behaviours of institutionalised elders with dementia in Taiwan, Complementary Therapies in Medicine 2: 113-119
Study type	Randomised controlled trial
Aim	To examine the effects of group music with movement on agitation in people with dementia
Patient characteristics	36 people with dementia Baseline characteristics: • Treatment group n= 18; 38.8% female; mean age = 76.78 years • Control group n= 18; 16..6% female; mean age = 78.44 years;

Bibliographic reference	Sung H, Chang SM, Lee W, Lee M (2006) The effects of group music with movement intervention on agitated behaviours of institutionalised elders with dementia in Taiwan, Complementary Therapies in Medicine 2: 113-119
Inclusion/ exclusion criteria	Inclusion: • Age 65 years or over • Diagnosed with dementia (DSM-IV) • Moderate to severe dementia (3-6 on GDS) • Ability to engage in a simple activity and follow simple directions • Ability to understand Taiwanese or Chinese • No hearing impairment • Did not receive medications for agitation • Presence of agitated behaviours (CMAI) • No obvious symptoms of pain or infection Exclusion: • Not reported
Intervention	Group music with movement
Comparison	Usual care
Length of follow up	4 weeks
Location	Taiwan
Outcomes measures	• Modified CMAI- modified for time duration of study
Authors conclusion	Agitated behaviours significantly reduced in intervention group compared to control
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes; block randomisation • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Van der Ploeg E, Eppingstall B, Camp CJ, Runci SJ et al (2013) A Randomised crossover trial to study the effect of personalised one to one interaction using Montessori-based activities on agitation, affect and engagement in nursing home residents with Dementia, International Psychogeriatrics, 25, 564-575
Study type	Randomised controlled trial
Aim	To test if personalised one to one interaction activities based on Montessori principles would improve agitation, engagement and affect n people with dementia, compared to a control condition
Patient characteristics	Baseline characteristics: • N= 44 Mean age = 78.1 years; 68% female; Mean MMSE 6
Inclusion/ exclusion criteria	Inclusion: • Chart diagnosis of dementia • Physical agitated behaviour occurring at least several times a day • Behaviour not due to untreated pain, physical illness or depression • Resident in special dementia unit for at least 3 months Exclusion: • Refusal of intervention on two occasions • If psychotropic medications were to change over the course of study • Reports of an acutely life threatening illness • Behaviour presented a potential hazard to researchers
Intervention	Individual personalised session lasting 30 mins
Comparison	Non personalised intervention
Length of follow up	4 weeks
Location	Australia (16 Residential care settings)
Outcomes measures	• Agitation • Positive affect • Neutral affect • Negative affect • Constructive engagement • Neutral engagement • Negative engagement
Authors conclusion	Both personalised and non-personalised interventions can assist in reducing agitated behaviours
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	Van der Ploeg E, Eppingstall B, Camp CJ, Runci SJ et al (2013) A Randomised crossover trial to study the effect of personalised one to one interaction using Montessori-based activities on agitation, affect and engagement in nursing home residents with Dementia, International Psychogeriatrics, 25, 564-575
	• Was the assignment of patients to treatments randomised? Yes controlled blocks • Were patients, health workers and study personnel blinded? Not clear • Were the groups similar at the start of the trial? N/A crossover study • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

Bibliographic reference	van den Elsen GAH, Amir IA, Verkes R-J, KramersC et al (2015) Tetrahydrocannabinol for neuropsychiatric symptoms in dementia: a randomised controlled trial, American Academy of Neurology,84:2338-2344
Study type	Randomised controlled trial
Aim	To determine the efficacy and safety of low dose oral tetrahydrocannabinol (THC) in neuropsychiatric symptoms in people with dementia
Patient characteristics	50 people with dementia Baseline characteristics: • Treatment group n= 24; mean age = 79.0 years; female = 55.2%; mean MMSE = 15.9; • Control group n= 26; mean age = 78.0 years; female = 47.2%; mean MMSE= 14.0
Inclusion/ exclusion criteria	Inclusion: • Diagnosed with Alzheimer's disease, vascular dementia or mixed dementia (NINCDS/ADRDA) • Clinically relevant neuropsychiatric symptoms (NPI ≥10) • Agitation, aggression or aberrant motor behaviour • Caregiver in contact with patient at least twice a week Exclusion: • Major psychiatric diseases or unstable concomitant disorders • Frequent falling due to orthostatic hypotension • History or current alcohol or drug abuse
Intervention	Oral administration of Tetrahydrocannabinol (THC) 1.5mg 3 times per day
Comparison	Matched placebo

Bibliographic reference	van den Elsen GAH, Amir IA, Verkes R-J, KramersC et al (2015) Tetrahydrocannabinol for neuropsychiatric symptoms in dementia: a randomised controlled trial, American Academy of Neurology,84:2338-2344
Length of follow up	3 weeks
Location	Netherlands
Outcomes measures	• NPI total score • CMAI • Barthel Index • CGIC • QoL AD
Authors conclusion	Oral administration of THC showed no benefit of neuropsychiatric symptoms but was well tolerated
Source of funding	European regional development fund
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes computer generated randomisation • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes. Recruited as showing NP symptoms but baseline differences between treatment groups not stated • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

Bibliographic reference	Wang LY, Shofer JB, Rohde K, Hart KL, Hoff DJ et al (2008) Prazosin for the treatment of behavioral symptoms in Alzheimer's disease patients with agitation and aggression, American Journal of Geriatric Psychiatry, 17: 744-751
Study type	Randomised controlled trial
Aim	To examine the efficacy and tolerability of prazosin for behavioural symptoms in people with agitation and aggression in Alzheimer's disease
Patient characteristics	22 nursing home residents with Alzheimer's disease (NINCDS-ADRDA) Baseline characteristics: • Treatment group n= 11; mean age = 83.2 years; 82.0% female; mean MMSE = 9.3 • Control group n= 11; mean age = 78.1 years; 87.0% female; mean MMSE = 14.0

Bibliographic reference	Wang LY, Shofer JB, Rohde K, Hart KL, Hoff DJ et al (2008) Prazosin for the treatment of behavioral symptoms in Alzheimer's disease patients with agitation and aggression, American Journal of Geriatric Psychiatry, 17: 744-751
Inclusion/ exclusion criteria	Inclusion: • Diagnosed with Alzheimer's disease (NINCDS/ADRDA) • Exhibit agitation or aggression at least twice weekly for two weeks • Score ≥4 on BPRS (anxiety, tension, hostility, uncooperativeness or excitement sub scales) Exclusion: • Supine systolic blood pressure <110 (Orthostatic hypotension ≥20mmHg drop in systolic BP following 2 minutes of standing) • Concurrent administration of other Alpha-1 AR antagonists • Uncontrolled persistent distressing symptoms • Current delirium • Current depression or history of bipolar disorder or schizophrenia • Unstable medical conditions that could contribute to cognitive or behavioural impairment
Intervention	Prazosin
Comparison	Matched placebo
Length of follow up	8 weeks
Location	USA
Outcomes measures	• CGIC • BPRS • NPI • Adverse events
Authors conclusion	Prazosin was well tolerated and improved behaviour in peol with agitation and aggression in Alzheimer's disease
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes but method not reported • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? No – high level of dropout • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Wang LY, Shofer JB, Rohde K, Hart KL, Hoff DJ et al (2008) Prazosin for the treatment of behavioral symptoms in Alzheimer's disease patients with agitation and aggression, American Journal of Geriatric Psychiatry, 17: 744-751
	Overall risk of bias: High

Bibliographic reference	Yang MH, Lin LC, Wu, SC Chiu JH (2015) Comparison of the efficacy of aroma-acu-pressure and aromatherapy for the treatment of dementia associated agitation, Bio Med Central 15: 377-383
Study type	Randomised controlled trial
Aim	To explore the ability of aroma-acupressure therapy and aromatherapy to improve agitation in people with dementia
Patient characteristics	186 people with dementia Baseline characteristics: • Aroma acupressure treatment group n= 56; 17.9% female; mean age = 85.3 years • Aroma treatment group n= 73; 34.2% female; mean age = 83.67 years • Control group n= 57; 24.6% female; mean age = 81.56 years;
Inclusion/ exclusion criteria	Inclusion: • Participants recruited from6 institutions specialising in dementia care in Taiwan Exclusion: • Not reported
Intervention	Aromatherapy Aromatherapy plus acupressure
Comparison	Control – usual care
Length of follow up	4 weeks
Location	Taiwan (6 centres)
Outcomes measures	CMAI
Authors conclusion	Both aromatherapy and aroma acupressure had a significant effect on reducing agitation. Aroma acupressure had a greater effect
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes stratified sampling method • Were patients, health workers and study personnel blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes

Bibliographic reference	Yang MH, Lin LC, Wu, SC Chiu JH (2015) Comparison of the efficacy of aroma-acu-pressure and aromatherapy for the treatment of dementia associated agitation, Bio Med Central 15: 377-383
	• Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Low

Bibliographic reference	Zwijsen SA, Smallbrugge M, Eefsting J et al (2014) Coming to Grips with Challenging Behaviour: A cluster randomised controlled trial on the effects of a multidisciplinary care program on challenging behaviour in dementia, JAMDA, 15, 531.e1 – 531.e10
Study type	Randomised controlled trial
Aim	To determine if application of the grip care program would lead to a decrease in challenging behaviour for people living with dementia in nursing homes
Patient characteristics	• Intervention = 3 units • Control = 14 units Baseline characteristics: • 659 people with dementia; mean age 84 years; 69.7% female • 17 care homes randomly assigned to 5 groups - resulting in all care homes having implemented intervention at final assessment
Inclusion/ exclusion criteria	Inclusion: • All residents with dementia at participating care homes were eligible Exclusion: • Not reported
Intervention	Grip on challenging behaviour - stepped randomisation
Comparison	Usual care
Length of follow up	Every 4 months for 20 months(6 time assessments)
Location	Netherlands (17 care homes)
Outcomes measures	• CMAI • NPI Agitation • NPI –Nursing home
Authors conclusion	A small but significant decrease was found after implementation of Grip programme
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	Zwijsen SA, Smallbrugge M, Eefsting J et al (2014) Coming to Grips with Challenging Behaviour: A cluster randomised controlled trial on the effects of a multidisciplinary care program on challenging behaviour in dementia, JAMDA, 15, 531.e1 – 531.e10
	• Was the assignment of patients to treatments randomised? Yes care units randomised into 5 groups using random allocation software • Were patients, health workers and study personnel blinded? Unclear Not stated • Were the groups similar at the start of the trial? Not reported – baseline characteristics only reported as full population with dementia • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Unclear- does not report on population of residents only on care home • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes Overall risk of bias: Moderate

E.11 Supporting informal carers

E.11.1 Supporting informal carers of people living with dementia

- How effective are carers' assessments in identifying the needs of informal carers of people living with dementia?
- What interventions/services are most effective for supporting the wellbeing of informal carers of people living with dementia?

E.11.1.1 Interventions/services for informal carers

Systematic reviews

Bibliographic reference	Jensen M, Agbata N, Canavan M McCarth G (2015) Effectiveness of educational interventions for informal caregivers of individuals with dementia residing in the community: systematic review and meta-analysis of randomised controlled trials, International journal of Geriatric Psychiatry, 2, 130-145
Study type and aim	Systematic review to evaluate the effectiveness of educational interventions compared with usual care for informal carers of people with dementia
Included study criteria	RCTs of any geographic or socioeconomic setting
Included participant criteria	Informal caregivers (un paid, non-professionals, who take extraordinary day to day care of an individual with dementia) of people with dementia
Interventions	Educational interventions – for teaching skills relevant to dementia caring (communication skills, coping and management strategies, facts about dementia, availability of support services) Specialised interventions (for example communication skills, cognitive behavioural, anger management) were excluded Multicomponent interventions were excluded Comparator was usual care (pharmacological interventions , provision of access to information sources; support services
Outcome measures	• Carer burden • Carer quality of life • Carer depression • Number of transitions to long stay care
Included studies	7 RCTs included (De Rotrou, 2011; Gavrilova, 2009; Guerra, 2011; Hepburn, 2001; Kurz, 2010; Martin-Carrasco, 2009; Palavanzadeh, 2010)
Study dates	Dates searched – February 2010 to February 2013
Risk of bias (systematic review)	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes

Bibliographic reference	Jensen M, Agbata N, Canavan M McCarth G (2015) Effectiveness of educational interventions for informal caregivers of individuals with dementia residing in the community: systematic review and meta-analysis of randomised controlled trials, International journal of Geriatric Psychiatry, 2, 130-145
	• Was a comprehensive literature search performed? All major databases searched- no language restrictions • Was the status of publication (i.e. grey literature) used as an inclusion criterion? No RCTs only • Were the characteristics of the included studies provided? Yes – summary tables • Was the scientific quality of the included studies assessed and documented? Yes Risk of bias assesed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? N/a • Was the conflict of interest included? No

Bibliographic reference	Laver K, Milte R, Dyer S, Crotty M (2016) A systematic review and meta analysis comparing carer focused and dyadic multicomponent interventions for carers of people with dementia, Journal of Aging anf Health, 1-42
Study type and aim	Systematic review to compare the efficacy of multicomponent interventions that focus on the carer and dyadic interventions for the carer and person with dementia with usual care
Included study criteria	RCTs published in English
Included participant criteria	Carers of people with any type of dementia
Interventions	Multicomponent interventions – involving a number of different techniques(for example- education, counselling, information regarding services, enhancing carer skills to provide care, problem solving and strategy development, increasing resilience and coping skills) Comparator was usual care
Outcome measures	• Carer burden • Carer quality of life • Carer depression • Number of transitions to long stay care
Included studies	17 RCTs included for interventions for carer 23 RCTs included for interventions involving carer and person with dementia
Study dates	Dates searched – Originally used published systematic review findings from Olazaran (2010). Updated this by searching databases for trials published after September 2008 to October 2015
Risk of bias (systematic	• Was an 'a priori' design provided? Yes

Bibliographic reference	Laver K, Milte R, Dyer S, Crotty M (2016) A systematic review and meta analysis comparing carer focused and dyadic multicomponent interventions for carers of people with dementia, Journal of Aging anf Health, 1-42
review)	• Was there duplicate study selection and data extraction? Partly – one reviewer involved in screening – two reviewers involved in extraction • Was a comprehensive literature search performed? All major databases searched • Was the status of publication (i.e. grey literature) used as an inclusion criterion? No RCTs only • Were the characteristics of the included studies provided? Yes – summary tables • Was the scientific quality of the included studies assessed and documented? Yes - risk of bias assessed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? N/a • Was the conflict of interest included? No

Bibliographic reference	Lins S, Hayder-Beichel D, Rucker G, Motschall E, Antes G, Meyer G, Langer G (2014) Efficacy and experiences of telephone counselling for informal carers of people with dementia, Cochrane Database of Systematic Reviews, 9,
Study type and aim	Systematic review to consider the efficacy of telephone counselling for informal carers of people with dementia
Included study criteria	All individually randomised parallel group controlled trials
Included participant criteria	Informal carers who provide care for a person with dementia at home and do not receive a reimbursement for their caring work (for example a relative, friend or neighbour). There was no restriction according to age, sex or ethnic background.
Interventions	Interventions focusing on telephone counselling for carers of people with dementia lasting for at least two months and did not involve face to face contact and it was not part of a multicomponent intervention Interventions had to comprise: General information on dementia Educating carers in coping skills and caring for their health Psychosocial support where carers could share feelings and shown how to build a social network Comparator was usual care
Outcome measures	• Caregiver depression • Caregiver burden • Distress • Anxiety • Quality of life • Care-giving self-efficacy

Bibliographic reference	Lins S, Hayder-Beichel D, Rucker G, Motschall E, Antes G, Meyer G, Langer G (2014) Efficacy and experiences of telephone counselling for informal carers of people with dementia, Cochrane Database of Systematic Reviews, 9,
	• Satisfaction
Included studies	9 RCTs included
Study dates	Dates searched – Databases searched in May 2011 and updated in February 2013
Risk of bias (systematic review)	Was an 'a priori' design provided? Yes Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? All major databases searched, hand search abstracts archive • Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes • Were the characteristics of the included studies provided? Yes – summary tables/extraction/risk of bias reported • Was the scientific quality of the included studies assessed and documented? Yes Risk of bias assessed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? Yes • Was the conflict of interest included? No

Bibliographic reference	Maayan N, Sores-Weiser K, Lee H, (2014) Respite care for people with dementia and their carers, Cochrane Database of Systematic Reviews, 1,
Study type and aim	Systematic review to consider the benefits and harms of respite care for people with dementia and their carers
Included study criteria	All randomised controlled trials in which respite care was given to people with dementia and their carers
Included participant criteria	Full time carers of people with dementia
Interventions	Respite care defined as any service or group of services designed to provide temporary periods of relief or rest or both for caregivers, provided in community or an institution. Respite accumulated to less than 50 percent total care time Comparator was otherwise similar care without respite or alternative interventions
Outcome measures	Caregiver burden Psychological stress and health Physical health Economic impact Quality of life
Included studies	9 RCTs included

Bibliographic reference	Maayan N, Sores-Weiser K, Lee H, (2014) Respite care for people with dementia and their carers, Cochrane Database of Systematic Reviews, 1,
Study dates	Databases searched in December 2012
Risk of bias (systematic review)	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Sought additional information from study authors • Was the status of publication (i.e. grey literature) used as an inclusion criterion? No • Were the characteristics of the included studies provided? Yes – summary tables/ extraction/ Risk of bias reported • Was the scientific quality of the included studies assessed and documented? Yes Risk of bias assessed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? Yes • Was the conflict of interest included? No

Bibliographic reference	Parker D, Mills S, Abbey J (2008) Effectiveness of interventions that assist caregivers to support people with dementia living in the community: a systematic review, International Journal of Evidence Based Health, 6 137-172
Study type and aim	Systematic review to assess the effectiveness of interventions that assist caregivers to provide support for people with dementia in the community
Included study criteria	Any meta analyses, systematic reviews, randomised controlled trials, quasi experimental, cohort studies, case control, observational studies that considered the effectiveness of interventions that assist caregivers to provide support for people living with dementia.
Included participant criteria	Adult caregivers who provide support to people with dementia in the community
Interventions	Interventions that support caregivers (Supportive approaches eg: skills training, education; formal approaches eg: support, care planning; multicomponent approaches) Comparator was not clearly specified
Outcome measures	• Psychological morbidity • Self-reported perceptions of knowledge • Quality of life • Health service utilisation (including caregiver satisfaction)
Included studies	13 studies considered psycho educational interventions; 7 studies considered support; 12 studies reported multicomponent
Study dates	Dates searched – published records from 200 to 2005

Bibliographic reference	Parker D, Mills S, Abbey J (2008) Effectiveness of interventions that assist caregivers to support people with dementia living in the community: a systematic review, International Journal of Evidence Based Health, 6 137-172
Risk of bias (systematic review)	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Additional search using MeSH and keywords and hand searching reference lists • Was the status of publication (i.e. grey literature) used as an inclusion criterion? No • Were the characteristics of the included studies provided? Yes – summary tables/ extraction/ Risk of bias reported • Was the scientific quality of the included studies assessed and documented? Yes Risk of bias assessed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? Yes • Was the conflict of interest included? No

Bibliographic reference	Scott J, Dawkins S, Quinn M, Sanderson K, Elliott, K, Stirling C et al (2016) Caring for a carer: A systematic review of pure technology based cognitive behavioural therapy (TB-CBT) interventions for dementia carers, Aging and Mental health, 20, 793-803
Study type and aim	Systematic review of trials of pure TB –CBT interventions for carers of people with dementia
Included study criteria	Randomised controlled trials, quasi experimental studies Qualitative assessments were excluded Comparator not specified
Included participant criteria	Informal dementia carers
Interventions	Interventions were CBT based delivered via internet/ DVD and include at least one component of cognitive cognitive restructuring) or behavioural (relaxation training) therapy (Supportive approaches e.g. skills training, education; formal approaches e.g. support, care planning; multicomponent approaches) Comparator was not clearly specified
Outcome measures	• Caregiver depression
Included studies	4 studies included in the review
Study dates	Dates searched – published records from 1995 onwards
Risk of bias (systematic review)	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Sreveral major databases searched • Was the status of publication (i.e. grey literature) used as an inclusion criterion? Not reported

Bibliographic reference	Scott J, Dawkins S, Quinn M, Sanderson K, Elliott, K, Stirling C et al (2016) Caring for a carer: A systematic review of pure technology based cognitive behavioural therapy (TB-CBT) interventions for dementia carers, Aging and Mental health, 20, 793-803
	• Were the characteristics of the included studies provided? Yes – summary tables/ Risk of bias reported • Was the scientific quality of the included studies assessed and documented? Yes Risk of bias assessed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes- Meta analysis for depression outcome • Was the likelihood of publication bias assessed? Not reported • Was the conflict of interest included? Not reported

Bibliographic reference	Thompson C, Spilsbury K, Hall J, Birks Y, Barnes C, Adamson J (2007) Systematic review of information and support interventions for caregivers of people with dementia (Biomed Central, 7, 7-18
Study type and aim	Systematic review of RCTs to evaluate the efficacy of individual or group based technology interventions
Included study criteria	Randomised controlled trials,
Included participant criteria	Principal informal dementia caregiver (not professional), and care recipient (diagnosed with dementia) dyad
Interventions	Information and/ or support intervention Comparator was not clearly specified
Outcome measures	• Quality of life • Physical and mental health • Burden or satisfaction • Time spent on caring activities
Included studies	4 studies classed as technology based; 13 studies classed as group based; 27 studies classed as individual based
Study dates	Dates searched – published records from November 2003 to October 2005
Risk of bias (systematic review)	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Partly- one screened on relevance; two reviewers screened on protocol • Was a comprehensive literature search performed? Several major databases searched • Was the status of publication (i.e. grey literature) used as an inclusion criterion? Not reported • Were the characteristics of the included studies provided? Yes – summary tables/ Risk of bias reported • Was the scientific quality of the included studies assessed and documented? Yes Risk of bias assessed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes- Meta analysis where appropriate

Bibliographic reference	Thompson C, Spilsbury K, Hall J, Birks Y, Barnes C, Adamson J (2007) Systematic review of information and support interventions for caregivers of people with dementia (Biomed Central, 7, 7-18
	• Was the likelihood of publication bias assessed? Not reported • Was the conflict of interest included? Not reported

Bibliographic reference	Vernooij-Dassen M, Draskovic I, McCleery J, Downs M (2011) Cognitive reframing for carers of people with dementia
Study type and aim	Systematic review of RCTs to evaluate the efficacy of individual, group or technology based cognitive reframing interventions
Included study criteria	Randomised controlled trials, with no restrictions on length of trial or number of measurements
Included participant criteria	Family carer taking care of a person with any type of dementia (spouse, child, other family member or friend)
Interventions	Interventions provided singularly or in a group setting. Interventions were accepted as cognitive reframing if the goal of intervention was to reduce caregiver problems by identifying and modifying family carers responsibilities to people with dementia; family carers beliefs about their own need for support; family carers interpretations of the behaviours of people with dementia
Outcome measures	• Psychological morbidity and distress of family carer including depression and anxiety • Quality of life • Family carers appraisal of their role performance including burden, coping, self-efficacy, and appraisal of problem behaviours • Healthcare utilisation
Included studies	11 trials were included
Study dates	Dates searched – published records searched in April 2009
Risk of bias (systematic review)	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? three reviewers involved in screening • Was a comprehensive literature search performed? All major databases searched • Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes • Were the characteristics of the included studies provided? Yes – summary tables/ Risk of bias reported • Was the scientific quality of the included studies assessed and documented? Yes Risk of bias assessed • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes- Meta analysis where appropriate • Was the likelihood of publication bias assessed? Yes

Bibliographic reference	Vernooij-Dassen M, Draskovic I, McCleery J, Downs M (2011) Cognitive reframing for carers of people with dementia
	• Was the conflict of interest included? Not reported

Randomised controlled trials

Bibliographic reference	Arango-Lasprilla JC, Panyavin I, Herrera Merchán EJ, Perrin PB, Arroya-Anlló, Snipes DJ, Arabia J (2014) Evaluation of a group cognitive behavioural dementia caregiver intervention in Latin America, American Journal of Alzheimer's Disease and other Dementia, 29, 548-555
Study type	A randomised controlled trial to test the effectiveness of a caregiver intervention for caregivers of individuals with dementia
Participants	Inclusion criteria: Informal family caregivers who provided care to an individual diagnosed with dementia from Colombia; related to person with dementia; been providing care for at least 3 months; knowledgeable about patient's family and medical history; no self-reported history of neurological or psychiatric disorders; Exclusion: Not reported
Sample characteristics	N=69 carers n= 39 experimental intervention; 87.2%= female; 12.8% male; mean age (SD) = 59.4 years (12.37) N=30 control group 73.3% female; 26.7% male; mean age (SD) 55.1 (11.2) years
Intervention	Cognitive behavioural intervention 'coping with frustration' class 8 weeks intervention to introduce strategies to manage negative feelings- Interventions included relaxation; identifying and challenging negative thoughts; use of self-positive statements; Taught in a classroom format in small groups plus practical application
Comparison	A control educational program of 8 weeks Same educational content of intervention but no practical elements
Outcome measures	Depressive symptoms; Burden; life satisfaction; perceived stress
Study dates	Not reported
Study location	Colombia
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- no further details • Were clinicians and investigators blinded? Unclear- not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes

Bibliographic reference	Arango-Lasprilla JC, Panyavin I, Herrera Merchán EJ, Perrin PB, Arroya-Anlló, Snipes DJ, Arabia J (2014) Evaluation of a group cognitive behavioural dementia caregiver intervention in Latin America, American Journal of Alzheimer's Disease and other Dementia, 29, 548-555
	• At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs (Cohens D effect reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Au A, Li S, Lee K, Leung P, Pan P-C, Thompson L (2010) The coping with caregiving group program for Chinese caregivers of patients with Alzheimer's disease in Hong Kong, Patient Education and Counselling, 78, 256-260
Study type	A pilot randomised controlled trial to evaluate the effectiveness of a cognitive-behavioural programme for family caregivers of people with Alzheimer's disease in Hong Kong
Participants	Inclusion criteria: Chinese female caregivers with first language as Cantonese; had been the main family caregiver of a person living with Alzheimer's disease for at least 6 months; caregivers did not show signs of any psychotic disorder or evidence of severe intelligence deficit Exclusions: Not reported
Sample characteristics	Caregivers N= 27 Intervention n=13 mean age (SD) 54.15 (12.46) Control n=17 mean age (SD) 51.57 (14.62)
Intervention	Coping with caregiving (CWC) psychoeducational programme Participants completed 13 educational sessions. Classes were conducted in groups of 5-8 people; a 2 hour workshop for 13 weeks comprising a variety of relaxation techniques; education about dementia; skill training and cognitive behavioural therapy; understanding communication and providing information on access to services
Comparison	Wait list control group. Received access to intervention at end of study period
Outcome measures	Caregiver self-efficacy; Responding to disruptive behaviours ; caregiver distress; caregiver coping
Study dates	Not reported
Study location	Hong Kong
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- but method not reported • Were clinicians and investigators blinded? Unclear- not reported • Were the groups similar at the start of the trial? Yes

Bibliographic reference	Au A, Li S, Lee K, Leung P, Pan P-C, Thompson L (2010) The coping with caregiving group program for Chinese caregivers of patients with Alzheimer's disease in Hong Kong, Patient Education and Counselling, 78, 256-260
	• Aside from the experimental intervention, were the groups treated equally? Unclear- not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Blom MM, Zarit SH, Groot Zwaaftlink RBM, Cuijpers P, Pot AM (2015) Effectiveness of an internet intervention for family caregivers of people with dementia: results of a randomised controlled trial, Plos One
Study type	A randomised controlled trial to assess the effectiveness of an internet intervention 'Mastery over Dementia' compared to a minimal intervention of 'e bulletins' for caregivers of people with dementia
Participants	Inclusion criteria: Family caregivers of people with dementia Inclusion: Family caregivers with some symptoms of depression, anxiety, feelings of burden were eligible (CES-D>4); HADS-A>3; Burden score ≥6 on a scale of 0-10) Exclusion: Not reported
Sample characteristics	N= 245 carers n= 149 received internet (experimental) intervention; n=96 received e-bulletins (comparator) 69.4%= female; 31.6% male; mean age = 61.2 years (SD= 12.37; range = 26 years to 87 years) N=245 people with dementia n= 149 Experimental group- mean age = 76.36 (SD= 9.45, range = 39 to 93 years) ; severity of dementia Mean (SD) IQCODE= 58.09 (6.42) n=96 comparison group - mean age = 75.20 (SD= 9.32; range = 54 to 91 years) ; severity of dementia Mean (SD) IQCODE= 60.07 (4.29)
Intervention	Internet course (Mastery in Dementia) 8 lessons and a booster session – a coach to monitor progress and evaluate homework Booster session provided one month after all 8 lessons completed Coach provided study feedback Coach was a psychologist employed by a health agency with additional training in CBT

Bibliographic reference	Blom MM, Zarit SH, Groot Zwaaftlink RBM, Cuijpers P, Pot AM (2015) Effectiveness of an internet intervention for family caregivers of people with dementia: results of a randomised controlled trial, Plos One
Comparison	E-bulletins (digital newsletters with practical information on providing care for people with dementia)
Outcome measures	Depressive symptoms; Anxiety symptoms
Study dates	1st April 2010 to 31st December 2011
Study location	Netherlands
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- computerised block randomisation • Were clinicians and investigators blinded? Yes – data collected via internet- participants did not know which intervention received • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs (Cohens D effect reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Bruvik FK, Allore H, Ranhoff AH, Engedal K (2013) The effect of psychosocial support intervention on depression in patients with dementia and their family caregivers: An assessor blinded randomized controlled trial , Dementia and Geriatric Cognitive Disorders, 3, 386-397
Study type	A multicentre assessor blinded randomised controlled trial of people with dementia and their carers receiving a psychosocial support programme compared to usual care
Participants	Inclusion criteria: People with dementia and their primary family caregiver Carers required to score at least 5 on the Relatives Stress Scale (RSS) Exclusion: Not reported
Sample characteristics	N= 230 dyads Carers n= 115 received psychoeducational (experimental) intervention; n=115 received usual care (comparator) 77%= female; 33%= male; mean age = 63.5 (SD= 12) years People with dementia n= 230 Mean age = 78.4 (SD= 7.5) years Mean MMSE score = 21.2 (SD= 3.6)
Intervention	3 part psychoeducational intervention

Bibliographic reference	**Bruvik FK, Allore H, Ranhoff AH, Engedal K (2013) The effect of psychosocial support intervention on depression in patients with dementia and their family caregivers: An assessor blinded randomized controlled trial , Dementia and Geriatric Cognitive Disorders, 3, 386-397**
	• Counselling- Family received five 1hour counselling sessions in first 3 months • Education- education about dementia in either a community based education programme or in two half day seminars • Group meetings- Six separate 2hour group meetings for carers and people with dementia conducted twice a month focusing on problem solving and implementing coping strategies
Comparison	Usual care – information about available services and free to seek treatment and support in addition to ongoing care
Outcome measures	Depressive symptoms; Stress symptoms
Study dates	October 2009 to May 2011
Study location	Norway
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- block computer randomisation- statistician monitored • Were clinicians and investigators blinded? Yes – all assessors blinded to dyads group randomization – interventionists were involved in inclusion • Were the groups similar at the start of the trial? Yes- • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	**Burgio L, Stevens A, Guy D, Roth DL, Haley WE (2003) Impact of two psychosocial interventions on white and African American family caregivers of individuals with Dementa, Gerentologist, 43, 568-579**
Study type	A randomised controlled trial to compare effectiveness of a skills training programme versus a minimal care programme for carers of people with Alzheimer's disease
Participants	Inclusion criteria: Family caregivers of a relative with Alzheimer's disease Carers required to be at least aged 21 years; had provided at least 4 hours f supervision or direct care per day to their relative in the last 6 months; self-reported white or African American Exclusion: Involvement in another caregiver psychosocial intervention; had an acute illness that would prevent participating for at least 6 months

Bibliographic reference	Burgio L, Stevens A, Guy D, Roth DL, Haley WE (2003) Impact of two psychosocial interventions on white and African American family caregivers of individuals with Dementa, Gerentologist, 43, 568-579
Sample characteristics	N=140 70 carers randomised to each condition 77%= female; 23%= male; mean age = 63.5 years (SD= 12)
Intervention	Group workshop lasting 3 hours. Providing instructional activities; ; skills training notebook and videos demonstrating critical kill techniques 16 at home treatment sessions over 12 months conducted by a REACH interventionist
Comparison	Minimal support programme= telephone support plus generic written material. REACH interventionists provided telephone contact; calls lasted approx. 15 minutes
Outcome measures	Problem behaviours; Caregiver appraisal; Social support; Well-being; Anxiety
Study dates	Not reported Follow up 6 months
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- States randomised – but method not reported • Were clinicians and investigators blinded? Unclear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Cheng S-T, Lau RWL, Mak EPM, Ng NSS, Lam LCW (2014) Benefit finding intervention for Alzheimer caregivers: Conceptual framework, implementation issues and preliminary efficacy, Gerontologist, 54, 1049-1058
Study type	Preliminary results of a pilot randomised controlled trial to determine the efficacy of a benefit finding intervention compared to psychoeducational groups intervention for caregivers of people with Alzheimer's disease
Participants	Inclusion criteria: Family caregivers of people with Alzheimer's disease Exclusion: Not reported
Sample characteristics	N= 25 caregivers n=13 benefit finding intervention; 85% female; 15% male mean age (SD) 54.2 (7.0)

Bibliographic reference	Cheng S-T, Lau RWL, Mak EPM, Ng NSS, Lam LCW (2014) Benefit finding intervention for Alzheimer caregivers: Conceptual framework, implementation issues and preliminary efficacy, Gerontologist, 54, 1049-1058
	n=12 psychoeducation group; 92% female; 8% male mean age (SD) 53.8 (10.8)
Intervention	Benefit finding intervention: Standard psychoeducation with positive reappraisal coping
Comparison	Standard psychoeducation group
Outcome measures	Depression; Overload and burden
Study dates	Not reported
Study location	China
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- preliminary results of a pilot study – but method not reported • Were clinicians and investigators blinded? Unclear • Were the groups similar at the start of the trial? Yes- • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs Cohen's d effect size • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Charlesworth G, Shepstone L, Wilson E, Reynolds, S, Mugford M, Price D, Harvey I, Poland F (2008) Befriending carers of people with dementia: randomised controlled trial., British Medical Journal, 1295-1297
Study type	A single blind randomised controlled trial to compare access to a befriender facility and usual care for family carers of people with dementia
Participants	Inclusion criteria: Family carers of a community dwelling care recipient with primary progressive dementia; spending 20 hours or more per week on care tasks Exclusion criteria: Carers with pronounced congenital or acquired cognitive impairment; carers with terminal illness ; carers of people in permanent residential nursing
Sample characteristics	N= 236 carers Intervention n=116 Mean age (SD) 68.4 (11.3) years; 66% female; 34% male Control n= 84 Mean age (SD) 67.6 (11.6) years; 63% female; 37% male N=171 care receivers

Bibliographic reference	Charlesworth G, Shepstone L, Wilson E, Reynolds, S, Mugford M, Price D, Harvey I, Poland F (2008) Befriending carers of people with dementia: randomised controlled trial., British Medical Journal, 1295-1297
	Intervention n=87 Mean age (SD) 78.6 (8.9) years Control n=84 Mean age (SD) 77.8 (8.5) years;
Intervention	Contact with a local befriending scheme BECCA Volunteers provided emotional support, and were permitted to provide informational support for matched carers Received usual care- access to community psychiatric services, day hospitals, day centres, home care, personal care respite care; carers information or support groups
Comparison	Usual care- access to community psychiatric services, day hospitals, day centres, home care, personal care respite care; carers information or support groups
Outcome measures	Carers depression; Health related quality of life; anxiety; loneliness; perceived social support
Study dates	April 2002 and July 2004 Follow up 24 months
Study location	UK
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- states randomisation but method not reported • Were clinicians and investigators blinded? Single blind- • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Chu H, Yang C-Y, Liao Y-H, Chang L-I, Chen HC, Lin C-C, Kuei-Ru C (2011) The effects ofd a support group on denetia caregivers' burden and depression, Journal of Aging and Mental Health, 23, 228-241
Study type	A randomised controlled trial to assess the effects of a support group on depression levels and burden among dementia caregivers in Taiwan.
Participants	Inclusion criteria: Caregivers who were caring for a family member or loved one with dementia for at least 4 hours per day; had been a caregiver for at least 6 months prior to taking part in the study; living and residing in the city and/or rural municipality of Taipei; people with dementia had to be aged 65 years or older with a physician diagnosis of Alzheimer's

Bibliographic reference	Chu H, Yang C-Y, Liao Y-H, Chang L-l, Chen HC, Lin C-C, Kuei-Ru C (2011) The effects ofd a support group on denetia caregivers' burden and depression, Journal of Aging and Mental Health, 23, 228-241
	disease or Vascular dementia. Exclusion criteria: Caregivers providing care to another family member with chronic physical illness in addition to the person with dementia; patients were excluded if they had Parkinson's disease, depression or any other psychiatric illness.
Sample characteristics	N= 60 caregivers Experimental condition n=30 (female = 53.3%, male = 46.7%) Control condition n=30 (female= 60%, male = 40%)
Intervention	A 12 week structured support group providing an introduction to the process; open discussion on caregivers emotions and feelings about caring; care receiver's reactions and common behaviour problems; needs of caregivers to take care of themselves; availability of Taiwanese community resources and financial services
Comparison	Control
Outcome measures	Caregiver depression; Caregiver burden
Study dates	Not stated Follow up 12 weeks
Study location	Taiwan
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- permuted block randomization • Were clinicians and investigators blinded? Single blind- Caregivers were blinded- does not state info about investigators • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear- not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Connell CM , Janevic MR (2009) Effects of a telephone based exercise intervention for dementia caregiving wives: a randomized controlled trial, Journal of Appiled Gerentology, 28, 171-194
Study type	A randomised controlled trial to compare effectiveness of a six month telephone based exercise intervention skills training programme versus a minimal care programme for carers of people with Alzheimer's disease
Participants	Inclusion criteria: Female caregivers whose husband had been diagnosed with Alzheimer's disease Exclusion: If person with dementia was deceased or no longer lived at home

Bibliographic reference	Connell CM , Janevic MR (2009) Effects of a telephone based exercise intervention for dementia caregiving wives: a randomized controlled trial, Journal of Appiled Gerentology, 28, 171-194
Sample characteristics	N=137 caregivers ; Mean age (SD) = 66.8 (9.4) years range = 40-87 years N=74 Health first telephone based (Intervention) ; N=63 Control
Intervention	Health first intervention- A flexible exercise prescription of efficacy enhancing techniques; setting individual goals in conjunction with a telephone counsellor
Comparison	Did not receive Health first intervention but did receive telephone counselling and written materials
Outcome measures	Caregiving burden; Exercise behaviour; Exercise self-efficacy; Depressive symptoms;
Study dates	Not reported: Follow-up 6 and 12 months
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- States randomised – but method not reported • Were clinicians and investigators blinded? Unclear • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Cristancho-Lacroix V, Wrobel J, Cantegriell-Kallen I, Dub T, Rouquette A, Rigaud A-S (2015) A web based psychoeducational program for informal caregivers of patients with Alzheimer's disease: A pilot randomized controlled trial, Journal of Medical Internet Research, 17, e117
Study type	An un-blinded pilot randomised controlled trial to evaluate the impact of a web based psychoeducational program (Diapason) on caregivers' perceived stress
Participants	Inclusion criteria: French speaking caregivers of community dwelling people with Alzheimer's disease; caregivers had to be 18 years or older; spend at least 4 hours per week with their relative; score 12 or more on Perceived Stress scale; have access to a computer and internet connection. Exclusion criteria: Professional caregivers
Sample characteristics	N= 49 carers Intervention n=25 Mean age (SD) 64.2 (10.3) years; 64% female; 36% male

Bibliographic reference	Cristancho-Lacroix V, Wrobel J, Cantegriell-Kallen I, Dub T, Rouquette A, Rigaud A-S (2015) A web based psychoeducational program for informal caregivers of patients with Alzheimer's disease: A pilot randomized controlled trial, Journal of Medical Internet Research, 17, e117
	Control n= 24 Mean age (SD) 59 (12.4) years; 67% female; 33% male N=49 care receivers Intervention n=25 onset of symptoms (years) Mean (SD) 4.62 (3.53) years; MMSE (SD) 18.5 (5.4) Control n=24 onset of symptoms (years) Mean (SD) 4.11 (3) years; MMSE (SD) 19.0 (4.6)
Intervention	A web based program (Diapason) with 12 thematic sessions (caregiver stress; understanding Alzheimer's disease; maintaining loved ones' autonomy; understanding reactions-BPSD; coping with behavioural and emotional troubles; communicating with loved ones; improving daily lives; avoiding falls; pharmacological and non-pharmacological interventions; social and financial support; about the future- disease progression – encouragement to seek support; acceptance of support Plus a web-based user forum Caregivers received an initial 10 minute training on how to use the website, a printed version of the user manual Participants completed one session per week Participants also received usual care
Comparison	Usual care- given access to program at the end of their participation
Outcome measures	Caregiver stress; Caregiver self-efficacy; caregiver burden; reaction to cognitive and behavioural problems;
Study dates	2011 to 2014 Follow up 6 months
Study location	France
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- block computer generated randomisation • Were clinicians and investigators blinded? No – un-blinded • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	**Danucalov MAD, Kozasa EH, Ribas KT, Galduróz JCF, Garcia MC, Verreschi ITN, Oliveira KC, de Oliveira LR, Leite JR (2013) A yoga and compassion meditation program reduces stress in familial caregivers of Alzheimer's disease patients, Evidence-based Complementary and Alternative Medicine,**
Study type	A randomised controlled trial to investigate whether practicing a yoga and compassion meditation program might alter the stress, anxiety and depression levels of family carers of people with Alzheimer's disease
Participants	Inclusion criteria: Older than 18 years of age; minimum education corresponding to elementary education; exhibiting resistant stages of stress on Lipp's stress symptoms Inventory for Adults (LSSI) Exclusion criteria: Diagnosis of Cushing's syndrome; ongoing treatment with corticoids in previous 30 days; diagnosis of Asthma or COPD; more than 5 units of alcohol per week or use of drugs; regular practice of yoga or meditation
Sample characteristics	N= 46 familial carers Intervention n=25 Mean age (SD) 55.5 (8.1) years; 88% female; 12% male Control n= 21 Mean age (SD) 53.4 (8.2) years; 90% female; 10% male
Intervention	Stress reduction programme 8 sessions over 2 month period, lasting 1 hour and 15 minutes, Sessions occurred 3 times per week (1 live session per week, 2 others at home using a DVD) Yoga body poses (asanas); exercises involving awareness and voluntary regulation of breath; meditational practices; compassion meditation
Comparison	Control – no intervention group
Outcome measures	Caregiver stress; Caregiver depression
Study dates	Not stated
Study location	Brazil
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? States yes- method not reported • Were clinicians and investigators blinded? Unclear- not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear- not reported • At the end of the trial, were all patients accounted for? Unclear- Not reported • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Dias, A Dewey Me, d'Souza J, Dhume R, Motghare D D, Shaji KS, Menon R, Prince M, Patel V (2008) The effectiveness of a home care program for supporting caregivers of persons with dementia in developing countries : A randomised controlled trial from Goa, India , Plos One, 6 e2333
Study type	A multi-centre randomised controlled trial to test the effect of a short term psychosocial intervention for family carers of people with dementia
Participants	Inclusion criteria: Carers were eligible if patients were living at home; patient fulfilled ICD-10 criteria for dementia; had at least weekly face to face contact with patient Exclusion criteria: Not reported
Sample characteristics	N= 81 carers Intervention n=41 Mean age (SD) 53.2 (14) years; 90.2% female; 9.8% male Control n= 40 Mean age (SD) 53.8 (16) years; 84% female; 16% male N=81 care receivers Intervention n= Mean age (SD) 79.4 (8) years; Control n=84 Mean age (SD) 77.3 (8) years;
Intervention	Intervention delivered by community team (2 full time home care advisors; 1 part time psychiatrist) HCA carried out intervention: A flexible approach tailored to individual needs comprising: Basic education about dementia; education about common behaviour problems; support to caregiver; referral to psychiatrist or family doctor; family networking; advice on government schemes
Comparison	Control arm received information and education regarding dementia and placed on a wait list to receive intervention after 6 months
Outcome measures	Caregiver mental health; Caregiver burden; distress due to behavioural disturbances
Study dates	Not stated- follow up 6 months
Study location	India
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- simple random number • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	**Ducharne FC, Levesque LL, Lachance LM. Kergoat M-J, Legault AJ, Beaudet LM, Zarit SH (2011) Learning to become a family caregiver: Efficacy of an intervention program for caregivers following diagnosis of dementia in a relative, The Gerontologist, 51, 484-494**
Study type	A multi-centre randomised controlled trial to test the efficacy of an individual psycho educational program “learning to become a family caregiver” to facilitate transition to the caregiver role for family carers of people newly diagnosed with Alzheimer’s disease
Participants	Inclusion criteria: Self defined as primary caregiver (spouse or offspring) of a relative aged 65 years or over diagnosed with Alzheimer’s disease in last 9 months; Exclusion criteria: Caregivers receiving psychotherapy or participating in a support group
DSample characteristics	N= 111 care givers Intervention n=62 Mean age (SD) 60.37 (13.2) years; 79% female; 21% male Control n= 49 Mean age (SD) 62.75 (13.22) years; 79.6% female; 20.4% male
Intervention	6 health professionals applied the program 90 min individual sessions once a week 7 sessions Caregiver received a work book to practice strategies discussed : Sessions comprised Caregiver confidence; preparedness for caregiving ; frequency of social support; planning for relative’s future needs; caregiver self-efficacy; caregiver coping strategies; informal social support
Comparison	Usual care – putting carers in contact with local community centres
Outcome measures	Caregiver self-efficacy
Study dates	Not reported Follow up 3 months
Study location	Canada
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- blind block randomization • Were clinicians and investigators blinded? Yes- interviewers blinded • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes

Bibliographic reference	Ducharne FC, Levesque LL, Lachance LM. Kergoat M-J, Legault AJ, Beaudet LM, Zarit SH (2011) Learning to become a family caregiver: Efficacy of an intervention program for caregivers following diagnosis of dementia in a relative, The Gerontologist, 51, 484-494
	• Overall risk of bias: Low

Bibliographic reference	Fortinsky RH, Kulldorf M, Kleppinger A, Kenyon-Pesce L (2009) Dementia care consultation for family caregivers: collaborative model linking an Alzheimer's association chapter with primary care physicians, Aging and mental health, 13, 162-170
Study type	A randomised controlled trial to consider the efficacy of an individualised dementia care consultation intervention for family caregivers of people with dementia
Participants	Inclusion criteria: Caregivers were eligible if they were related to participants who had been diagnosed with any type of irreversible dementia Exclusions- not reported
Sample characteristics	84 family caregivers Intervention n= 54; mean age = 64.8 (14.8) years; 63% female; 37% male; Control n= 30; mean age = 57.7 (16.4) years; 80% female; 20% male People with dementia intervention n= 54; Mean age (SD) = 81.8 (8.8) years; Cognitive status score Mean (SD) = 11.7 (5.7) Control n=30; Mean age (SD) = 81.7 (7.6) years; Cognitive status score Mean (SD) = 11.0 (7.2)
Intervention	Dementia care consultation for family caregivers to learn about dementia management and available services to help them care for their relative Used as standardised assessment tool and process Monthly contact for 12 months Sent copies of plans to primary care physicians Individualised to caregiver needs and produced a care plan
Comparison	Received educational and community resource information but no care consultation
Outcome measures	Symptom management self-efficacy; Support service self-efficacy; Depression; Burden
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- randomised by practice site not physician or family caregiver • Were clinicians and investigators blinded? Participating physicians were blinded

Bibliographic reference	Fortinsky RH, Kulldorf M, Kleppinger A, Kenyon-Pesce L (2009) Dementia care consultation for family caregivers: collaborative model linking an Alzheimer's association chapter with primary care physicians, Aging and mental health, 13, 162-170
	• Were the groups similar at the start of the trial? – Age of caregivers in intervention group significantly higher than control- • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Gallagher-Thompson D, Gray HL, Dupart T, Jimenez D, Thompson LW (2008) Effectiveness of cognitive /behavioural small group intervention for reduction of depression and stress in non-Hispanic white and Hispanic/Latino women dementia family caregivers: Outcomes and monitors of change, Journal of Rational Emotional Cognitive Behavioral Therapy, 1, 286-303
Study type	A randomised controlled trial to compare a Coping with Caregiving (CWC) psychoeducational programme to a telephone based control condition (TSC) in non Hispanic white and Hispanic Latino female caregivers
Participants	Inclusion criteria: Female caregivers aged 21 years or older; have provided a minimum of 8 hours care per week to an older relative with significant memory loss or deterioration in cognitive ability for at least the last 6 months; have had a phone; plan to remain in the area for duration of study; Exclusions: Cognitively impaired caregivers; diagnosed with Cushing's or Adison's disease or terminally ill;
Sample characteristics	Caregivers N =184 Intervention n=97 Control n=87
Intervention	CWC intervention lasting 13-16 weeks. Meet weekly for 2 hr group meetings 12 Group sessions led by co-interventionists Provided information and support on education about dementia; helpful techniques for managing care recipient's problems; skills to take better care of oneself; planning for care recipient's future needs; how to obtain community resources; overall review.
Comparison	Empathic support provided over the telephone individually 1-20 min calls every 2 weeks. 7 calls over a 4 month period Also provided educational material about caregiving and home safety
Outcome measures	Depressive symptoms; perceived psychological stress; skill utilization; conditional bother

Bibliographic reference	Gallagher-Thompson D, Gray HL, Dupart T, Jimenez D, Thompson LW (2008) Effectiveness of cognitive /behavioural small group intervention for reduction of depression and stress in non-Hispanic white and Hispanic/Latino women dementia family caregivers: Outcomes and monitors of change, Journal of Rational Emotional Cognitive Behavioral Therapy, 1, 286-303
Study dates	Not reported Follow up 4 months
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- sealed envelopes • Were clinicians and investigators blinded? Yes- states research assistants were blind • Were the groups similar at the start of the trial? Unclear – only reports on ethnicity status/ drop out comparator • Aside from the experimental intervention, were the groups treated equally? Unclear- not reported • At the end of the trial, were all patients accounted for? Unclear- not reported • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Gaugler JE, Reese M, Mittelman MS (2015) Effects of the Minnesota adaptation of the NYU caregiver intervention on depressive symptoms and quality of life for adult child caregivers of persons with dementia, American Journal of Geriatric Psychiatry, 23, 1179-1192
Study type	A randomised controlled trial to determine whether the NYU caregiver intervention for adult children (NYUCI-AC) would reduce depressive symptoms and improve quality of life for adult child caregivers of people with dementia
Participants	Inclusion criteria: Adult child caregivers of Alzheimer's disease or related dementias; care recipient had to have a physician diagnosis of ADRD and live at home in the community; caregiver self identify as primary caregiver; visit care recipient at least once a week ; had not received professional counselling for problems arising from being a caregiver in the year before enrollment; Exclusions- not reported
Sample characteristics	107 adult child caregivers Intervention n= 54; mean age = 51.23 (6.95) years; 88.7% female; 11.3% male; Control n= 53; mean age = 49.68 (9.36) years; 100% female; 0% male
Intervention	NYUCI consisted of 3 components; Individual and family counselling; support group participation; ad hoc counselling Participants took part in 6 individual and family session=s with one or two trained counsellors Caregivers referred to local support groups

Bibliographic reference	Gaugler JE, Reese M, Mittelman MS (2015) Effects of the Minnesota adaptation of the NYU caregiver intervention on depressive symptoms and quality of life for adult child caregivers of persons with dementia, American Journal of Geriatric Psychiatry, 23, 1179-1192
Comparison	Control group
Outcome measures	Depressive symptoms; Quality of life
Study dates	Not reported Minimum of 2 years follow up assessment(max reported follow up 3.79 years)
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- but method not reported • Were clinicians and investigators blinded? Single blind – raters were initially blinded • Were the groups similar at the start of the trial? – Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SEs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Gaugler JE, Reese M, Sauld J (2015) A pilot evaluation of psychosocial support for family caregivers of relatives with dementia in long term care- The residential care transition module, Research in Gerentological Nursing, 8, 161- 172
Study type	A pilot randomised controlled trial to evaluate the effectiveness of a residential care transition module (RCTM) psychosocial intervention to help families manage emotional and psychological distress following residential care placement of a cognitively impaired relative
Participants	Inclusion criteria: Relative admitted to RLTC facility in past 12 months; family member was the person most responsible for caring for their relative; could speak and understand English; family member could hear adequately Exclusions: Not reported
Sample characteristics	Caregivers N= 36 Psychosocial plus pharmaceutical Intervention n=17; 88.2% female; 18.8% Pharmaceutical intervention n=19;73% female; 26.7% male
Intervention	6 sessions of RCTM including components on psychoeducation; promotion of communication; problem solving; Patient

Bibliographic reference	Gaugler JE, Reese M, Sauld J (2015) A pilot evaluation of psychosocial support for family caregivers of relatives with dementia in long term care- The residential care transition module, Research in Gerentological Nursing, 8, 161- 172
	behaviour management strategies; Concrete planning; awareness of psychopharmacological medical and rehabilitative strategies; ad hoc counselling
Comparison	Usual care plus quarterly check in phone calls to provide psychosocial support
Outcome measures	Caregiver stress; caregiver depression; caregiver adaption to placement
Study dates	Not stated (follow up 4 and 8 months)
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- by an online program • Were clinicians and investigators blinded? No – transition counsellor not blinded • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Gonyea JG, O' Connor MK, Boyle PA (2006) Project CARE: A randomized controlled trial of a behavioural intervention group for Alzheimer's disease caregivers, The Gerentologist, 46, 827-832
Study type	A randomised controlled trial to compare effectiveness of a behavioural intervention programme compared to a standard psychoeducational programme for carers of people with Alzheimer's disease
Participants	Inclusion criteria: Family caregivers of a relative with Alzheimer's disease Carers required to have provided at least 4 hours of supervision or direct care per day to their care recipient Care recipient had a physician confirmed diagnosis of Alzheimer's disease Care recipient MMSE was mild to moderate as defined by MMSE >10 Care recipient had to have at least one neuropsychiatric symptom at enrolment Exclusion: Not reported
Sample characteristics	N=80 caregivers (67% female 33% male; Mean age (SD) 64.4 (13.8) years
Intervention	Behavioural intervention based on behaviour therapy run over 5 week period Structured group meeting once a week for 90 minutes

Bibliographic reference	Gonyea JG, O' Connor MK, Boyle PA (2006) Project CARE: A randomized controlled trial of a behavioural intervention group for Alzheimer's disease caregivers, The Gerentologist, 46, 827-832
Comparison	Structured control group intervention based on receipt of general information about old age and Alzheimer's disease
Outcome measures	Caregiver burden
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- block randomization • Were clinicians and investigators blinded? Unclear • Were the groups similar at the start of the trial? Unclear – only full sample characteristics provided • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Gonyea JG, López LM, Velásquez EH (2016) The effectiveness of a culturally sensitive cognitive behavioural group intervention for Latino Alzheimer's caregivers. The Gerentologist, 56, 292-302
Study type	A randomised controlled trial to test the effectiveness of a culturally sensitive cognitive behavioural therapy (CBT) group intervention compared to a psychoeducational group (PED) in supporting Latino family carers of people with Alzheimer's disease
Participants	Inclusion criteria: Caregiver identifies own ethnicity as Latino or of Hispanic origin; provides a minimum of 5 hours per week of direct caregiving; care recipient had probable or possible Alzheimer's disease; care recipient exhibit at least one neuropsychiatric symptom; Exclusion criteria: Not eligible if care recipient had a history of severe psychotic disorder or substance abuse;
Sample characteristics	N= 67 caregivers Intervention n=33 Mean age (SD) 55.91 (12.95) years; 97% female; 3% male Control n=34 Mean age (SD) 55.50 (13.59) years; 94.1% female; 5.9% male N=67 care receivers Intervention n=33 Mean age (SD) 73.5 (8.7 years; Control n=34 Mean age (SD) 76.1 (6.8) years

Bibliographic reference	Gonyea JG, López LM, Velásquez EH (2016) The effectiveness of a culturally sensitive cognitive behavioural group intervention for Latino Alzheimer's caregivers. The Gerentologist, 56, 292-302
Intervention	CBT group – 5 week program 90 minute weekly sessions teach caregivers rationale and use of antecedent- behaviour- consequences (ABC) problem solving Delivered in group setting but behaviour individualised to specific concerns of each caregiver
Comparison	PED group 5 week program 90 minute weekly- educating caregivers about memory loss and progression of Alzheimer's disease; tips to finding community resources; home issues;; strategies for working together with doctors; communication in the context of Alzheimer's
Outcome measures	Neuropsychiatric symptom severity; neuropsychiatric symptom distress; caregiver depression; caregiver anxiety
Study dates	May 2001 to June 2003
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- block randomization • Were clinicians and investigators blinded? Unclear- not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Hattink B, Meiland F, van der Roest H, Kevern P, Abiuso F, Bengtsson J, Giulano A et al (2015) Web based STAR E learning course increases empathy and understanding in dementia caregivers: Results from a randomized controlled trial in the Netherlands and United Kingdom, Journal of Medical Internet Research, 17, e241
Study type	A multi-site randomised controlled trial to assess the usefulness of a web based support program (STAR) test the effect of a short term psychosocial intervention for lay and professional carers of people with dementia
Participants	Inclusion criteria: Caring for someone with dementia as an informal carer, voluntary role or professional carer; living in the Netherlands or UK. Exclusion criteria: Not reported

Bibliographic reference	Hattink B, Meiland F, van der Roest H, Kevern P, Abiuso F, Bengtsson J, Giulano A et al (2015) Web based STAR E learning course increases empathy and understanding in dementia caregivers: Results from a randomized controlled trial in the Netherlands and United Kingdom, Journal of Medical Internet Research, 17, e241
Sample characteristics	N= 142 carers 72/142 were informal carers 24/142 were volunteers (both classed as lay carers) Intervention lay carers n=27 Mean age (SD) 52.93 (11.43) years; 74% female; 26% male Control lay carers n= 32 Mean age (SD) 54.69 (14.36) years; 69% female; 31% male
Intervention	Use of STAR portal for 2-4 months: Online course with 8 modules (what is dementia?; living with dementia; getting a diagnosis; practical difficulties in daily life; emotional impact of dementia; support strategies; positive and empathic communication; emotional impact) Access to a learning path advisor through an online tool Facebook and Linked in communities to promote peer support Complete at own pace over 4 month period
Comparison	Wait list control group – wait 4 months to receive access to intervention
Outcome measures	Caregiver quality of life; Caregiver burden; caregiver sense of competence
Study dates	May 2013 to March 2014
Study location	Netherlands and United Kingdom
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? States randomised but method not reported • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD (SD) • Can the results be applied to the local population? Partly- lay people includes volunteers also • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Hirano A, Suzuki Y, Kuzuya M. Onishi J, Ban N, Umrgaki H (2011) Influence of regular exercise on subjective sense of burden and physical symptoms in community-dwelling caregivers of dementia patients: A randomised controlled trial, Archives of Gerentology and Geriatrics, e158 -e163
Study type	A randomised controlled trial to examine the effect of a regular exercise on sense of burden of caregivers of people with dementia

Bibliographic reference	Hirano A, Suzuki Y, Kuzuya M. Onishi J, Ban N, Umrgaki H (2011) Influence of regular exercise on subjective sense of burden and physical symptoms in community-dwelling caregivers of dementia patients: A randomised controlled trial, Archives of Gerentology and Geriatrics, e158 -e163
Participants	Inclusion criteria: Caregivers aged 65 years or over living with elderly patients diagnosed with Alzheimer's disease; good health; good control of chronic medical conditions; Exclusions: People who already took part in regular exercise (over 30 min a day more than twice a week); history of stroke, myocardial infarction or other serious medical condition;
Sample characteristics	Caregivers N= 31 Mean age (SD) 73. 7 (4.4) years; 67.7% female; 32.3% male Intervention n= 17 Mean age (SD) 72.6 (4.0) years; 64.7% female; 35.3% male Control n=14 Mean age (SD) 75.0 (4.6) years; 71.4% female; 28.6% male
Intervention	Regular exercise intervention- 3 metabolic equivalents (3METs) 3 times per week over a 12 week period
Comparison	Non exercise control group. Not advised to exercise
Outcome measures	Caregiver burden; physical activity score;
Study dates	Not reported. Follow up 12 weeks
Study location	Japan
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- states randomised but method not reported • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Means SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: High

Bibliographic reference	Horvath KJ, Trudeau SA, Rudolph J, Trudeau PA, Duffy ME, Berlowitz D (2013) Clinical trial of a home safety toolkit for Alzheimer's disease, International Journal of Alzheimer's disease,
Sudy type	A randomised controlled trial to consider effectiveness of self-directed educational intervention programme to improve caregiver competence for persons living with dementia in the community
Participants	Inclusion criteria: Family caregivers of a relative with diagnosis of Alzheimer's disease or related disorder Carers required to have provided at least 4 hours of supervision or direct care per day to their care recipient

Bibliographic reference	Horvath KJ, Trudeau SA, Rudolph J, Trudeau PA, Duffy ME, Berlowitz D (2013) Clinical trial of a home safety toolkit for Alzheimer's disease, International Journal of Alzheimer's disease,
	Carers to be living at home with care recipient Carers to have no apparent cognitive impairment Exclusion: Previous home safety visit and admission to long term care facility
Sample characteristics	N=127 dyads Caregiver n= 60 allocated to intervention; mean age = 69.4 (12.9) years; 79.2% female 21.8% male Caregiver n=48 allocated to control; mean age = 70.6 (11.4) years; 81.7% female 18.3% male Care receiver n= 60 Intervention; mean age = 80.9 (7.2) years; Mean MMSE = 13.0 (6.9) Care receiver n= 48 control mean age = 80.4 (6.7) years; Mean MMSE = 12.4 (6.6)
Intervention	A self-directed intervention to improve caregiver competence to create a safer home environment Home safety toolkit booklet on health literacy principles; to enhance self-efficacy to make safety modifications
Comparison	Customary care- a patient information worksheet –to make home safer
Outcome measures	Caregiver self-efficacy; Caregiver strain; Home safety; Risky behaviours and accidents
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes computer generated randomization stratified by site • Were clinicians and investigators blinded? Investigator unblinded but caregivers unaware which intervention recruited to • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Unclear

Bibliographic reference	Jansen APD, van Hout HPJ, Rijmen F, Dros R-M, Pot A-M, Schellevis FG, Stalman WAB, van Marwijk HWJ (2011) Effectiveness of case management among older adults with early symptoms of dementia and their primary informal caregivers: a randomised clinical trial, International Journal of Nursing, 48, 933-943
Study type	A randomised controlled trial to compare effects of case management and usual care among community dwelling older

Bibliographic reference	Jansen APD, van Hout HPJ, Rijmen F, Dros R-M, Pot A-M, Schellevis FG, Stalman WAB, van Marwijk HWJ (2011) Effectiveness of case management among older adults with early symptoms of dementia and their primary informal caregivers: a randomised clinical trial, International Journal of Nursing, 48, 933-943
	adults with early symptoms of dementia and their informal caregivers
Participants	Inclusion criteria: Pairs of community dwelling older adults with abnormal screening for symptoms of dementia (defined as MMSE score <24 and their informal caregivers who spent most hours on the caring process Exclusion: Criteria for care recipient was assistance by outpatient geriatric or psychiatric team for cognitive problems ; terminal illness or insufficient command of Dutch language Criteria for ;caregivers was terminal illness; providing < 1 hour care per week and insufficient command of Dutch language
Sample characteristics	N=85 dyads caregivers Intervention (case management) – n= 54 ; 66.6% female 33.3% male; Mean age (SD) 63.6 (13.8) years caregivers Control (usual care) – n= 45 ; 73.3% female ; 36.7% male; mean age (SD) 61.6(15.2) years care receivers Intervention; n= 54 mean age (SD) = 82.1 (5.7) years; MMSE mean (SD) 22.0 (4.2) care recipients control n=45 mean age (SD) = 81.0 (6.5) years; MMSE mean (SD) 22.7 (3.8)
Intervention	12 months of case management carried out by district nurses Intervention = 2 home visits ; assessment of patient using RAI-HC and client assessment protocols; capacity and burden questionnaire to develop a care plan ; plus a guide to social and welfare services Contact at least every 3 months by telephone
Comparison	Usual care- care dependent on dyads needs; no access to formal meetings ; no receipt of RAI-HC
Outcome measures	Caregiver sense of competence; caregivers quality of life; depressive symptoms; burden
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- random number tables (per practice) • Were clinicians and investigators blinded? practitioners and interviewers blinded to group assignment unless participants revealed allocation • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes

Bibliographic reference	Jansen APD, van Hout HPJ, Rijmen F, Dros R-M, Pot A-M, Schellevis FG, Stalman WAB, van Marwijk HWJ (2011) Effectiveness of case management among older adults with early symptoms of dementia and their primary informal caregivers: a randomised clinical trial, International Journal of Nursing, 48, 933-943
	• Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Kwok T, Wong B, Chui K, Young D, Ho F (2013) Telephone delivered psychoeducational intervention for Hong Kong Chinese dementia caregivers: a single blinded randomised controlled trial , Clinical Interventions in Aging, 8, 1191-1197
Study type	A randomised controlled trial to evaluate the effectiveness of a telephone delivered psychoeducational programme for family caregivers of people with dementia
Participants	Inclusion criteria: Not reported Exclusion criteria: Not reported
Sample characteristics	N=39 (Intervention n= 19; 66.7% female; 33.3%male; control n=0 80% female; 20% male)
Intervention	Structured telephone based psychoeducation intervention 12 sessions of consultation by telephone delivered by registered social workers Education and advice on topics related to dementia caregiving (knowledge of dementia, communicating skills, management of behavioural psychological symptoms of dementia, caregiver's emotional issues, resource availability in community.
Comparison	Provided with a DVD containing educational information about dementia caregiving
Outcome measures	Caregiver burden; caregiver self-efficacy
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- computerised randomization • Were clinicians and investigators blinded? States single blinded but no details of clarity • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	**Lavretsky H, Suddarth P, Nazarian N, St. Cyr N, Khalsa DS, Lin J, Blackburn E, Epel ES, Irwin MR (2013) A pilot study of yogic meditation for family dementia caregivers with depressive symptoms: Effects on mental health, cognition and tolomerase activity, International Journal of Geriatric Psychiatry, 28, 57-65**
Study type	A randomised controlled trial to examine the effects of brief daily yogic meditation in family dementia caregivers with mild depressive symptoms
Participants	Inclusion criteria: \adults or elderly caregivers of people with dementia being seen in the memory clinics; identified by the patient or clinical staff as the primary source of assistance or support; in contact with person living with dementia at least 3 times per week Exclusions: Those with a major depressive disorder (screened using structured clinical interview for DSMIV-R and Hamilton rating scale (HAM-D-24); history of psychiatric illness; alcohol and/or substance abuse; severe or acute medical illness; acute suicidal or violent behaviour; any other CNS disease or dementia
Sample characteristics	Caregivers N= 39 Mean age (SD) 60.3 (10.2) years Intervention n=23 Mean age (SD) 60.5 (28.2) years female = 100% Control n=16 Mean age (SD) 60.6 (12.5) years 87% female; 13% male
Intervention	Kirtan Kriya meditation practice for 12 minutes per day 8 week period; all caregivers also received psychoeducation about the prognosis and development of dementia
Comparison	Relaxation practice listening to relaxation music for 12 minutes per day 8 week period; all caregivers also received psychoeducation about the prognosis and development of dementia
Outcome measures	Depressive symptoms; mental and physical functioning;
Study dates	Not stated- follow up 8 weeks
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- computer generated • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderaate

Bibliographic reference	Leach MJ, Zialan T, Transcendental Meditation for the improvement of health and well-being in community-dwelling dementia caregivers (TRANSCENDENT): a randomised wait list controlled trial. BMC, 15, 145-156
Study type	A pilot randomised multi centre wait list controlled trial to ascertain whether Transcendental meditation (TM) can improve psychological stress, quality of life in dementia caregivers
Participants	Inclusion criteria: Family caregivers of a relative with Alzheimer's disease Exclusion: Not reported
Sample characteristics	N=17 caregivers (88% female; 12% male; mean age (SD) 66.12 (8.50) years
Intervention	12 week (14 hours) of TM training plus 12 week follow up face to face delivery by an experienced TM instructor
Comparison	24 week Wait list control
Outcome measures	Heath related quality of life; Stress; Mood and Stress
Study dates	April 2013 to March 2014
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- block randomization • Were clinicians and investigators blinded? Unclear • Were the groups similar at the start of the trial? Unclear – only full sample characteristics provided • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Liddle J, Smith-Conway ER, Baker R, Angwin AJ, Gallois C, Copland DA, Pachana NA et al (2012) Memory and communication support strategies in dementia: effect of a training program for informal caregivers, International Psychogeriatrics, 24, 1927-1942
Study type	A pre-test post-test randomised controlled trial to compare effectiveness of a DVD based training programme compared to no training for informal carers of people with dementia
Participants	Inclusion criteria: Informal caregivers of a person with a medically diagnosed dementia Exclusion: Not reported

Bibliographic reference	Liddle J, Smith-Conway ER, Baker R, Angwin AJ, Gallois C, Copland DA, Pachana NA et al (2012) Memory and communication support strategies in dementia: effect of a training program for informal caregivers, International Psychogeriatrics, 24, 1927-1942
Sample characteristics	N=29 dyads Caregiver Intervention n= 13 Control n= 16 Mean age(SD) 68.75 (9.91) years 87.8% female; 17.2% male Care receiver Mean age (SD) 76.93 (8.94) years; Median (IQR) MMSE 17; (7.00-22.00)
Intervention	Communication and memory training programme= (MESSAGE and RECAPS) and evaluation of the training of paid caregivers
Comparison	No training
Outcome measures	Caregiver burden ; Positive aspects of caring; depressive behaviours
Study dates	July 2009 to February 2011
Study location	Australia
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- states randomised but no method reported • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Logiudice D, Waltrowicz W, Brown K, Burrows (1999) Do memory clinics improve the quality of life of carers? A randomised pilot trial, International Jounal of Geriatric Psychiatry, 14, 626-632
Study type	Randomised controlled trial to evaluate the effectiveness of attendance at a memory clinic on the psychosocial health and burden of carers of people with cognitive impairment
Participants	Inclusion criteria: People with mild to moderate cognitive impairment and their carers Carers defined as one principally responsible for providing or coordinating resources required by the person and in personal contact with the care recipient at least weekly Exclusion: Not reported
Sample characteristics	N=50

Bibliographic reference	Logiudice D, Waltrowicz W, Brown K, Burrows (1999) Do memory clinics improve the quality of life of carers? A randomised pilot trial, International Jounal of Geriatric Psychiatry, 14, 626-632
	Caregiver Intervention n= 25 Mean age(SD) 61.4 (4.0) years 76% female; 24% male Caregiver Control n= 25 Mean age(SD) 60.7 (12.6) years 80% female; 20% male Care receiver Intervention Mean age (SD) 72.9 (7.9) years; MMSE (SD) 17.4; (6.5) Care receiver control Mean age (SD) 77.5 (8.6) years; MMSE (SD) 16.5; (6.2)
Intervention	Attendance at a memory clinic on two occasions: Attendance one = medical and cognitive assessment Attendance two = a family conference with carers, patient and family members
Comparison	Interviews conducted at home with no family conference
Outcome measures	Carers health related quality of life; Carer burden; Carer knowledge of dementia
Study dates	Not reported
Study location	Australia
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- randomised by independent person using blocks of 10 • Were clinicians and investigators blinded? No: People collecting data were not blinded • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Lósada A, Márquez-González M, Romero-Moreno R, (2010) Mechanisms of action of a psychological intervention for dementia caregivers : effects of behavioural activation and modification of dysfunctional thoughts, International Journal of Geriatric Psychiatry, 26, 1119-1127
Study type	A randomised controlled trial to test the efficacy of a Cognitive Behavioural intervention aimed at training caregivers to modify maladaptive thoughts
Participants	Inclusion criteria: Relative of person diagnosed with Alzheimer's or related dementia; self-identifying as primary caregivers devoting more than one hour of care to their relative ; provide care for more than 3 months

Bibliographic reference	Lósada A, Márquez-González M, Romero-Moreno R, (2010) Mechanisms of action of a psychological intervention for dementia caregivers : effects of behavioural activation and modification of dysfunctional thoughts, International Journal of Geriatric Psychiatry, 26, 1119-1127
	Exclusion: Not reported
Sample characteristics	N=118 caregivers Intervention n=82 Mean age(SD) 60.60 (11.52) years; 81.7% female; 18.3% male Control n= 75 Mean age(SD) 59.38 (12.58) years; 84% female; 16% male;
Intervention	Psychological intervention: 12 group based weekly sessions (8 caregivers max per group) conducted by psychologists Aimed at training caregivers in techniques to analyse maladaptive thoughts, cognitive barriers to self help and to pleasant activities
Comparison	Control group received usual assistance or care provided by social and health care centres No contact between research staff and caregivers was established
Outcome measures	Caregiver depression
Study dates	Not reported
Study location	Spain
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes: Table of random numbers • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Lósada A, Márquez-González M, Romero-Moreno R, Mausbech BT, López J, Fernández- Fernández V, Nogales-González C (2015) Cognitive Behavioural Therapy (CBT) versus Acceptance and Commitment Therapy (ACT) for Dementia family caregivers with significant depressive symptoms, Journal of Consulting and Clinical Psychology, 4, 760-772
Study type	A randomised controlled trial to test the efficacy of Acceptance and Commitment Therapy (ACT) or cognitive Behavioural

Bibliographic reference	**Lósada A, Márquez-González M, Romero-Moreno R, Mausbech BT, López J, Fernández- Fernández V, Nogales-González C (2015) Cognitive Behavioural Therapy (CBT) versus Acceptance and Commitment Therapy (ACT) for Dementia family caregivers with significant depressive symptoms, Journal of Consulting and Clinical Psychology, 4, 760-772**
	Therapy (CBT) compared to a control group for dementia family caregivers
Participants	Inclusion criteria: Dementia family caregivers self-identifying as a principal person taking care of a relative diagnosed with dementia; devoting at least 1 hour per day to the care of their relative; having cared for at least 3 months; not participated in any psychotherapeutic intervention aimed at helping the caregiver cope; scoring at least 116 on the CES-D scale Exclusion: Not reported
Sample characteristics	N=135 caregivers ACT n=45 Mean age(SD) 62.28 (12.92) years; 81.02% female; 18.98% male CBT n= 42 Mean age(SD) 61.69 (15.31) years; 82.2% female; 17.8% male; Control n= 48 Mean age(SD) 61.48 (12.40) years; 90.5% female; 9.5% male;
Intervention	CBT or ACT interventions carried out 8 weekly individual sessions over 2 months Provided by 6 clinical psychologists trained in CBT and ACT principles CBT- cognitive restructuring; assertive skills; relaxation; ; increasing pleasant activities ACT- acceptance of aversive internal events; choosing meaningful courses of action; action oriented towards values; learning the alternative to cope
Comparison	Minimal support group – a 2 hour workshop provided with a booklet and psychoeducation on dementia
Outcome measures	Caregiver burden ; Positive aspects of caring; depressive behaviours
Study dates	Not reported
Study location	Spain
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes: Computer generated randomisation • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	**Mittelman MS, Ferris SH, Steinberg G, Shulman E, Mackell JA, Ambinder A, Cohen J (1993) An intervention that delays institutionalization of Alzheimer's disease patients: treatment of spouse-caregivers, The Gerentologist, 33, 730-740**
Study type	A randomised controlled trial to evaluate the effectiveness of a caregiver intervention (individual and family counselling and support group participation) on caregiver outcomes and nursing home placement.
Participants	Inclusion criteria: Primary caregivers – spouses of people with a clinical diagnosis of Alzheimer's disease. Both person living with dementia and caregiver were living at home Exclusion: Caregivers who had previously received formal counselling or participated in a support group.
Sample characteristics	N=206 58.3% female; 42.7% male age (range 60 to 89)
Intervention	Formal counselling: 2 sessions with caregiver alone plus four sessions with the caregiver and family
Comparison	No formal counselling but access to other services provided to intervention group
Outcome measures	Caregiver use of services; Caregiver mental health; rates of institutionalisation
Study dates	August 1987 to February 1991. Follow up 12 months
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Unclear - poorly reported paper • Was the assignment of patients to treatment randomised? Unclear- states randomised but no method reported • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes- • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Regression analysis • Can the results be applied to the local population? Unclear • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: High

Bibliographic reference	**Mittelman MS, Brodaty H, Wallen AS, Burns A (2008) A 3 country randomised controlled trial of a psychosocial intervention for patients with Alzheimer's disease: Effects on carer depression, American Journal of Geriatric Psychiatry, 16, 893-904**
Study type	A randomised controlled trial conducted in 3 countries to evaluate the effectiveness of cholinesterase inhibitor therapy for people with Alzheimer's disease, combined with a psychosocial intervention for their spouse caregivers versus drug therapy alone

Bibliographic reference	Mittelman MS, Brodaty H, Wallen AS, Burns A (2008) A 3 country randomised controlled trial of a psychosocial intervention for patients with Alzheimer's disease: Effects on carer depression, American Journal of Geriatric Psychiatry, 16, 893-904
Participants	Inclusion criteria: People with probable Alzheimer's disease (defined by NINCDS/ADRDA and DSMIC=V criteria) with a GDS score of 4 to 5 (mild to moderate dementia); no contraindication to donepezil and be stable with other medications; Inclusion criteria: Caregivers were patients' spouse; self defined as primary caregiver; Exclusions: Caregivers who had previously received formal caregiver counseling
Sample characteristics	Caregivers N= 158 caregivers Psychosocial plus pharmaceutical Intervention n=79; 58.2% female; 42.8% Pharmaceutical intervention n=79;54.4% female ; 45.6% male
Intervention	5 sessions of individual (for person with dementia) and family counselling. Intervention occurred 3 months after patient received pharmacological therapy with cholinesterase inhibitors Sessions conducted in person plus ad-hoc counselling and counselling on demand by telephone . Content was dependent on the needs of each caregiving family
Comparison	No psychosocial intervention; people with Alzheimer's disease received pharmacological treatment
Outcome measures	Caregiver depression; satisfaction with social support
Study dates	June 1999- May 2001 (follow up 2 years)
Study location	USA, UK and Australia
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- by lottery • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear- Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Oken BS, Fonareva I, Haas M, Wahbeh DC, Lane JB, Zajdel D, Amen, A (2010) 1031-1038 Pilot controlled trial of mindfulness, meditation and education for dementia caregivers, Journal of Alternative and complementary medicine, 16, 1031-1038

Bibliographic reference	Oken BS, Fonareva I, Haas M, Wahbeh DC, Lane JB, Zajdel D, Amen, A (2010) 1031-1038 Pilot controlled trial of mindfulness, meditation and education for dementia caregivers, Journal of Alternative and complementary medicine, 16, 1031-1038
Study type	A pilot randomised controlled trial to evaluate the effectiveness of a mindfulness meditation based cognitive therapy programme compared to two control interventions (education class and respite only) for dementia carers
Participants	Inclusion criteria: Community dwelling caregivers aged 45 to 85 years caring for a relative with progressive dementia Providing at least 12 hours assistance per week to the person with dementia Exclusion criteria: Unstable medical conditions; cognitive dysfunction with a score < 25 on the Modified Telephone Interview for Cognitive Status; medications not stable for at least 2 months; significant visual impairment; (corrected binocular visual acuity worse than 20/50); previous experience with similar types of stress reduction class
Sample characteristics	N=31 caregivers Meditation n= 10 Mean age (SD)= 62.5 (11.61) years; 80% female; 20% male Education n=11 Mean age (SD) 67.09 (8.6) years; 72% female; 18% male Control n= 10 Mean age (SD) 63.80 (7.93) years; 90% female; 10% male
Intervention	Mindfulness based meditation and mindfulness based cognitive therapy both lasting 7 weeks with one 90 minute session per week: Aims – to help participants understand reactions to stress and teach skills to modify stress reactions Education class attended first weekly session of mindfulness group followed by 6 weekly lectures taught by trainers trained in powerful tools for carers (PTC) and receipt of a caregiver helpbook
Comparison	Respite only – provided 3 hours once per week for 7 weeks
Outcome measures	Caregiver stress; mood; fatigue; self-efficacy; mindfulness
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Dynamic randomisation • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Not reported • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	**Prick AE, deLange J, Pot AM (2015) The effects of a multi-component dyadic intervention on the psychological distress of family caregivers providing care to people with dementia: a randomised controlled trial, International Psychogeriatrics, 27, 2031-2044**
Study type	A randomised controlled trial to investigate the effects of a multicomponent intervention for carer and caregiver dyads of people with dementia.
Participants	Inclusion criteria: People with a formal diagnosis of dementia; minimum aged 55 years; living at home with a caregiver; willing to participate in home visits; Family caregivers defined as spouses, adult relatives or friends; living with or spending at least 4 hours caregiving each week; have at least some depressive symptoms; understanding of Dutch language enough to participate Exclusions: Caregivers with physical disorders; presence of psychotic symptoms; use of antidepressants. Person with dementia: Use of antidepressants; presence of psychotic symptoms; MMSE score <14 ; receiving more than 2 days respite care in a day care facility
Sample characteristics	N =111 caregiver dyads 72.1% female; 27.9% male Mean age (SD) 72 (10.9) years Intervention caregivers n=57 66.7% female; 33.3% male Mean age (SD) 73 (9.1) years Control caregivers n= 54 77.8% female; 22.2% male Mean age (SD) 71 (10.31) years
Intervention	Dyads received a physical exercise and a support intervention Completed 30 minutes of exercise at least 3 days a week for both caregiver and care receiver caregivers guided care receiver in personalised exercises; Support component included receipt of information and psychoeducation; communication skills training; pleasant activities training taught in presence of person living with dementia and caregiver
Comparison	Usual care plus a minimal intervention; written information bulletins received monthly (3 in total); monthly 10 minute phone calls to provide emotional listening support;
Outcome measures	Caregiver mood; caregiver depression;
Study dates	November 2008 and June 2012; follow up 6 months
Study location	Netherlands
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- block randomisation • Were clinicians and investigators blinded? Originally blinded but during intervention allocation became clear to the investigators • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear- not reported

Bibliographic reference	Prick AE, deLange J, Pot AM (2015) The effects of a multi-component dyadic intervention on the psychological distress of family caregivers providing care to people with dementia: a randomised controlled trial, International Psychogeriatrics, 27, 2031-2044
	• At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Rose KM, Taylor AG, Bourgignon C (2010) Effects of cranial electrical stimulation on sleep disturbances, depressive symptoms and caregiving appraisal in spousal caregivers of persons with Alzheimer's disease, Applied Nursing Research, 22, 119-125
Study type	A randomised double blind controlled pilot study
Participants	Inclusion criteria: Primary caregiver for a spouse with Alzheimer's disease or multi infarct dementia living at home; aged 60 years or greater; have cognitive abilities to complete a questionnaire; Have depressive symptoms as indicated by Geriatric Depression score of 10 or more; willing to wear device Exclusion criteria: Use of an antidepressant medication or botanical with antidepressant properties; implantable device such as a pacemaker or internal defibrillator;,
Sample characteristics	N=38 Cranial electrical stimulation n=19 Mean age(SD) 71.94 (7.78) years; 73.7% female; 26.6% male Sham stimulation n=19 Mean age(SD) 6.52 (5.60) years; 57.9% female; 43.1% male
Intervention	Cranial electrical stimulation (Alphastim) over 4 week period – Both Intervention and control given same instructions
Comparison	Sham stimulation
Outcome measures	Sleep disturbances; depressive symptoms; appraisal of caregiving situation
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- states randomised but no method reported • Were clinicians and investigators blinded? Unclear states double blind but details not specified • Were the groups similar at the start of the trial? No- CES group older than sham • Aside from the experimental intervention, were the groups treated equally? Yes- same instructions etc • At the end of the trial, were all patients accounted for? Yes

Bibliographic reference	Rose KM, Taylor AG, Bourgignon C (2010) Effects of cranial electrical stimulation on sleep disturbances, depressive symptoms and caregiving appraisal in spousal caregivers of persons with Alzheimer's disease, Applied Nursing Research, 22, 119-125
	• How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Salimazadeh A, Mirzae T, Ravari P (2017) The Impact of Spiritual Care Education on the Self-Efficacy of the Family Caregivers of Elderly People with Alzheimer's Disease, IJCBNM, 5, pp 231-238.
Study type	A two group quazi experimental randomised trial to examine the impact of Spiritual Care on the self-efficacy of caregivers of people living with Alzheimer's disease.
Participants	Inclusion criteria: AD family caregivers Read and write in Persian, Muslim, Provided care to a family member living with AD for at least six months, Had no history of chronic mental or physical problems, Had no history of drug abuse, Had no hearing impairment. Exclusions: Willing to withdraw from the study or if their elderly care receivers died during the study.
Sample characteristics	Caregivers N= 54 Intervention n=28 80.8% female;19.2% male; mean age 47.38 (10.44) years Control n= 26 89.3% female; 10.7% male mean age 50.57 (16.48) years
Intervention	Five Spiritual Care educational sessions held weekly for five weeks, lasting 45 to 60 minutes. All sessions The educational package included topics such as reliance on God, seeking help from holy people, patience, generosity, altruism, mantra, and prayer. The sessions explained the roles of reliance on God, seeking help from holy people, patience, generosity, and mantra and prayer in maintaining or regaining the inner peace.
Comparison	No spiritual care educational support

Bibliographic reference	Salimazadeh A, Mirzae T, Ravari P (2017) The Impact of Spiritual Care Education on the Self-Efficacy of the Family Caregivers of Elderly People with Alzheimer's Disease, IJCBNM, 5, pp 231-238.
Outcome measures	Caregiver self efficacy
Study dates	October to December 2015 Pre and post test assessment
Study location	Iran
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- using the drawing method • Were clinicians and investigators blinded? Not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear (not reported) • At the end of the trial, were all patients accounted for? Yes some attrition • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate quazi experimental design, limited reporting of allocation concealment

Bibliographic reference	Shata ZN, Amin MR, El-Kady HM, Abu-Nazel MW (2017), Efficacy of a multi-component psychosocial intervention program for caregivers of persons living with neurocognitive disorders, Alexandria, Egypt: A randomized controlled trial. Avicenna J Med, 7:54-63.
Study type	A randomised controlled trial to evaluate the short‑term efficacy of a multicomponent psychosocial intervention program for informal caregivers of persons with neurocognitive disorders.
Participants	Inclusion criteria: Primary informal caregivers currently living with older people diagnosed with any type of dementia= based on DSM IV criteria; MMSE<20) Exclusions: Caregivers of patients suffering from serious diseases, e.g., terminal stage cancer, communication problems, or those who have been recently hospitalized (within last month).
Sample characteristics	Caregivers N= 114 Intervention n=55 61.8% female;38.2% male; mean age 49.35 (10.44) years

Bibliographic reference	**Shata ZN, Amin MR, El-Kady HM, Abu-Nazel MW (2017), Efficacy of a multi-component psychosocial intervention program for caregivers of persons living with neurocognitive disorders, Alexandria, Egypt: A randomized controlled trial. Avicenna J Med, 7:54-63.**
	Control n= 60 69.5% female; 30.5% male mean age 48.63 (12.31) years
Intervention	Multi-component program of 8 sessions lasting 45*60 minutes each, including psycho-education, group cognitive-behavioural therapy, and group social support.
Comparison	Not reported
Outcome measures	Caregivers dementia related knowledge questionnaire Caregiver depression -Hamilton depression rating scale Caregiver anxiety –Taylor manifest anxiety scale Caregiver burden – Zarit burden Interview
Study dates	April to November 2012 Post test assessment and 3 months assessment
Study location	Egypt
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- using the drawing method • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear (not reported) • At the end of the trial, were all patients accounted for? Yes some attrition • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate lack of blinding, unclear control group, limited reporting of methods

Bibliographic reference	**Spijker A, Wolersheim H, Terenstra S, Graff M, Adang E, Verhey F, Vernooij-Dassen M (2011) Systematic care for caregivers of patients with dementia: A multicentre, cluster-randomized controlled trial , American Journal of Geriatric Psychiatry, 19, 521-531**
Study type	A single blind multi centre randomised controlled trial to evaluate the effectiveness of a systematic care program for dementia (SCPD)

Bibliographic reference	Spijker A, Wolersheim H, Terenstra S, Graff M, Adang E, Verhey F, Vernooij-Dassen M (2011) Systematic care for caregivers of patients with dementia: A multicentre, cluster-randomized controlled trial , American Journal of Geriatric Psychiatry, 19, 521-531
Participants	Randomisation was made to the community mental health professionals trained in the SCPD Informal caregiver- care recipient dyads were recruited Inclusion criteria: Informal carers were required to visit the patient at least twice per week, be willing to participate and give informed consent Exclusion: Dyads were excluded if the informal caregiver was a client of the mental health service; was too ill; did not speak fluent Dutch
Sample characteristics	N=295 dyads SCPD caregivers (intervention) n= 155 Mean age(SD) 58.4 (12.2) years; 73.5% female; 26.5% male Usual care caregivers(control) n= 140 Mean age(SD) 59.2 (12.9) years; 75.0% female; 25.0% male
Intervention	SCPD – professionals were trained in systematic interpretation and assessment of caregiver's sense of competence and depressive symptoms and training in strategies to deal with deficiencies. Involved screening; psychosocial support and transfer to regular healthcare
Comparison	Usual care
Outcome measures	Caregiver sense of competence; caregiver burden ; Caregiver quality of life; caregiver depressive behaviours
Study dates	July 2009 to February 2011
Study location	Netherlands
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes sealed envelopes • Were clinicians and investigators blinded? Only dyads blinded to allocation • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs • Can the results be applied to the local population? -Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	**Torkamani M, McDonald L, Saez Agueyo I, Kanios C, Katsanou M-N, Madeley L, Limousin PD, Lees AJ, Jahanshahi M, et al (2014) A randomized controlled pilot study to evaluate a technology platform for the assisted living of people with dementia and their carers, Journal of Alzheimer's disease, 41, 515-523**
Study type	A pilot randomised controlled trial of ALADDIN (a computerised platform) to provide sources of support and information to carers.
Participants	Inclusion criteria: Outpatients identified as having dementia and their primary carers Exclusion: Not reported
Sample characteristics	N=60 dyads Caregivers ALADDIN (Intervention) n=30 carer 55% female; 45% male Mean age (SD) 57.57 (12.5) years Control group n=30 55% female; 45% male Mean age(SD) 60.69 (13.9) years Care receivers n= 960 Mean age (SD) = 78.03 (6.91) years MMSE Mean (SD) = 19.32 (5.00)
Intervention	Provided with ALADDIN platform to use for study duration Carers chose schedule of tasks System monitored by technical teams Instructions to work through contents over one week period
Comparison	Control group – not provided with the ALADDIN platform
Outcome measures	Caregiver distress; Caregiver burden; Caregiver quality of life
Study dates	Project ran for 6 months
Study location	International
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear- states randomised but method not reported • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes- • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Low • Overall risk of bias: Unclear

Bibliographic reference	**Tremont G, Davis JD, Papandonatos GD, Ott BR, Fortinsky RH, Gozalo P,Mun Sang Yue, MS et al (2015) Psychosocial telephone intervention for dementia caregivers: a randomised controlled trial, Alzheimer's Dementia, 11, 541-548**
Study type	A randomised controlled trial to examine the effects of a telephone based intervention on caregiver wellbeing
Participants	Inclusion criteria: Primary caregivers of people diagnosed with dementia, endorsing at least 2 out of 9 negative experiences associated with caregiving (sad, overwhelm, mood, family conflict exhaustion) and in caregiving role for at least 6 months providing at least 4 hours of assistance per day Exclusion: Caregivers with acute medical illness; not primarily English speaking; MMSE impaired for age and education; no access to telephone
Sample characteristics	N=250 78% female; 22% male
Intervention	FITT-C – family intervention telephone tracking intervention 16 telephone contacts over 6 months focusing on dementia education; emotional support; directing caregivers to appropriate resources; encouraging attendance to physical and emotional needs; teaching coping strategies
Comparison	Telephone support control condition Nonspecific therapeutic factors; nondirective approach
Outcome measures	Caregiver burden; Caregiver depression; reaction to caregiver behaviour problems
Study dates	Not stated but recruitment lasted 53 months
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- urn randomised procedure • Were clinicians and investigators blinded? Unclear not reported • Were the groups similar at the start of the trial? Not all demographics provide in publication; No significant differences between groups except intervention group a significantly greater years in education • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Regression analysis • Can the results be applied to the local population? Unclear • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	**Ulstein ID, Sandvik L, Wyller TB, Engedal K (2007) A one year randomised controlled psychosocial intervention study among family carers of dementia patients, effects on patients and carers, Dementia and Geriatric Cognitive Disorders, 24, 469-475**
Study type	A multi-centre randomised controlled trial to test the effect of a short term psychosocial intervention for family carers of people with dementia
Participants	Inclusion criteria: Carers were eligible if patients were living at home; patient fulfilled ICD-10 criteria for dementia; had at least weekly face to face contact with patient Exclusion criteria: Not reported
Sample characteristics	N= 171 carers Intervention n=87 Mean age (SD) 63.6 (12.84) years; 67% female; 33% male Control n= 84 Mean age (SD) 66 (12.75) years; 61% female; 39% male N=171 care receivers Intervention n=87 Mean age (SD) 75.7 (7.49) years; MMSE (SD) 20.8 (5.60) Control n=84 Mean age (SD) 75.4 (7.37) years; MMSE (SD) 20.9 (4.88)
Intervention	A 3 hour educational programme about dementia; Carers taught about symptoms and normal course of dementia and took part in 6 group meetings lasting 2 hrs each session,
Comparison	Treatment as usual at a memory clinic but with guaranteed on year follow up
Outcome measures	Caregiver stress; Caregiver neuropsychiatric symptoms;
Study dates	May 2001 to June 2003
Study location	Norway
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- blind block randomization • Were clinicians and investigators blinded? Single blind- none of the investigators had access • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? • MD (SD) • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	**Warren Brown K, Coogle CL, Wegelin J (2016) A pilot randomized controlled trial of mindfulness-based stress reduction for caregivers of family members with dementia, Aging & Mental Health, 20, pp 1157-1166**
Study type	A randomised controlled trial to test the efficacy of an adapted mindfulness-based intervention for reducing markers of stress, improving psychological morbidity and caregiver-recipient relationships in caregivers of people in the early stages of dementia
Participants	Inclusion criteria: Blood or marriage related adult caregivers who were caring for people living with early stage AD or other dementia's (Functional Assessment Staging of Alzheimer's disease- FAST- stage 5 or lower). Exclusion: Self report of psychiatric disorders or history; major depression with psychotic features; psychosis; history of schizophrenia, bipolar disorder, psychotic disorder, organic brain syndrome, or mental retardation; and alcohol or substance abuse within the previous year; major, uncorrected sensory impairments or cognitive deficits, (a score < 31 on the Telephone Interview for Cognitive Status)
Sample characteristics	N=38 carers; 84.2%= female; .8% male; mean age (SD) = 61.4 years (10.41) n= 23 experimental intervention; N=15 control group
Intervention	Adapted mindfulness-based stress reduction intervention 8 weeks intervention lasting 1.5 to 2 hour sessions 10-20 participants in each group Interventions included mindful movement, meditation, and mindful communication.
Comparison	A control social support program 8 weeks duration Leader facilitated discussion of topics generated by the group based on caring for the recipient
Outcome measures	Zarit Burden Interview Perceived stress scale
Study dates	Not reported
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- method not reported • Were clinicians and investigators blinded? Unclear- not reported

Bibliographic reference	Warren Brown K, Coogle CL, Wegelin J (2016) A pilot randomized controlled trial of mindfulness-based stress reduction for caregivers of family members with dementia, Aging & Mental Health, 20, pp 1157-1166
	• Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? Mean values SDs (Cohens D effect reported • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Moderate

Bibliographic reference	Whitebird RR,Kreitzer MJ, Crain AL, Lewis BA, Hanson LR, Enstad CJ (2012) Mindfulness-based stress reduction for family caregivers: A randomised controlled trial. The Gerentologist, 53, 676-686
Study type	A randomised controlled trial to compare a mindfulness based stress reduction intervention (MBSR) to a community caregiver education and support (CCES) intervention for family caregivers of people with dementia
Participants	Inclusion criteria: Self-identified primary caregivers of a community dwelling family member with dementia ; older than 21 years; spoke English; could read all course materials; willing to participate in group sessions ; had not participated in a community caregiver program; had not practiced yoga, tai chi or medication; scored 5 or higher on perceived stress scale; had no psychiatric hospitalisations or a diagnosis of mental illness in previous 2 years; not taking antipsychotics or anticonvulsants; no thoughts of harming themselves in previous 6 months Exclusions: Not reported
Sample characteristics	N= 88 Mean age (SD) 56.8 (9.9) years; 88.5% female; 12.5% male n=40 CCES Mean age (SD) 56.4 (10.2) years; 90% female 10% male n=38 MBSR Mean age (SD) 57.2 (9.6) 86.8% female 14.2% male
Intervention	MBSR – 8 weekly 2.5hr group sessions Instruction about concepts of mindfulness; practised meditation and gentle yoga exercises;
Comparison	CCES- 8 weekly 2.5 hr group sessions Education on issues affecting family caregivers and group social and emotional support Received educational information on topics such as dementia, legal and financial issues, community resources, self-care, communication, grief and loss
Outcome measures	Perceived stress; Depression; Anxiety;
Study dates	2007 to 2010

Bibliographic reference	Whitebird RR,Kreitzer MJ, Crain AL, Lewis BA, Hanson LR, Enstad CJ (2012) Mindfulness-based stress reduction for family caregivers: A randomised controlled trial. The Gerentologist, 53, 676-686
	Follow up 2 months and 6 months
Study location	USA
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- computer algorithm • Were clinicians and investigators blinded? Not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD SD effect size (Cohen's d) p values • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Bibliographic reference	Xiao LD, De Bellis A, Kyriazopoulos BA, Draper B, Ullah S (2016) The effect of a personalized dementia care intervention for caregivers from Australian minority groups, American Journal of Alzheimer's disease and other dementias, 31, 57-67
Study type	A randomised controlled trial to consider if a personalised caregiver support programme led by a care coordinator of the person with dementia would improve competence for caregivers from minority groups in managing dementia
Participants	Inclusion criteria: caregivers from a minority group and cared for a community dwelling older person with dementia from the same minority group; primary caregiver in family; cared for the person with dementia for at least 1 year and had at least two face to face contacts with care recipient per week; aged 18 years or over care recipient had a score ≤22 on RUDAS (Rowland Universal dementia Assessment scale; Exclusions: If caregivers had cognitive impairment or a terminal illness ; in first year of caregiving role;
Sample characteristics	Caregivers N= 61 Intervention n=31 83.9% female;16.1% male; median age (IQR) 56.0 (50.0.-69.0) years Control n= 30 83.3% female; 16.7% male median age (IQR) 56.0 (50.0-65.0) years
Intervention	Caregivers assigned to a care coordinator – a person currently managing the care receiver Care coordinators trained to use a personal caregiving support plan (PCSP) and caregiving diary Initial home visit to assess needs plus quarterly home visits
Comparison	Usual caregiver support group

Bibliographic reference	Xiao LD, De Bellis A, Kyriazopoulos BA, Draper B, Ullah S (2016) The effect of a personalized dementia care intervention for caregivers from Australian minority groups, American Journal of Alzheimer's disease and other dementias, 31, 57-67
Outcome measures	Caregivers distress; Sense of competence; Severity of care receivers BPSD
Study dates	Not stated Assessed at 3, 6 and 12 months; dependence score;
Study location	Australia
Comments Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes- using simple random sampling methods • Were clinicians and investigators blinded? Not reported • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear (not reported) • At the end of the trial, were all patients accounted for? Yes • How large was the treatment effect? How precise was the outcome effect? MD SD • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes • Overall risk of bias: Low

Components of multicomponent interventions

Component	Carer only interventions (n=18)	Dyadic interventions (n=16)
Mode of administration		
Telephone	4 (22%)	5 (31%)
Group	8 (44%)	7 (44%)
Home	3 (17%)	7 (44%)
Individual	9 (50%)	8 (50%)
Internet	0 (0%)	2 (13%)
Intervention components		
Structured assessment	1 (6%)	7 (44%)
Behavioural management training	13 (72%)	12 (75%)
Education about dementia and its effects	13 (72%)	13 (81%)
Skills training on managing dementia	4 (22%)	7 (44%)

Component	Carer only interventions (n=18)	Dyadic interventions (n=16)
Identifying pleasant activities	4 (22%)	2 (13%)
Home visits for observation of behaviours	2 (11%)	2 (13%)
Stress management techniques	6 (33%)	6 (38%)
Own-health advice	6 (33%)	1 (6%)
Medication training	2 (11%)	2 (13%)
Information about available support services	7 (39%)	6 (36%)
Emotional adjustment	4 (22%)	3 (19%)
Training on carer-staff interaction	1 (6%)	0 (0%)
Communication training	4 (22%)	4 (25%)
Counselling	7 (39%)	4 (25%)
Training on forward planning	6 (33%)	5 (31%)
Support	9 (50%)	8 (50%)
Contact line	0 (0%)	3 (19%)
Case management	3 (17%)	3 (19%)
Respite	1 (6%)	1 (6%)
Psychotherapy	1 (6%)	1 (6%)
Physical exercise	0 (0%)	4 (25%)
Finance training	0 (0%)	1 (6%)
Environmental assessment	0 (0%)	4 (25%)

E.12 Staff training

E.12.1 Staff training

- What effect does training for staff working with people living with dementia have upon the experiences of people living with dementia in their care?

Bibliographic reference	**Beer, C. et al. (2011). A cluster-randomised trial of staff education to improve the quality of life of people with dementia living in residential care: the DIRECT study. PLoS ONE, 6, e28155.** **Beer, C. et al. (2010). Dementia in residential care: education intervention trial (DIRECT); protocol for a randomised controlled trial. Trials, 11, 63**
Study type	Cluster randomised controlled trial. Care facilities and GPs were independently randomised to intervention or control groups. Allocation was done by a centrally held computer generated randomisation table, managed by an independent statistician.
Participants	Inclusion criteria: Permanent resident of a low-level or high-level residential care facility, greater than 65 years of age, and MMSE score ≤24. Exclusion criteria: Participant's general practitioner works at more than one facility participating in the trial, subject is identified by facility as medically unstable or as suffering delirium or in the terminal stages of a co-morbid illness, subject unable to participate in assessment instruments in English.
Sample characteristics	N= 351 people living with dementia n= 99 experimental intervention 1: Residential care facility staff training and GP training 78%=female; 22%=male; mean age (SD)= 86.4 years (6.6); median MMSE (IQR)= 15 (7-20) n= 62 experimental intervention 2: Residential care facility staff training and GP 'control' 77%=female; 23%=male; mean age (SD)= 86.1 years (8.4); median MMSE (IQR)= 10 (4-17) n= 58 experimental intervention 3: Residential care facility staff 'control' and GP training 75%=female; 25%=male; mean age (SD)= 84.6 years (8.8); median MMSE (IQR)= 16 (8-20) n= 132 comparator: Residential care facility staff 'control' and GP 'control' 73%=female; 27%=male; mean age (SD)= 84.4 years (8.1); median MMSE (IQR)= 12 (6-19)
Intervention	There were three intervention groups: 1) Residential care facility staff training and GP training, 2) residential care facility staff training and GP 'control', 3) residential care facility staff 'control' and GP training. The educational package was delivered to GPs, clinical and direct care staff. The main topics of the educational programs were: • Communication with residents and family members. • Personal care and activities. • Positive values.

Bibliographic reference	**Beer, C. et al. (2011). A cluster-randomised trial of staff education to improve the quality of life of people with dementia living in residential care: the DIRECT study. PLoS ONE, 6, e28155.** **Beer, C. et al. (2010). Dementia in residential care: education intervention trial (DIRECT); protocol for a randomised controlled trial. Trials, 11, 63**
	• Behaviours of concern. • Pain management. • Dementia, depression and delirium. • Effective working between GPs and residential care facility staff. The GP education program consisted of five modules, delivered during three evening sessions. A fourth, reflective, session was also held. The sessions used case scenarios from DVDs and role plays with volunteers and professional actors to stimulate participation, consistent with adult learning principles. They were facilitated by study staff and one or two of the authors. A self-directed learning package (DVD of the first three sessions plus supporting materials), and a reflection session, were offered to GPs not attending face-to-face workshops. The GP program was approved for Continuing Professional Development points for the period 2008-2010. The residential care facility education intervention comprised 27 brief modules which were delivered on-site at each facility by one of two educators. This format was chosen to facilitate flexibility in delivery of the program. Each of the 27 lessons was in half hour blocks which could be built into sessions of varying lengths of time. Education sessions ranged from 1 hr blocks to full 7.5 hr days.
Comparison	Residential care facility staff 'control' and GP 'control'. GPs and residential care facility staff assigned to the control group did not receive any specific intervention. The protocol did not preclude GPs and residential care staff assigned to the intervention or control groups independently accessing education, nor did they attempt to measure their participation in education other than that provided for the purposes of the study intervention.
Outcome measures	Primary and Secondary Outcomes were assessed at baseline and again 4 weeks and 6 months after the conclusion of the educational intervention. However, we will only report on the data collected at baseline and at 6 months post-intervention. **Primary Outcome**. The primary outcome of the study was the quality of life of the participants with dementia rated using the self-rated Quality of Life - Alzheimer's Disease Scale (QOL-AD) modified for use in long-term care settings. Higher scores on the QOL-AD indicate better quality of life (minimum 15, maximum 60). Research assistants were trained in the standard administration of assessment tools and adequate inter-rater reliability was established for the QOL-AD. **Secondary outcomes**. Quality of life was also measured using the staff and next-of-kin rated QOL-AD and the Alzheimer Disease Related QOL Scale (ADRQOL) which relies on caregiver interview. Higher scores on the ADRQOL (minimum 0, maximum 100) also indicate better quality of life. Informant ratings are required when the severity of a person's cognitive impairment precludes self-rating. However, because informant ratings may differ from people's own ratings of their quality of life, informant ratings were regarded as secondary outcomes. Family informants for the person living with dementia living in Residential care were required to have visited the PWD on average at least once per week over the previous year.

Bibliographic reference	**Beer, C. et al. (2011). A cluster-randomised trial of staff education to improve the quality of life of people with dementia living in residential care: the DIRECT study. PLoS ONE, 6, e28155.** **Beer, C. et al. (2010). Dementia in residential care: education intervention trial (DIRECT); protocol for a randomised controlled trial. Trials, 11, 63**
	Staff informants were required to have known the resident for at least two weeks, and to have observed that resident at least 10 times, or for one hour in total, during the previous two weeks. Other outcomes of interest were factors likely to impact on participants' quality of life including behavioural and psychological symptoms of dementia (measured with the Neuropsychiatric Inventory- NH version), pain (measured using the Brief Pain Inventory modified verbal form and PAIN_AD), and use of physical restraint. Research staff recorded whether physical restraints were applied to the resident. This included fixed tray tables, ''fall out'' chairs and zipped bedding, as well as overt restraints.
Study dates	2008-2009
Study location	Australia
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes. Outcomes were measured by blinded research assistants. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Burgio, L. D., Stevens, A., Burgio, K. L., Roth, D. L., Paul, P. and Gerstle, M. S. (2002). Teaching and maintaining behavior management skills in the nursing home. The Gerontologist, 32, 487–496.**
Study type	Randomised controlled trial.
Participants	Inclusion criteria: Participants in this study were nursing home residents who displayed behavioural disturbances. Research staff screened all residents in two nursing homes for possible participation. Reisberg's BEHAVE-AD was used to assess overall severity of behavioural disturbances. Residents receiving a score of one (mildly troubling) or greater, on average, were considered eligible. Exclusion criteria: They excluded residents if they were living on a rehabilitation unit with a limited length of stay.

Bibliographic reference	**Burgio, L. D., Stevens, A., Burgio, K. L., Roth, D. L., Paul, P. and Gerstle, M. S. (2002). Teaching and maintaining behavior management skills in the nursing home. The Gerontologist, 32, 487–496.**
Sample characteristics	N= 88 people living in residential care who displayed behavioural disturbances. n= 47 experimental intervention: Formal staff management (FSM). 85%=female; 15%=male; mean age (SD)= 82.17 years (10.10); mean MMSE (SD)= 6.69 (9.17) n= 32 comparator: Conventional staff management (CSM). 66%=female; 34%=male; mean age (SD)= 77.44 years (11.73); mean MMSE (SD)= 6.59 (7.59)
Intervention	Following baseline assessment, all nursing assistants and nurses received 4 weeks of behaviour management training with knowledge and performance-based assessments of skill acquisition. Upon training nurses to established criteria of behavioural skill performance, they instructed supervisory nursing staff on formal staff management (FSM) units to implement the FSM system, and they instructed those on conventional staff management (CSM) units to continue their normal supervisory routine. In order to examine any changes in resident behaviour, they repeated assessments during a 4-week post-intervention phase immediately after staff training. They conducted follow-up assessments during week-long periods at 3 and 6 months after training to assess maintenance of change resident behaviours.
Comparison	The comparison staff received the same training as the intervention staff. However, in the comparison group, supervisory nursing staff were told to continue their normal supervisory routine.
Outcome measures	Time-sampling was used to observe resident behaviours throughout the day on the nursing units. They scheduled residents to be observed and coded for two 30-min sessions during each hour between 8am and 8pm Thus, they attempted 24 observations on each resident during the 4 weeks of baseline and repeated them during the 4-week post-intervention phase. Resident agitation was defined as disruptive vocalizations, restlessness, or physical aggression.
Study dates	Not provided. This study was submitted in 2001. The length of the study was 4 years.
Study location	Alabama, USA.
Comments **Risk of bias**	• Did the trial address a clearly focused issue? No. Both groups of staff received the same training. • Was the assignment of patients to treatment randomised? Unclear. There are no details regarding the randomisation method. • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Unclear. MMSEs and ages were similar. Participant numbers and gender were not. • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Unclear. Overall attrition was described but not given separately for each group. • Can the results be applied to the local population? Yes

Bibliographic reference	**Burgio, L. D., Stevens, A., Burgio, K. L., Roth, D. L., Paul, P. and Gerstle, M. S. (2002). Teaching and maintaining behavior management skills in the nursing home. The Gerontologist, 32, 487–496.**
	• Were all clinically relevant outcomes reported? Yes Overall risk of bias: Very high. Both arms received the same training, randomisation method not given and no blinding.

Bibliographic reference	**Chang, C. C. and Lin, L.-C. (2005). Effects of a feeding skills training program on nursing assistants and dementia patients. Journal of Clinical Nursing, 14, 1185–1192.**
Study type	Quasi-experimental study. Two residential care facilities were randomly assigned to either the intervention or control.
Participants	Inclusion criteria: People living with dementia who were identified by nursing assistants as having eating problems and needing assistance. Exclusion criteria: None
Sample characteristics	N= 20 people living with dementia in residential care. n= 12 experimental intervention: Feeding skills training program. n= 8 comparator: Usual care No baseline characteristics of the participants was given.
Intervention	The content of the classes included the purpose of this training programme, overview of dementia, aetiology and behaviours of feeding among dementia patients and protocol for feeding dementia patients regarding how to manage feeding problems of dementia patients. The protocol contained the preparation for the mealtime environment, interactions between caregivers and dementia patients and feeding skills to deal with food refusal. Nursing assistants who participated in the in-service classes also obtained a written manual of this feeding skills training programme. The in-service classes were taught during the regular working hours and completed over two consecutive days by the principal investigator. There were Chinese and English versions of this training programme. Both Chinese and English versions of the entire training programme were reviewed by a gerontological expert to determine the appropriate content and meaning and equivalence between two versions. In addition, the training programme was piloted with three nursing assistants and revised based on the feedback of those nursing assistants. Immediately following the in-service, hands-on training was provided to enhance the effectiveness of this feeding skills training programme. The hands-on training used one-to-one teaching and provided nursing assistants opportunities to practice and give feedback. The principal investigator followed each nursing assistant during one entire mealtime lasting approximately one hour. The content of the hands-on training followed the instruction guideline that was developed based on the feeding protocol. The nursing assistants had opportunities to feed several dementia patients at one mealtime and deal with different feeding problems of dementia patients.
Comparison	Usual care.

Bibliographic reference	**Chang, C. C. and Lin, L.-C. (2005). Effects of a feeding skills training program on nursing assistants and dementia patients. Journal of Clinical Nursing, 14, 1185–1192.**
Outcome measures	The feeding difficulty of dementia patients was measured by the Edinburgh Feeding Evaluation in Dementia (EdFED) scale. The nursing assistants were interviewed with the EdFED scale to assess the feeding difficulties of each dementia patient they assisted. There are 11 items in the EdFED scale and each item has three possible responses: A-never, B-sometimes, and C-often. In this study, the three possible responses were labelled as A-0, B-1 and C-2, respectively. Higher scores indicate more feeding difficulties of dementia patients with the total possible score from 0 to 22. The food intake was measured by, the research assistant using percentage of food that has been eaten during mealtime. It was coded as 0, 1/4, 1/2, 3/4 and 1.
Study dates	Not provided. This study was submitted for publication in 2004.
Study location	North Taiwan
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. It is possible that participants joined the study after randomisation of the residential care facilities. • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? • Aside from the experimental intervention, were the groups treated equally? Unclear. Residents in each group were in different residential care facilities. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Chenoweth, L. et al. (2009). Caring for aged dementia care resident study (CADRES) of person-centred care, dementia-care mapping, and usual care in dementia: a cluster-randomised trial. The Lancet Neurology, 8, 317–325.**
Study type	Cluster randomised controlled trial of 15 residential care homes.
Participants	Inclusion criteria: Diagnosis of dementia, older than 60 years of age, had an Australian resident classification scale denoting high dependency, had low cognitive function, and need-driven dementia compromised behaviours, had written informed consent given on their behalf by their guardian or had given verbal assent themselves, and were in permanent placement in residential care. Exclusion criteria: Lack of consent, serious comorbidities complicating or masking dementia, palliative care,

Bibliographic reference	**Chenoweth, L. et al. (2009). Caring for aged dementia care resident study (CADRES) of person-centred care, dementia-care mapping, and usual care in dementia: a cluster-randomised trial. The Lancet Neurology, 8, 317–325.**
	unremitting pain and distressing physical symptoms and respite placement.
Sample characteristics	N= 236 people living with dementia in residential care. n= 95 experimental intervention 1: dementia-care mapping. 83%=female; 17%=male; mean age (SD)= 83 years (7.6); mean global deterioration scale (SD)= 5.6 (1.3) n= 77 experimental intervention 2: person-centred care. 74%=female; 26%=male; mean age (SD)= 84 years (6.4); mean global deterioration scale (SD)= 5.6 (0.73) n= 64 comparator: usual care. 73%=female; 27%=male; mean age (SD)= 85 years (6.6); mean global deterioration scale (SD)= 5.3 (1.1)
Intervention	The researchers implemented person-centred care and dementia-care mapping. The researchers were trained by people accredited by Bradford University, UK, were supervised and assessed for competence at unrelated sites during the pilot study, had participated in hundreds of hours of both intervention procedures in ten care homes for the elderly before this study, and used Bradford University's learning resources and protocols for staff training and support. For the person-centred care group, there were 2-day training sessions in person-centred care for two care staff selected by managers as competent and interested from each of the five sites. Bradford University's training manual was used as a resource during and after the sessions. Topics covered included understanding that behaviour is a form of communication, recognising that feelings persist despite cognitive impairment, acknowledging feelings during social interactions, and focusing on the unique way that residents express feelings and needs to change usual care. The training sessions explored how staff actions contribute to behaviours of residents that result from dementia. Training challenged previously held beliefs by emphasising that social interactions, especially those that engage residents on an affective level, help to preserve personhood and build meaningful relationships. The researcher assisted the trained staff to develop and implement care practices based in person-centred care for 28 of the 98 participating residents from the five sites. Central to these practices was a careful review of residents' life histories. The researcher visited each site twice to help staff change practices to include person-centred care for all 98 residents. The researcher also supported staff via regular telephone contact during the 4 month intervention period to assess the planned changes to practice and care approaches as needed. For dementia-care mapping group, two other researchers did dementia-care mapping at the five sites after their inter-rater reliability for scoring had been established (concordance coefficient 0·86). Two care staff at each site who were trained by a Bradford-trained expert did mapping with the two researchers for 6 hours per day for 2 days (before, during, and after breakfast and lunch times and during recreational activity time in the afternoon), to identify factors related to resident wellbeing. Observations included positive and negative care delivery, namely positive events and personal detractions, and wellbeing scores within the 24 behavioural categories defined in dementia-care mapping. The two researchers' observation data were reported to nurses within 24 hours of mapping and included composite wellbeing scores for individual residents, associations between care practices and staff–resident

Bibliographic reference	**Chenoweth, L. et al. (2009). Caring for aged dementia care resident study (CADRES) of person-centred care, dementia-care mapping, and usual care in dementia: a cluster-randomised trial. The Lancet Neurology, 8, 317–325.**
	interactions (positive events and personal detractions), and wellbeing expressions present in need-driven dementia-compromised behaviours. The two researchers conferred with the trained staff to develop individual care plans for residents by considering the individuals' histories, needs, and preferences. Trained staff subsequently helped their colleagues to implement person-centred care plans over the 4-month intervention period, with regular telephone support from a researcher and supported by the results of the therapeutic environment screening survey for nursing homes (TESS-NH) baseline site screen, and typical of Australian residential care for elderly people and people with dementia.
Comparison	Usual care continued uninterrupted at the five control sites. Usual care was characterised by custodial and physical task-oriented practices, including unwarranted use of physical restraint, a tendency to neglect residents' psychosocial needs when meeting activities of daily living, with little attention being paid to promotion of resident choice and encouragement of self-determination.
Outcome measures	Outcome measures were assessed before the intervention and directly after the 4 months of intervention, and then at 4 months' follow-up. We will only report on the baseline and 4-month follow-up results. The researchers recorded need-driven dementia-compromised agitation with the 29-item Cohen-Mansfield agitation inventory (CMAI), which measures the frequency (from never, 1, to several times an hour) of agitation during the past 2 weeks (range 29–203), with high scores relating to agitation. The CMAI was chosen a priori as the primary outcome measure because it was expected to be more responsive than other measures to the effects of the psychosocial care interventions tested in this study (because it includes 29 discrete and readily observable behaviours of agitation such as pushing, biting, scratching, hiding things, and hoarding things). They recorded psychological and psychiatric behaviours occurring in dementia with the neuropsychiatric inventory for the nursing home, which measures frequency and severity of 12 domains of severe symptoms (delusions, hallucinations, agitation or aggression, depression or dysphoria, anxiety, elation or euphoria, apathy or Indifference, disinhibition, irritability or lability, aberrant motor behaviour, sleep, and appetite and eating disorders) occurring per day during one week (range for each domain from 0 to 12), for which higher scores indicate worse behaviour. Quality of life in late-stage dementia (QUALID) recorded 11 observable behaviours in affective states: discomfort, activity engagement, and interactions with others in the previous week. The scale captures the frequency of each item (range 11–55) and lower scores show higher perceived quality of life. They recorded the observed number, type, and duration of use of physical restraint over 2 days during QUIS observations. Incidents and subsequent admissions to hospital were discerned from official records of incidents including residents' falls, fractures, lacerations, bruises, medication errors, and behavioural incidents (e.g., absconding, physical aggression), and any subsequent admissions to hospital in the 3 months before the study started, the 3 months before the end of treatment, and the 3 months before the 4 month follow-up were obtained from each site: variables for analysis were number of incidents per resident, and number of admissions to hospital. They recorded information about up to five medicines given in the past month from medical records. Antipsychotic and benzodiazepine doses were converted into chlorpromazine and diazepam equivalents, respectively. One trained

Bibliographic reference	**Chenoweth, L. et al. (2009). Caring for aged dementia care resident study (CADRES) of person-centred care, dementia-care mapping, and usual care in dementia: a cluster-randomised trial. The Lancet Neurology, 8, 317–325.**
	research assistant collected data for care environment quality at all 15 care sites with the TESS-NH. Three other research assistants were trained in measurement of all baseline values and outcomes at an uninvolved dementia unit and their inter-rater reliabilities were established (concordance coefficient 0·89). These research assistants were each assigned to one intervention group (five sites per group) for the study duration and remained masked to group intervention by means of a signed agreement with staff and managers not to mention the intervention, by ensuring that questionnaires included no intervention information, and by regularly checking with the research assistants that they remained unaware of treatment allocation throughout the study. These three assistants collected data on quality of care practice and use of physical restraints through direct QUIS observations. Data for CMAI, neuropsychiatric inventory for the nursing home, quality of life in late-stage dementia, and global deterioration rating scale for assessment of primary degenerative dementia were obtained through observation and interviews with the nurses and direct care staff who were judged to be most knowledgeable of individual residents' disorders and who regularly cared for them. Interviews were done with individuals and small groups of staff, and scores were derived through consensus. The three research assistants interviewed the same staff from each site at all three stages of data collection to achieve the best reliability of outcome measure scoring. The repeated measures design and analysis ensured that any systematic difference due to allocation of research assistants to intervention groups was adjusted for in the statistical analysis of the main study hypotheses. Demographics, basic clinical information, and information on incidents and use of drugs were obtained from clinical charts and official site records with support from managers and quality assurance personnel.
Study dates	Not provided. Study was submitted for publication in 2009.
Study location	Sydney, Australia
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes. Research assistants recording results were blinded. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Chenoweth, L. et al. (2014). PerCEN: a cluster randomized controlled trial of person-centered residential care and environment for people with dementia. International Psychogeriatrics, 26, 1147–1160.**

Bibliographic reference	**Chenoweth, L. et al. (2014). PerCEN: a cluster randomized controlled trial of person-centered residential care and environment for people with dementia. International Psychogeriatrics, 26, 1147–1160.**
Study type	Cluster randomised controlled trial.
Participants	Inclusion criteria of residential care homes: Government accreditation and building certification; high-level care homes; located within a 500 km radius of Sydney, Australia; with room for improvement in both person-centred environment (PCE) and person-centred care (PCC) according to the Person-Centred Environment and Care Assessment Tool (PCECAT), a 44-item rating instrument with three domains designed for evaluation of residential aged care. The PCECAT 4-point scale was rescored 0 (the best possible rating) and 1, 2, 3 (the worst possible ratings, ranked). A total "room for improvement score" (RFI) was calculated by summing across items (20 items in Domain 2 (Care Services), and 19 in Domain 3 (Environment). Homes that scored 1–3 for both Care Services and Environment RFI were considered eligible. Inclusion criteria of participants: The ability to give consent to participate in the study, proxy consent or Guardianship Tribunal consent; recorded dementia diagnosis; permanent stay; admission at least 3 months prior to baseline; assessed high care needs and presence of agitation. Exclusion criteria of participants: Florid mental illness or end-stage dementia. In other words, the participant had to be able to participate for the duration of the study.
Sample characteristics	N= 296 people living with dementia in residential care. n= 64 experimental intervention: person-centred care (PCC) 67%=female; 33%=male; mean age (SD)= 84 years (8); Global Deterioration Scale severe/very severe = 90% n= 64 experimental intervention: person-centred environment (PCE) 66%=female; 34%=male; mean age (SD)= 84 years (8); Global Deterioration Scale severe/very severe = 82% n= 89 experimental intervention: person centred care and person-centred environment (PCC + PCE) 60%=female; 30%=male; mean age (SD)= 84 years (7); Global Deterioration Scale severe/very severe = 85% n= 64 comparator: usual care and usual environment (UC + UE) 77%=female; 23%=male; mean age (SD)= 86 years (7); Global Deterioration Scale severe/very severe = 88%
Intervention	Following pre-test data collection at all 38 homes the study interventions were randomised to care homes as follows: PCC + UE in 10 homes; PCE + UC in 10 homes: PCC + PCE in 10 homes and UC + UE continuing in 8 homes. All study interventions were funded by the study grant including: the cost of training and supervising PCC site staff; the cost of replacing the PCC-trained staff with relief staff during training and on-site facilitation; the cost of implementing recommended and agreed PCE interventions of approximately $10,000 per site. Person-centred care: Using experiential and adult learning approaches, were facilitated by two chief investigators with expertise in PCC approaches and one expert PCC trainer from Alzheimer's Australia, employing a train-the-trainer processes. Five staff (one care manager, one Registered Nurse, two Enrolled Nurses or Assistants in Nursing, 1 Diversion/Recreation Therapist) from each of the 10 PCC+UE and 10 PCC+PCE homes were involved in the PCC training. The 32-hour off-site training occurred over 1 week, complemented by a further 32 hours of onsite

Bibliographic reference	Chenoweth, L. et al. (2014). PerCEN: a cluster randomized controlled trial of person-centered residential care and environment for people with dementia. International Psychogeriatrics, 26, 1147–1160.
	education and support to implement PCC in daily care practices and recreation activities. Prior experiences, case studies, role plays and simulations were utilised to develop awareness and insight of the relationship between care and the resident's QOL. The PCC trainer guided and supported PCC-trained staff to employ PCC learning resources, mentoring and role modelling in educating all care and therapy staff in PCC. With the support of their managers and the PCC trainer, direct-care staff members were assisted to develop person-centred resident care and recreation activity plans, and to implement changes in care routines and procedures, with the focus on improving residents' QOL and reducing BPSD. Ongoing telephone support continued for PCC-trained staff by the PCC trainer until post-test. Centred dementia environment design: Two chief investigators (CIs) with expertise in Person-Centre Environment design and a Master of Design research student took responsibility for implementing the PCE interventions at each of the 10 PCE + UC and 10 PCE + PCC sites. The Environment Audit Tool (EAT) was employed to evaluate the relationships between operations and space in terms of effectiveness and ideal resident care, and determining required environmental changes to meet PCE principles at the sites. Discussions of EAT findings were held with the home's executive staff and managers to initially determine their understanding of the dysfunction generated for residents through the poor physical environment features identified. Planning then occurred with these senior staff to determine the best ways to undertake the most essential and inexpensive environmental changes required. Planned modifications to the environment were then undertaken in each of the 20 homes by a contracted building company. The environment interventions, agreed to by the managers and priced by the contractor, were as follows: (1) two facilities needed extensions of activity space made by covering balconies or areas that were previously open; (2) two facilities had changes made to internal walls that would allow better visual access to activity and bedroom spaces; (3) one facility was to be altered to provide access to a courtyard from a dining area needed for activity and group activities; (4) two facilities needed internal divisions with added partitions to reduce the overstimulation in larger group spaces; (5) two facilities had walls removed to make sub-sitting areas visible to residents passing in the corridor; (6) one facility had fire doors relocated to improve access to the garden and (7) the remaining facilities all had some variation of external paving, new sitting areas in gardens or covered spaces in a landscaped exterior. All these changes were considered to provide maximum benefit in achieving improved support for staff undertaking PCC-focused activities while engaging with residents. Person-Centred Care and Environment: Both PCC and PCE, described above, were implemented in 10 of the homes at the same time (PCC + PCE).
Comparison	Usual Care and Environment. UC practices and care environments were maintained in eight homes throughout the intervention to follow-up periods, and regular records were made by RAs of any reported changes in the homes' structures, management arrangements, staff education and resident and staff profiles. The PCECAT and the EAT are repeated at post-test and follow-up in all 38 homes by two independent RAs and additional questions are asked of care managers and senior staff to ascertain any changes occurring during the study that might have changed care practice and/or the care environment and how the environment was being used by staff and residents.
Outcome measures	Measurements were obtained pre-test and at 8 months follow-up.

Bibliographic reference	**Chenoweth, L. et al. (2014). PerCEN: a cluster randomized controlled trial of person-centered residential care and environment for people with dementia. International Psychogeriatrics, 26, 1147–1160.**
	Dementia quality of life (DEMQOL): This measured quality of life of people with dementia. It included five domains, which including daily activities and self-care, health and well-being, cognitive functioning, social relationships and self-concept. It was filled out by both the person with dementia, if possible, and their proxy. The DEMQOL self-report contains 28 items covering 4 dimensions (daily activities, memory, negative emotion, positive emotion) plus a global item. DEMQOL proxy contains 31 items covering 2 domains: functioning and emotion and a global item to assess resident's feeling about their overall quality of life, as perceived by the carers. It was obtained by the resident self-report if possible and resident proxy, either frequently visiting family/friend, or staff regularly caring for resident Cohen-Mansfield agitation inventory (CMAI)-long form: This measured agitation, unique aspects of behaviour and the effects of cognitive enhancers and other types of psychotropic drugs on behaviour. It included a seven-point rating scale (1-never observed to 7-observed a few times in an hour) assessing the frequency with which patients manifest up to 29 behaviours associated with agitation, as observed by care staff over the past week. It was obtained by a review of clinical files, resident observation and consensus by staff who care daily for resident. RAs will refer to care staff who have daily and the closest contact with the resident to confirm assessment. Emotional responses in care assessment: This measured the person with dementia's emotional responses to care delivery. It covered the following domains: observed emotional responses to care delivery quantifies the proportion of time, 3 positive and/or 3 negative emotional responses are made in defined situations. It was obtained by direct observation of residents by RAs during care delivery.
Study dates	2009-2011
Study location	Sydney, Australia.
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different sites were used. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Clare, L. et al. (2013). AwareCare: a pilot randomized controlled trial of an awareness-based staff training intervention to improve quality of life for residents with severe dementia in long-term care settings. International Psychogeriatrics, 25, 128–139.**

Bibliographic reference	**Clare, L. et al. (2013). AwareCare: a pilot randomized controlled trial of an awareness-based staff training intervention to improve quality of life for residents with severe dementia in long-term care settings. International Psychogeriatrics, 25, 128–139.**
Study type	Randomised controlled trial
Participants	Inclusion criteria: Care homes were eligible for inclusion if they offered the potential to recruit 10 people with severe dementia and up to 10 members of the care staff. Inclusion criteria for participants were that they should have severe dementia, meeting criteria for stage 6 or 7 on the Functional Assessment Staging (FAST) and no, or only very limited, verbal communication, indicated by an inability to clearly verbally communicate needs and wishes, with speech either very circumscribed and limited to single words or phrases, or completely absent. Inclusion criteria for care staff were that the staff member should be a permanent employee, working 15 hours or more per week, who had been in post for at least two months. Recruitment took place between 14 July 2010 and 25 July 2011. Exclusion criteria: None.
Sample characteristics	N= 65 people living with dementia in residential care homes. n= 32 experimental intervention: Awareness and communication training. 78%=female; 22%=male; mean age (SD)= 82.3 years (7.4); “severe dementia” n= 33 comparator: Usual care. 79%=female; 21%=male; mean age (SD)= 84.6 years (8.5); “severe dementia”
Intervention	The intervention took place over an eight-week period in each care home. In weeks 1 and 2, care staff in each home participated in two 90- minute training sessions led by an accredited trainer. In these sessions, staff were encouraged to consider the nature of residents’ awareness, were introduced to, and instructed in the use of, the AwareCare observational measure of awareness in severe dementia, and were given guidance on developing their skills in communicating with severely impaired residents. Staff practised using the measure between the two sessions. In session 2, staff members were each given an individualized schedule for observing during weeks 3 to 8 a small number of designated residents who were participating in the study. Each staff member was asked to carry out six 10-minute observations per week according to this schedule (a total of 36 observations over the six-week period), in public areas of the home while residents were awake, and to participate in fortnightly group supervision sessions. Individual support was offered weekly between sessions and where staff members were unable to attend scheduled sessions. In the final meeting at the end of the intervention period, the researchers asked the participating care staff about their perceptions of the intervention, and recorded responses in their field notes. These responses were later collated and examined to identify common themes. In some cases, responses could be linked to comments made at an earlier stage and recorded in the field notes, demonstrating changes in staff perceptions over the course of the intervention.
Comparison	Usual care.
Outcome measures	All measures were administered at baseline and at follow-up assessment at 8 weeks. The primary outcome measure was quality of life for the person with dementia. This was assessed with the Quality of Life in Late-stage

Bibliographic reference	**Clare, L. et al. (2013). AwareCare: a pilot randomized controlled trial of an awareness-based staff training intervention to improve quality of life for residents with severe dementia in long-term care settings. International Psychogeriatrics, 25, 128–139.**
	Dementia scale. Quality of life was rated independently by a family member (where available) and by a member of the care staff. Secondary outcomes for the person with dementia were: • Well-being, assessed by the Positive Response Schedule. • Cognitive functioning, assessed by the Guy's Advanced Dementia Schedule (GADS). • Behaviour, assessed by the self-care, sensory ability, and mobility sub-scales of the Behavioural Assessment Scale of Later Life.
Study dates	Not provided. Study was submitted in 2012.
Study location	UK
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. The groups were in different residential care homes. • At the end of the trial, were all patients accounted for? No. Some data from patients is missing in the results table. • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Davison, T. E., Mccabe, M. P., Visser, S., Hudgson, C., Buchanan, G. and George, K. (2007). Controlled trial of dementia training with a peer support group for aged care staff. International Journal of Geriatric Psychiatry, 22, 868–873.**
Study type	Cluster randomised controlled trial.
Participants	Inclusion criteria: Senior staff in each facility selected residents with dementia and associated challenging behaviours to be included in the study. Exclusion criteria: None
Sample characteristics	N= 113 people living with dementia in residential care homes. n= 46 experimental intervention: staff training for challenging behaviours. n= 35 experimental intervention: staff training for challenging behaviours plus a peer support group.

Bibliographic reference	**Davison, T. E., Mccabe, M. P., Visser, S., Hudgson, C., Buchanan, G. and George, K. (2007). Controlled trial of dementia training with a peer support group for aged care staff. International Journal of Geriatric Psychiatry, 22, 868–873.**
	n= 32 comparator: usual care Baseline characteristics of each group were not provided.
Intervention	Dementia training program: Facilities received a dementia training program that consisted of eight sessions of 60–90 min duration, which was delivered using a combination of didactic and experiential learning. The training program focused on skills to use in caring for residents with dementia-related behaviours, and was delivered by experienced mental health clinicians. Peer support program: The aim of the peer support program was to facilitate informal group support, whereby staff members could discuss challenging behaviours, their subsequent emotional reactions and how to cope with work-related stress. The research team facilitated five peer support sessions.
Comparison	Usual care.
Outcome measures	Frequency of behaviours: The Cohen-Mansfield Agitation Inventory (CMAI). This was staff-rated. It is a measure of the frequency with which aged care residents manifest 29 agitated behaviours. It was recorded over a two week period.
Study dates	Not provided. Study was submitted in 2006.
Study location	Victoria, Australia.
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? No. The method of residential care home randomisation was not given. Senior staff in each facility selected the residents with dementia. • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Unclear. Participant baseline data was not given. • Aside from the experimental intervention, were the groups treated equally? Unclear. The groups were in different residential care homes. • At the end of the trial, were all patients accounted for? Unclear. Attrition rates of people living with dementia is not given. • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High. Senior staff in each facility selected the residents with dementia. Participant baseline data was not given. There was no blinding. The staff attrition rate in the training only group was 48%.

Bibliographic reference	Deudon, A. et al. (2009). Non-pharmacological management of behavioural symptoms in nursing homes. International Journal of Geriatric Psychiatry, 24, 1386–1395.
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: doctors were asked to select participants they considered suitable for inclusion in the study. Patients with a diagnosis of dementia according to the ICD 10 criteria, an MMSE score ≤24 and presenting at least one of the following BPSD at least once a week: opposition, denial of care, aberrant motor behaviour, agitation, delusions, hallucinations or screaming. Exclusion criteria: None
Sample characteristics	n= 242 people living with dementia in residential care homes. n= 144 experimental intervention: Residential care staff training for challenging behaviours. 77%=female; 23%=male; mean age (SD)= 86.5 years (7.6); mean MMSE (SD)= 9.2 (6.8) n= 98 comparator: usual care 79%=female; 21%=male; mean age (SD)= 86 years (6.7); mean MMSE (SD)= 12.1 (6)
Intervention	The training programme was conducted by two independent professionals with extensive experience of working with residents with dementia. In each nursing home the programme began with a 90-min teaching session on dementia, BPSD and the use of 'how to' instruction cards. There were four instructions cards, summarising practical advice on how to deal with BPSD. They were designed in order to be small and resistant enough to be easily carried by staff members. The first card gave general guidelines on what to do and what to avoid when faced with opposition, denial of care, aberrant motor activity, agitation, aggression, delusions, hallucinations or screaming. The second card explained how to act during the day to avoid or to decrease the emergence of BPSD, such as what to do at the patient's bed time or during meals. The other two cards provided recommendations on non-pharmacological interventions, giving examples and ideas for mini interventions designed to deal with individual instances of BPSD. The remainder of the training programme consisted of individual and interactive sessions in which trainers provided constructive feedback on how staff members dealt with BPSD. They also emphasised the importance of using the instruction cards in daily practice. The trainers were at each staff member's disposal, rather like a coach, for 2 h twice a week during the first month and then once a week during the second month, thus providing an opportunity for more personalised training, advice and feedback. The total training time was thus 24 hours. Follow-up was at 20 weeks.
Comparison	Usual care.
Outcome measures	Assessments were performed by four psychologists blind to the intervention condition and previously trained in the assessment tools. None of them participated in the staff training programme. Each psychologist visited the same nursing homes during the study. Data on residents were collected from nursing staff and they were asked not to talk about the intervention. Before assessments, the first step at baseline was to confirm screening data and to collect demographic, clinical and therapeutic information. For outcome measures, data were collected at week 20. Assessment tools were the Neuropsychiatric Inventory (NPI), the Cohen-Mansfield Agitation Inventory (CMAI) and

Bibliographic reference	Deudon, A. et al. (2009). Non-pharmacological management of behavioural symptoms in nursing homes. International Journal of Geriatric Psychiatry, 24, 1386–1395.
	an Observation Scale (OS). The NPI nursing home version is an interview-based instrument designed to elicit information from an informal caregiver to evaluate behavioural disturbances. The NPI evaluates 12 behavioural symptoms. NPI items were divided into four subgroups: Psychotic, Hyperactivity, Apathy and Affective subgroups. In the present study, targets were the Psychotic subgroup, including NPI items hallucinations and delusions, and the Hyperactivity subgroup, including NPI items agitation, euphoria, disinhibition, irritability and aberrant motor behaviour. The scores for each subgroup were the sum of the frequency x severity for each of the NPI items. The CMAI is an interview-based instrument designed to measure the frequency of 29 behaviours as observed by the care giver over the previous 2 weeks. In addition to the global score (range 0–203), it is also possible to consider four subscale scores: Physically aggressive behaviour (PA) (9 items), Physically non-aggressive behaviour (PNA) (13 items), Verbally aggressive behaviour (VA) (3 items) and verbally non-aggressive behaviour (VNA) (4 items). For the CMAI subscales, they considered mean scores in order to avoid items that were not evaluable. For each CMAI subscale, the score corresponded to the mean scores of the evaluable items divided by the theoretical total number of items. The OS is a scale derived from the Agitated Behaviour Mapping Instrument and was specifically developed for the study in order to assess behavioural disturbances directly through patient observation. The OS focuses predominantly on agitated behaviours. Clinical raters observed the patient for 3 min. The OS comprises 25 items describing positive BPSD, especially agitated behaviours (e.g. screaming, hitting, tearing things, making verbal sexual advances, biting): the higher the score, the more severe the patient's behavioural disturbance. For this scale the assessment was done at baseline and week 20.
Study dates	October 2007 to March 2008
Study location	France
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation was not given. • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. The groups were in different nursing homes. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Döpp C.M.E., Graff M.J.L., Teerenstra S., Olde Rikkert M.G.M., Nijhuis–van der Sanden M.W.G., Vernooij-Dassen M.J.F.J., (2015) Effectiveness of a training package for implementing a community-based occupational therapy program in dementia: a cluster randomized controlled trial. Clinical Rehabilitation, 29, 974-986.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Occupational therapy service units delivering outpatient dementia care were included in the study if they met the following inclusion criteria: • Availability of at least two occupational therapists who completed the standard postgraduate course prior to the start of the study. • Availability of one manager. • Availability of one physician who was able to recruit at least eight client–caregiver couples for participation in the study. People living with dementia and their carers were included if they met the following inclusion criteria: • The person living with dementia was diagnosed with mild or moderate dementia (MMSE 10–24). • The person living with dementia lived in the community. • The person living with dementia had an informal caregiver (relative or friend) that cared for or assisted the client at least twice a week. Exclusion criteria: The person living with dementia was diagnosed with depression and/or severe behavioural problems (as judged by the referring physician).
Sample characteristics	N= 33 people living with dementia and their carers. Living at home. n= 21 experimental intervention: occupational therapist interdisciplinary training 50%=female; 50%=male; mean age (SD)= 77.3 years (6.6); mean MMSE (SD)= 21 (4.1) n= 12 comparator: usual training 37%=female; 63%=male; mean age (SD)= 78.1 years (5.7); mean MMSE (SD)= 20.4 (4.5)
Intervention	Occupational therapists in the experimental group also completed the usual three-day postgraduate course prior to the study. In addition, service units received the interdisciplinary training package. This package was developed based on various implementation theories and the implementation barriers assessed prior to this study. The primary aim of the training for occupational therapists was to increase their adherence to the program. Training components targeting physicians focused on increasing the number of referrals to create the opportunity for occupational therapists to get more experienced with the program. Training components targeting managers aimed to increase the number of referrals and to improve appropriate support for occupational therapists in implementing 'community-based occupational therapy program for people with dementia and their caregiver' (COTiD) in clinical practice. Occupational therapists could opt to receive accreditation points for the Dutch professional quality registry. Therefore, the training package consisted of both obligatory and optional parts. For occupational therapists this

Bibliographic reference	**Döpp C.M.E., Graff M.J.L., Teerenstra S., Olde Rikkert M.G.M., Nijhuis–van der Sanden M.W.G., Vernooij-Dassen M.J.F.J., (2015) Effectiveness of a training package for implementing a community-based occupational therapy program in dementia: a cluster randomized controlled trial. Clinical Rehabilitation, 29, 974-986.**
	training package consisted of: (1) two additional training days providing knowledge on promoting COTiD and more in-depth knowledge on COTiD (obligatory); (2) five to seven coaching-on-the-job sessions led by a COTiD expert (role model) who was trained in using motivational interviewing (obligatory); (3) four regional network meetings (obligatory attendance at three meetings); (4) access to a discussion platform (optional); and (5) access to an electronic reporting system (optional). For physicians and managers the strategy consisted of four components: (1) access to an educational website including information on the evidence and content of the COTiD program and on referral and insurance options; (2) four newsletters reporting experiences of physicians, managers, and other professionals with COTiD; and (3) at least one phone call to address individual problems and/or questions of physicians and managers. For physicians and managers all interventions were optional. Couples were withdrawn from the study when the person living with dementia was permanently admitted to an institution.
Comparison	The usual three-day post-graduate course. Occupational therapists in the control group completed the usual three-day postgraduate course prior to the start of the study. This course consisted of lectures on the background and content of the COTiD program. In addition, communication skills were trained using role playing, and therapists needed to complete homework assignments including videotaping of the application of COTiD skills in clinical practice. Managers and physicians in the control group did not receive any training or information. Couples were withdrawn from the study when the person living with dementia was permanently admitted to an institution.
Outcome measures	The clinical state of the couples treated by the service units was assessed at baseline and 12 months after the start of the occupational therapy treatment. The daily functioning of the people living with dementia was assessed using the Assessment of Motor and Process Skills (AMPS) and the performance part of the Interview for Deterioration of Daily Activities in Dementia (IDDD). The Canadian Occupational Performance Measure (COPM) was used to assess the self-perceived performance in meaningful daily activities of both the person living with dementia and their caregiver. Quality of life was assessed for both the person living with dementia and their caregiver using the Dementia Quality of Life Instrument (DQOL). Finally, the Sense of Competence Questionnaire (SCQ) was used to assess the level of caregiver competence. All assessments were performed at the home of the person living with dementia.
Study dates	January 2009 to December 2011
Study location	The Netherlands
Comments	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	**Döpp C.M.E., Graff M.J.L., Teerenstra S., Olde Rikkert M.G.M., Nijhuis–van der Sanden M.W.G., Vernooij-Dassen M.J.F.J., (2015) Effectiveness of a training package for implementing a community-based occupational therapy program in dementia: a cluster randomized controlled trial. Clinical Rehabilitation, 29, 974-986.**
Risk of bias	• Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Unclear • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low. Although this was a small study, the findings at 6 months had more participants and the results were similar.

Bibliographic reference	**Finnema, E. et al. (2005). The effect of integrated emotion-oriented care versus usual care on elderly persons with dementia in the nursing home and on nursing assistants: a randomized clinical trial. International Journal of Geriatric Psychiatry, 20, 330–343.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria for residential care homes: Residential care homes in the Netherlands that had people living with dementia. Exclusion criteria for residential care homes: Of the 84 residential care homes that volunteered to take part, 26 were excluded for reasons such as: planned reconstruction of the building, care or management reorganisation, and already systematically using emotion-oriented approaches, such as validation. Inclusion criteria for participants: probable diagnosis dementia of the Alzheimer Type (DAT), combined DAT and vascular dementia, Dementia syndrome (NAO) or amnestic syndrome, age 65 or older, level of functioning needing assistance or care (intensive nursing excluded), and a minimum of one month institutionalization at baseline. All residents were diagnosed by the nursing home physicians and checked on the criteria of DSM-IV (American Psychiatric Association, 1994) for dementia syndrome by examination of their medical record (also to rule out physical and psychiatric causes of the cognitive impairments). Exclusion criteria for participants: None
Sample characteristics	N= 146 people living with dementia in residential care homes. n= 67 experimental intervention: integrated emotion-oriented care in combination with working according to the guidelines in the Model-Care plan. 81%=female; 19%=male; mean age (SD)= 83.8 years (5.3); GDS-score: mild 3%, moderate-moderately severe

Bibliographic reference	Finnema, E. et al. (2005). The effect of integrated emotion-oriented care versus usual care on elderly persons with dementia in the nursing home and on nursing assistants: a randomized clinical trial. International Journal of Geriatric Psychiatry, 20, 330–343.
	43%, severe-very severe 54%. n= 79 comparator: Usual care: Working in accordance with the guidelines of the Model-Care plan of the Dutch Association of Nursing Home Care. 81%=female; 19%=male; mean age (SD)= 83.6 years (5.8); GDS-score: mild 6%, moderate-moderately severe 51%, severe-very severe 43%.
Intervention	Offering integrated emotion-oriented care in combination with working according to the guidelines in the Model-Care plan. Model-care plan training course: The introductory course Model-Care plan took place in all of the participating nursing homes and consisted of two half-day periods. The course addressed various aspects of approaching one's work methodically, and drawing up individual care plans for each resident. In addition, agreements reached in the multidisciplinary consultation group were monitored. They attempted to stay as close as possible to the way of working already used on the wards. One staff member per unit was asked to become an adviser, whose main task was to stimulate the staff on the wards during the study period to work according to the principles of the Model-Care plan. In addition to the training course, the advisers received a minimum of three half days supervision on the work-floor by a nursing consultant, and they participated in three one-day network meetings. The advisers met to exchange experiences and information, and to receive support. The network meetings for advisers were continued during the course of the experimental period, and the nursing consultant came to the ward one half day per month to supervise the working according to the principles of the Model-Care plan. Implementation of integrated emotion-oriented care: In addition to training in and supervision of working according to the principles of the Model-Care plan, the experimental wards received training and supervision in the application of integrated emotion-oriented care over a period of nine months. The following training courses were offered: • Basic training emotion-oriented care for all staff members involved in the care. • Advanced course 'emotion-oriented care worker' for five staff members on each ward. • A training course 'adviser emotion-oriented care' for one staff member per ward. The basic training course emotion-oriented care was organized in the nursing homes and started immediately after the baseline measurement. The course took two days, and included an intermediary period of two weeks for homework. The basic course addressed the staff members' own experience, the phases of ego-experience of the demented residents, and the application of (non-)verbal empathic skills. Participants were asked to characterize several residents on the basis of an observation form and their life history. The basic course was attended by 230 nursing assistants and by professionals from the other disciplines, such as activity therapists, nursing home physicians and psychologists. They selected 75 staff members for the worker course (advanced course), which consisted of seven days spread over a period of seven to eight months. From each experimental ward the team leader or head of the ward, the psychologist and two or three nursing assistants participated in this training course. Central issues in this course

Bibliographic reference	**Finnema, E. et al. (2005). The effect of integrated emotion-oriented care versus usual care on elderly persons with dementia in the nursing home and on nursing assistants: a randomized clinical trial. International Journal of Geriatric Psychiatry, 20, 330–343.**
	were: the experiences of the residents, making a life history, being alert to how the past may affect the present, and acknowledgement of the resident's experiences. Fourteen staff members were selected for the adviser course. These were motivated, enthusiastic staff members with the skills to stimulate and coach colleagues in applying the integrated emotion-oriented care approach. This course consisted of ten days, spread over nine months. Prior to the experimental period, the consultants attended both the basic course and the worker course. During the experiment the trained advisers were responsible for the implementation of integrated emotion-oriented care on their ward. They also learned to organize and lead an emotion-oriented group for residents. A nursing adviser visited the wards four times for one day, to provide supervision on the application of the integrated emotion-oriented approach in the daily care, to train the empathic skills, to use the newly developed care forms, to give feedback about the participation in the multidisciplinary consultation group and the emotion-oriented group.
Comparison	Usual care: working in accordance with the guidelines of the Model-Care plan of the Dutch Association of Nursing Home Care.
Outcome measures	Measurements were taken at baseline and after 7 months. In their selection of effect variables, they started from the seven adaptive tasks of the Adaptation-coping model. Each of these tasks was operationalized by means of behavioural and/or mood variables. Subsequently they were measured by using existing measurement instruments, for example the Behaviour observation scale for Intramural Psychogeriatrics (BIP), the Cornell Scale for Depression in Dementia, the Cohen-Mansfield Agitation Inventory, the Geriatric Resident Goal Scale (GRGS) and the Philadelphia Geriatric Center Morale Scale (PGCMS).
Study dates	Not provided. This study was submitted in 2004.
Study location	The Netherlands
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Fossey, J. et al. (2006). Effect of enhanced psychosocial care on antipsychotic use in nursing home residents with severe dementia: cluster randomised trial. British Medical Journal, 332, 756–758.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria for residential care homes: Eligible homes were those registered to accept elderly mentally impaired people and with a minimum of 25% of residents with dementia who were taking neuroleptic drugs. Inclusion criteria for residents: people living with dementia. Exclusion criteria: None
Sample characteristics	N= 346 people living with dementia. Living in residential care homes. n= 176 experimental intervention: training and support intervention delivered to nursing home staff over 10 months, focusing on alternatives to drugs for the management of agitated behaviour in dementia. 35%=female; 65%=male; mean age (range)= 82 years (60-98); none, questionable or mild dementia= 15%, moderate dementia= 27%, severe dementia= 58% n= 170 comparator: usual care 49%=female; 61%=male; mean age (range)= 82 years (53-101); none, questionable or mild dementia= 23%, moderate dementia= 20%, severe dementia= 58%
Intervention	The package was delivered by a psychologist, occupational therapist, or nurse based in each of the three centres. These staff received training in the delivery of person centred care and skills development in training and supervision. They were supervised weekly over the study period by two of the researchers, both experienced in dementia care. The package involved a systemic consultation approach. This tackled “whole home” issues, such as environmental, care practice, and attitudinal factors. The clinicians started and supported the use of activities through didactic training, skills modelling, and supervision of groups and individual staff. Key elements in the programme involved initial skills training, behavioural management techniques, and ongoing training and support. Initial skills training for care staff involved the philosophy and application of person centred care, positive care planning, awareness of environmental design issues, the use of antecedent behaviour consequence models, development of individualised interventions, active listening and communication skills, reminiscence techniques, and involvement of family carers. Behavioural management techniques included training in the Cohen-Mansfield approach. Ongoing training and support included group supervision and further development of skills involving individual case supervision and supervision of issues requiring organisational change within the home.
Comparison	Usual care
Outcome measures	Measurements were recorded at baseline and at 12 months. Percentage of residents taking neuroleptics, mean dose in chlorpromazine equivalents, percentage of residents taking other psychotropics, percentage of residents who had at least once fall in the past 12 months, mean Cohen-Mansfield agitation inventory, percentage of patients who had at least one episode of aggression in the past 12 months, mean wellbeing (measured using dementia care mapping), percentage of residents spending some time asleep, and percentage of patients spending some time withdrawn.
Study dates	This information is not provided. Study was accepted in 2006.

Bibliographic reference	**Fossey, J. et al. (2006). Effect of enhanced psychosocial care on antipsychotic use in nursing home residents with severe dementia: cluster randomised trial. British Medical Journal, 332, 756–758.**
Study location	London, Newcastle and Oxford, UK.
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Huizing, A., Hamers, J., Gulpers, M. and Berger, M. (2006). Short-term effects of an educational intervention on physical restraint use: a cluster randomized trial. BMC Geriatrics, 6, 17.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Residents in psychogeriatric residential care homes. Diagnosed with dementia. Exclusion criteria: Residents suffering from Korsakov's disease and psychiatric diseases were excluded because these residents in general differ from other residents with dementia (e.g., in being younger and having better mobility) and live in special Korsakov's or psychiatric wards in the residential care homes.
Sample characteristics	N= 126 people living with dementia in residential care homes. n= 72 experimental intervention: residential care home nurse training regarding physical restraint use 73%=female; 27%=male; mean age (SD)= 81.8 years (7.7); MDS Cognitive performance scale (0-6, 4 is moderate impairment) (SD)= 4.4 (1.5) n= 54 comparator: usual care 69%=female; 31%=male; mean age (SD)= 82.7 years (6.6); MDS Cognitive performance scale (0-6, 4 is moderate impairment) (SD)= 3.3 (2.0)
Intervention	The intervention consisted of an educational programme combined with consultation with a nurse specialist. The educational programme developed was based on an educational programme of restraint use in Dutch hospitals and on advice of the Dutch Institute for Healthcare Improvement about the decision-making process concerning restraint use in care situations. The educational programme was designed to encourage nurses to embrace a philosophy of restraint-free care and be familiar with techniques of individualised care. The educational programme was taught by the nurse specialist

Bibliographic reference	Huizing, A., Hamers, J., Gulpers, M. and Berger, M. (2006). Short-term effects of an educational intervention on physical restraint use: a cluster randomized trial. BMC Geriatrics, 6, 17.
	and was carried out over a two-month period. Several subjects concerning physical restraints were discussed during five meetings each lasting for two hours, such as the decision-making process towards restraint use, the effects and consequences of restraint use, strategies to analyse risk behaviour of residents and alternatives for restraints. Nurses were also invited to discuss real-life cases during the educational meetings. The nurses could, therefore, combine practical experience with information from the educational programme. There are indications in the literature that interactive and personal educational meetings are more effective than passive education. Therefore, this educational programme consisted of small-scale meetings with an active learning environment for the nurses. The basic principle for selection of nurses for the educational programme was the inclusion of 'key figures' and the inclusion of nurses with different degrees of innovativeness (different types of 'adopters'). Seven nurses, about one third of the nurses per ward and including the charge nurse, from each experimental ward, were invited to attend the meetings. A total of 23 nurses were divided into three groups. Each group consisted of nurses from different wards and 1 charge nurse, in order to promote the exchange of knowledge and experiences between wards. A plenary session, lasting for one-and-a-half hours, was organized after the five educational meetings for all the nurses of the experimental wards to inform them about restraint use and restraint-free care. The consultation with the nurse specialist focused on supporting nurses in achieving restraint-free care and complying with the decision-making process concerning restraint use as defined in the Dutch guideline for restraint use in care situations. The nurse specialist was, therefore, available for consultation for 28 hours a week, visited the wards once a week, attended multidisciplinary meetings about residents and stimulated nurses to use alternatives for physical restraints, such as electronic devices. During the visits to the wards and the multidisciplinary meetings the nurse specialist evaluated the use of restraints in residents and discussed difficulties in achieving restraint-free care.
Comparison	Usual care
Outcome measures	Data was collected via observers and from questionnaires at baseline and 1 month post-intervention. Restraint use with psycho-geriatric nursing home residents was measured during observations. Restraint use was confirmed visually by independent, trained observers on four separate occasions during a 24-hour period for each measurement. The observers (two nurses, one occupational therapist and one member of management) were not told to the exact design of the study, the intervention and the division into experimental and control wards. All three shifts were included in the observations and the day of visit to each unit was randomized to discourage any artificial removal of restraints by staff. The restraint prevalence, intensity, types and multiple restraint use were determined. Restraint prevalence was defined as the percentage of residents observed restrained at any time during the 24-hour period. Restraint intensity indicated the number of times in four observations that a particular resident was restrained. Restraint types were also recorded in order to gain insight into the types of restraint used with residents. Any device with limitation on an individual's freedom of movement was regarded as a restraint. Examples of restraint types are chairs with tables, belts tied to a chair or bed, bilateral bed rails, sleep suits, special sheets (a fitted sheet including a coat that encloses a mattress), chairs with a board (a chair with chair legs fixed to a board), infrared systems, safe

Bibliographic reference	**Huizing, A., Hamers, J., Gulpers, M. and Berger, M. (2006). Short-term effects of an educational intervention on physical restraint use: a cluster randomized trial. BMC Geriatrics, 6, 17.**
	seats, and deep or overturned chairs. Multiple restraints indicated the number of different restraint types used per resident recorded during the four observations.
Study dates	November 2003 to June 2004
Study location	The Netherlands
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation was not given. • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Uncertain as to whether the use of restraints in the UK is similar to the use of restraints in the Netherlands. In addition, the staff in the residential care homes in this study were nurses rather than care staff. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Leone, E. et al. (2013). Management of apathy in nursing homes using a teaching program for care staff: the STIM-EHPAD study. International Journal of Geriatric Psychiatry, 28, 383–392.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: A diagnosis of dementia according to medical record information, MMSE <24, and presence of apathy according to the proposed diagnostic criteria for apathy in AD and other neuropsychiatric disease. Exclusion criteria: None.
Sample characteristics	N= 230 people living with dementia with apathy. Living in residential care homes. n= 119 experimental intervention: Residential care home staff education to manage apathy in older individuals with a diagnosis of dementia. 72%=female; 28%=male; mean age (SD)= 87.83 years (6.8); mean MMSE (SD)= 11 (6.7) n= 111 comparator: Usual care. 87%=female; 13%=male; mean age (SD)= 88.82 years (5.8); mean MMSE (SD)= 13.9 (5.4)
Intervention	Two psychologists conducted training with staff in the intervention group (IG). The first intervention consisted of a 2-hour training including a description of the study and a didactic session on AD and BPSD. The information provided

Bibliographic reference	Leone, E. et al. (2013). Management of apathy in nursing homes using a teaching program for care staff: the STIM-EHPAD study. International Journal of Geriatric Psychiatry, 28, 383–392.
	was summarised on two types of index cards. Card type 1 provided general guidelines or "Do's and Don'ts" when faced with apathy or depression. It also explained how staff could act to avoid or decrease the emergence of BPSDs especially in carrying out ADL. Card type 2 provided recommendations for nonpharmacological interventions. In the second stage of the intervention, NH staff received a weekly 4-hour training for a month. It consisted of suggested methods and practical advice on how to deal with apathy and depression. Two hours was devoted to techniques for dealing with deficits in ADL. This training aimed at teaching NH staff how to promote patients' autonomy and, thus, increase their sense of competence. Another 2 hours was spent on teaching those staff whose work is to engage patients in various structured activities how to structure these activities and to learn techniques and exercises that could help improve the three dimensions of apathy in their patients. Note the aim of the training program was to provide on-site, hands-on-advice to the caregivers on treating the NH residents. Psychologists attempted to integrate their teaching with the regular on-going functioning of the institutions. To insure that the psychologists were able to train and interact with the maximum number of caregivers, training sessions were offered at different times of the day and on different days (depending on the rotation of medical and paramedical staff).
Comparison	Residential care homes assigned to the reference group (RG) were informed that the purpose of the study was to regularly assess the frequency of BPSD recorded by independent raters. They were also requested to take care of the residents as usual with their standard practices and procedures (usual care: provision of medical care, ADL assistance, nonpharmacological intervention).
Outcome measures	At baseline and at week 17: Neuropsychiatric Inventory Nursing Home Version, Katz ADL Scale, Apathy Inventory Clinician version, Group Observation Scale, Individual Observation Scale. Nursing home staff completed the Katz ADL Scale to assess functional abilities and the 12 domains of the Neuropsychiatric Inventory–Nursing Home (NPI–NH) version to evaluate the residents' neuropsychiatric symptoms. NPI domains were divided into four subgroups: (a) psychotic = hallucinations and delusions; (b) hyperactive = agitation, euphoria, disinhibition, irritability, aberrant motor behaviour; (c) apathetic = apathy, eating abnormalities; and (d) affective = depression, anxiety. Eight independently trained research psychologists blinded to the resident's group assignment collected behavioural and functional measures at all residential care homes. Research team psychologists completed the following: (1) The Apathy Inventory–Clinician version (AI–C), designed to evaluate the three dimensions of apathy. Each dimension was rated from 0 (no clinical symptom) to 4 (severe clinical symptom). (2) A Group Observation Scale (GOS) specifically developed for the study to assess behavioural disturbance through direct observation of residents of a given NH during normal mealtimes. The GOS includes items describing initiative (21 items), interest (seven items) and emotion (seven items). The higher the score, the less severe the

Bibliographic reference	**Leone, E. et al. (2013). Management of apathy in nursing homes using a teaching program for care staff: the STIM-EHPAD study. International Journal of Geriatric Psychiatry, 28, 383–392.**
	residents' behavioural symptoms. (3) An Individual Observation Scale (IOS) specifically developed for the study to assess behavioural disturbance in a one-on-one interview. The IOS includes items covering initiative (15 items), interest (four items) and emotion (seven items). The psychologist determined whether each of the listed behaviours, such as smiling, saying or just responding to a goodbye, appeared "a little" (one to three times), "sometimes" (four to six times) or "often" (seven times or more). The higher the score, the less severe the resident's behavioural symptoms. The same scale was used for scoring the GOS and the IOS.
Study dates	Not provided. This study was published in 2013.
Study location	France
Comments **Risk of bias**	• Did the trial address a clearly focused issue? • Was the assignment of patients to treatment randomised? Uncertain. The method of randomisation was not given. • Were clinicians and investigators blinded? No. NPI and ADL were not blinded. Apathy Inventory Clinician version, Group Observation Scale and Individual Observation Scale were blinded. • Were the groups similar at the start of the trial? No • Aside from the experimental intervention, were the groups treated equally? Uncertain. Different residential care homes were used. • At the end of the trial, were all patients accounted for? Uncertain. The attrition rates for the intervention and control groups is not given separately. However, the attrition rate is mild at approximately 10%. • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Magai, C., Cohen, C. I. and Gomberg, D. (2002). Impact of training dementia caregivers in sensitivity to nonverbal emotion signals. International Psychogeriatrics, 14, 25–38.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Diagnosis of dementia Exclusion criteria: None
Sample characteristics	N= 68 people living with dementia in residential care homes. n= 41 experimental intervention: Residential care staff training in sensitivity to nonverbal emotion signals. 93%=female; 7%=male; mean age (SD)= 84.6 years (8.1); mean MMSE (SD)= 3.2 (4.5) n= 27 comparator: Usual care. 96%=female; 4%=male; mean age (SD)= 86.4 years (9.3); mean MMSE (SD)= 4.2 (5.3)

Bibliographic reference	Magai, C., Cohen, C. I. and Gomberg, D. (2002). Impact of training dementia caregivers in sensitivity to nonverbal emotion signals. International Psychogeriatrics, 14, 25–38.
Intervention	This group received training in nonverbal sensitivity. The training curriculum consisted of 10 one-hour lecture/experiential sessions scheduled over 2 weeks around issues of nonverbal communication and emotion expression. The 10 units covered the universal and culture-specific aspects of the basic emotions, selective perception of emotion, personal emotional triggers, facial, vocal, and bodily indicators of emotion, cues distinguishing the various emotions, practice with various media to improve ability to recognize emotion cues, a discussion of the deleterious effect of certain kinds of emotion communication, and training in emotion validation skills.
Comparison	No training control (usual care).
Outcome measures	Behavioural Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD): This consists of 25 items that include various types of delusions and hallucinations commonly found in dementia. In the present study the instrument was adapted for continuous ratings to improve its sensitivity. For each item on the BEHAVE, such as "'People are stealing things' delusion," the respondent indicated how often the behaviour had been observed over the last 3 weeks. The scale's values were as follows: 1 (not present), 2 (observed once a week), 3 (two or more times a week), 4 (once a day), 5 (two or more times a day), 6 (every hour), and 7 (several times an hour). The validity of the scale has been demonstrated for dementia patients at both early and later stages of the disease; it is particularly useful for rating disturbance in late-stage patients and in longitudinal studies of behavioural and psychological symptoms. Cohen-Mansfield Agitation Inventory (CMAI): This scale consists of 29 types of agitated behaviour that are rated on a 7-point scale of frequency ranging from resident never manifests the behaviour (1) to resident manifests behaviour several times an hour (7). Cornell Scale for Depression in Dementia (CDS): This 19-item instrument is designed to detect depression among persons with dementia, based on interview with patient and collaterals. Symptom items are rated as follows: 0 = absent; 1 = mild or intermittent; 2 = severe. Scores range from 0 to 38 (most depressed). The scale has good interrater reliability, internal consistency, and validity; moreover, it performs well in rating depressive symptomatology in dementia patients regardless of level of severity of cognitive impairment. Facial expressions of emotion during a semi-structured interview: Facial expressions were coded by coders trained in the MAX. The patient's facial expressive behaviour was observed during a semi-structured interview, the Adult Developmental Interview, which is designed to elicit affective responses from dementia patients. One researcher (the examiner) conducts the interview and two other researchers observe the facial behaviour; because facial behaviours are relatively infrequent, both the examiner and observers can record the responses. Items in the interview protocol include some of the following: Examiner calls the patient's name, introduces self, strokes the patient's hand, repositions the patient's hand, tests the grasp reflex, asks how the patient is feeling, whether there is any pain, inquiries about the patient's family, uses a mirror to reflect the patient's face to himself/herself, takes leave of the patient, returns, and leaves again. The patient's emotional behaviour is coded in real time by the examiner and two observers, all of whom are trained on the MAX system of Izard (1979). In the event that coders disagree on a code, it is resolved in favour of the two coders who agreed with one another.

Bibliographic reference	**Magai, C., Cohen, C. I. and Gomberg, D. (2002). Impact of training dementia caregivers in sensitivity to nonverbal emotion signals. International Psychogeriatrics, 14, 25–38.**
	Two scores were derived from the facial data, a positive affect score (frequency of joy expressions) and a negative affect score (frequency of contempt, disgust, fear, sadness, anger, and shame). Brief Symptom Inventory (BSI): This instrument consists of 53 items concerning depression, anxiety, and somatic symptoms.
Study dates	Not provided. This study was published in 2002.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation was not given. • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? No. There were major differences in baseline characteristics between the two study arms • Aside from the experimental intervention, were the groups treated equally? Unclear. This was a cluster randomised trial with a different residential care home for both groups. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**McCallion, P., Tosel, R. W., Lacey, D. and Banks, S. (1999). Educating nursing assistants to communicate more effectively with nursing home residents with dementia. The Gerontologist, 39, 546–558.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Diagnosis of at least moderate dementia and the presence of at least one problem behaviour. Exclusion criteria: None
Sample characteristics	N= 105 people living with moderate dementia and the presence of at least one problem behaviour. Living in residential care homes. n= 49 experimental intervention: Nursing Assistant Communication Skills Program (NACSP) 86%=female; 14%=male; mean age (SD)= 84.5 years (9.0); mean MMSE (SD)= 6.3 (6.6) n= 56 comparator: wait-list control 89%=female; 11%=male; mean age (SD)= 83.3 years (9.0); mean MMSE (SD)= 4.9 (6.0)
Intervention	Nursing Assistant Communication Skills Program (NACSP).—NACSP was offered on all three shifts to small groups of three to six nursing assistants at each of the two nursing homes. NACSP consisted of five 45-minute group

Bibliographic reference	McCallion, P., Tosel, R. W., Lacey, D. and Banks, S. (1999). Educating nursing assistants to communicate more effectively with nursing home residents with dementia. The Gerontologist, 39, 546–558.
	sessions and four 30-minute individual conferences. The group sessions were supplemented by individual conferences with NAs to permit more personalised training, practice, and feedback about skills taught in the group sessions. Also, individual make-up sessions were provided to NAs who, because of time conflicts, were unable to attend a specific group session. This ensured that all NAs received the same level of training in the intervention. NACSP was delivered by a master's level social worker (MSW) with experience in working with residents with dementia. Prior to beginning the training, the MSW was required to do some background reading. The MSW then participated in four half-day NACSP training sessions that included (a) education on the stages of dementia and on available resources designed to equip the leader to respond knowledgeably to questions raised by NAs; (b) a review of the verbal and nonverbal communication strategies that are effective with persons with moderate and severe dementia; (c) role playing and practice of these strategies; (d) instruction on developing and utilizing memory aids; and (e) approaches to training NAs, including agendas for individual and group instructional sessions, the design and use of overheads in group sessions, and techniques for conducting observations and providing constructive feedback. The four days of training relied on a leader manual, participant workbook, and a training videotape (all available from the corresponding author) adapted from previous studies. NACSP was designed to address four areas: (a) knowledge of dementia, (b) verbal and nonverbal communication, (c) memory aids, and (d) problem behaviours. Group Session 1.—After the rationale for NACSP was explained, the impact of normal age-related changes on communication and information regarding the progression of dementia were presented. Also presented were basic strategies to enhance communication with older persons such as ensuring that persons who use eyeglasses and hearing aids are wearing them, reducing background noise and other distractions, and ensuring that there is adequate lighting. The first group meeting also enabled NAs to share with each other and with the NACSP leader their experiences, frustrations, and suggestions for caring for residents with dementia. Individual Conference 1.—The NACSP leader spent approximately 30 minutes on the unit with each participating NA. The NACSP leader helped each NA identify barriers to good communication for each participating resident and the stage of dementia each was experiencing. Group Session 2.—In the second group session, NAs were taught techniques for more effective verbal and nonverbal communication with persons experiencing moderate and severe dementia. A portion of the session was spent discussing why techniques such as correcting, reorienting, ignoring, and attempting to engage in a rational conversation often do not work, and why they may actually increase agitation. Emphasis was placed on opening lines of communication by viewing the residents' behaviour as an attempt to communicate, recognizing the dementia-related communication deficits each resident is experiencing, and making maximum use of residents' remaining communication strengths. The remainder of the meeting was spent role playing and practicing nonverbal and verbal techniques for fostering supportive interactions with persons with dementia. Individual Conference 2.—The NACSP leader again spent approximately 30 minutes on the unit with each participating NA. The NACSP leader observed interactions between the NA and the residents assigned to her. The leader discussed her observations, helped the NA identify and understand verbal and nonverbal messages

Bibliographic reference	McCallion, P., Tosel, R. W., Lacey, D. and Banks, S. (1999). Educating nursing assistants to communicate more effectively with nursing home residents with dementia. The Gerontologist, 39, 546–558.
	conveyed by residents, and worked with her to implement the alternative verbal and nonverbal interaction strategies they had practiced in Group Session 2. Group Session 3.—In the third group session, NAs were introduced to memory aids such as labelling residents' possessions with the name of the possession, putting written and graphic signs on important locations in the unit like the bathroom and the dining room, and developing Memory Charts (MCs) for each resident. With the help of visiting family members, meaningful photographs and other items were identified, selected, and placed on a chart with a short statement in bold letters describing up to four persons, events, or topics that are most meaningful to the resident and likely to encourage continued communication. MC items may address facts that are important to the resident, information on conversation topics the resident likes or wants to talk about, and facts that the resident often gets confused. MCs are placed on large, laminated pieces of cardboard posted on residents' bedroom walls at heights that take into account whether residents are ambulatory or spend most of the day in a wheelchair. NAs are taught to use MCs consistently and frequently. During the third session, NAs practiced developing an MC. The NACSP leader encouraged NAs to role play use of the MC in accordance with the following guidelines: (a) the NA should point to the appropriate section of the MC when discussing the person, event, or topic to which it relates, even when the resident does not appear to understand the NA's words; (b) the NA should encourage the resident to point to the appropriate section of the MC when discussing the person, event, or topic to which it relates; and (c) the MC should be used as often as possible in interactions with the resident. Variations on the MC for visually impaired residents were also presented. Individual Conference 3.—The NACSP leader again spent about 30 minutes on the unit with each participating NA. The NACSP leader observed the NA using an MC with a resident according to the previously described guidelines. The NACSP leader then gave the NA feedback on the use of the MC, discussed successes and frustrations in using the MC, and offered advice and encouragement on developing MCs for other residents with dementia. Group Session 4.—The NACSP leader outlined a three-step communications-based approach to problem behaviours: (1) find and respond to the need, (2) find the memory, and (3) ensure safety. Strategies recommended to NAs to discover the nature of the need include (a) asking yes/no questions to narrow down what is agitating the resident; (b) interpreting resident's gestures and other nonverbal signs; (c) trying to look at the situation through the resident's eyes; and (d) recalling what caused similar incidents in the past. In regard to finding the memory, the NACSP leader explained that some experts believe that as residents with dementia reminisce more about their past they also revisit past conflicts and problems. This, in turn, can cause agitation. Strategies recommended to NAs for dealing with this include listening for familiar names and events and asking simple questions that encourage and assist residents to explain what is upsetting them. Strategies to ensure safety include staying calm, speaking in soothing tones and keeping all body language nonthreatening, distracting the resident with a favourite activity, and getting help if there is a danger of injury to the NA or to the resident. The three-step approach to problem behaviours was demonstrated for eight types of problem behaviours: (1) agitation; (2) wandering; (3) repetitive speech; (4) resistance to care; (5) hiding and hoarding items; (6) self-injury; (7) hitting, kicking, and biting; and (8) hallucinations, delusions, and paranoia. Individual Conference 4.—The ffiACSP leader spent approximately one hour with each NA at a time when problem

Bibliographic reference	McCallion, P., Tosel, R. W., Lacey, D. and Banks, S. (1999). Educating nursing assistants to communicate more effectively with nursing home residents with dementia. The Gerontologist, 39, 546–558.
	behaviours are likely to occur, for example, during mealtimes or when dressing a resident. The leader also discussed with NAs how they can modify the techniques they have learned as residents' dementia-related deterioration continues. Group Session 5.—The final session provided an opportunity to recognize each NA for the effort she put into learning the NACSP through the presentation of a certificate of completion. It was also a time for NAs to practice any techniques they are not yet comfortable with, and to reconsider what techniques might be most helpful for particular residents. The NACSP leader gave the NAs additional feedback on their implementation of communication, memory aid, and behaviour management approaches they learned in each of the sessions, discussed successes and frustrations in implementing the techniques, and offered further advice and encouragement. Follow-up Monitoring.—The NACSP trainer visited with each NA on each shift once a month for three months after the intervention ended. The trainer verified continued use of the NACSP techniques and gave implementation advice as needed.
Comparison	Wait-List Control (WC) Condition.—NAs in the WC group did not participate in any intervention-related activity. Wait-list NAs received all other in-services and training offered by the nursing homes during the 6-month period.
Outcome measures	Data were collected at baseline and at 6 months. The primary outcome measures for residents were signs and symptoms of depression and aggressive behaviours. However, data were also collected on disorientation, irritability, and withdrawal symptoms as well as physical restraint and psychotropic medication use, because these secondary measures could also have an impact on the quality of life of nursing home residents with dementia. Cornell Scale for Depression in Dementia (CSDD): The CSDD is a 19-item instrument that assesses signs and symptoms of depression in the following areas: (a) mood-related signs, (b) behavioural disturbance, (c) physical signs, (d) cyclic functions, and (e) ideational disturbance. The CSDD is clinician administered and uses information obtained from both the resident and the nursing home staff. Cohen-Mansfield Agitation Inventory (CMAI): The CMAI is a 30-item instrument that is used to measure agitated behaviour of elderly people. The 30 items encompass three broad categories of behaviour: aggressive behaviour, physically nonaggressive behaviour, and verbally agitated behaviour. The occurrence of behaviours for a previous 2-week period were rated by nurse managers on each shift on 7-point scales ranging from 1 = never to 7 = several times an hour. Multidimensional Observation Scale for Elderly Subjects (MOSES): Three subscales from the 24-item short form of the MOSES—disorientation, irritability, and withdrawal— were used in this study. Psychotropic Medication and Restraint Use: Data from the MDS+ were abstracted for (a) psychotropic drug use, that is, the number of days in the prior week resident received antipsychotic, antianxiety, or antidepressant medications, and (b) mechanical restraint use, that is, whether bedrails, trunk restraints, limb restraints, or a chair that prevents rising were used daily (2), less than daily (1), or not used (0). Because the participating nursing homes did not complete the MDS+ on a schedule that was consistent with the assessment periods for this study, the

Bibliographic reference	McCallion, P., Tosel, R. W., Lacey, D. and Banks, S. (1999). Educating nursing assistants to communicate more effectively with nursing home residents with dementia. The Gerontologist, 39, 546–558.
	relevant sections of the MDS+ were completed by nursing staff during each assessment period.
Study dates	Study dates were not provided. The study was submitted for publication in October 1998.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation is not given. • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. This was a cluster randomised controlled trial using different residential care homes. • At the end of the trial, were all patients accounted for? Unclear. Attrition of the people living with dementia was not discussed. • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	Pellfolk, T. J., Gustafson, Y., Bucht, G. and Karlsson, S. (2010). Effects of a restraint minimization program on staff knowledge, attitudes, and practice: a cluster randomized trial. Journal of the American Geriatrics Society, 58, 62–69.
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: People living with dementia in residential care homes. Exclusion criteria: None.
Sample characteristics	N= 353 people living with dementia in residential care homes. n= 128 to 149 for experimental intervention depending on outcome measured. 69%=female; 31%=male; mean age (SD)= 80.5 years (9.1); mean cognitive score (range 0-27) (SD) = 11.7 (7.5) n= 124 to 139 for comparator depending on outcome measured. 78%=female; 22%=male; mean age (SD)= 83.4 years (6.4); mean cognitive score (range 0-27) (SD) = 10.2 (7.3)
Intervention	The intervention consisted of an education program for nursing staff (registered nurses, licensed practical nurses, and nurse's aides) and was conducted for 6 months. The education program comprised six different themes, one for each month: Main Content of the Education Program by month: 1. Dementia: Different types of dementia, symptoms, diagnosis, and treatment

Bibliographic reference	**Pellfolk, T. J., Gustafson, Y., Bucht, G. and Karlsson, S. (2010). Effects of a restraint minimization program on staff knowledge, attitudes, and practice: a cluster randomized trial. Journal of the American Geriatrics Society, 58, 62–69.**
	2. Delirium in old people: Aetiology, prevention, diagnosis, and treatment of delirium 3. Falls and fall prevention: Precipitating and predisposing factors for falls and prevention 4. Use of physical restraints: Adverse effects of, alternatives to and legislation controlling the use of physical restraints 5. Caring for people with dementia: Aspects of interaction and communication between staff and residents 6. Complications in dementia: Continuation of fist theme and complications in dementia (e.g., depression and behavioural symptoms) Before the program started, one volunteer from each unit attended the whole education program compressed into 2 days of seminars. The remaining staff received their education in six 30-minute videotaped lectures. Three of the lectures also included a clinical vignette presented in writing, which could be used for group discussions. The content of the education program was based on previous research and the clinical experience of experts in geriatric medicine and nursing. The emphasis was on the importance of investigating the underlying causes of the symptoms instead of focusing on the symptoms alone. For example, if a resident has sustained a fall, the cause of the fall should be investigated instead of simply resorting to the use of physical restraints. The staff were encouraged to use physical restraints only as a last resort. Emphasis was also placed on the negative effects of and alternatives to the use of physical restraints and on legislation concerning their use. Each unit was responsible for making arrangements for staff to watch the lectures and for group discussions afterwards, if desired. The education program ran parallel with ordinary work at the units, with no further involvement by the researchers apart from distribution of the videotaped lectures and data collection.
Comparison	Usual care.
Outcome measures	Residents were assessed using the MDDAS, which measures, for example, motor and ADL function and behavioural and psychiatric symptoms and includes the Gottfries cognitive scale. The staff who knew the residents best and were most involved in their care performed the assessment based on observations made over the preceding 7 days. The items in the MDDAS have been found to have good inter- and intra-rater reliability. An ADL score ranging from 4 to 24 was calculated based on the resident's ability to manage hygiene, dressing, eating, and bladder and bowel control. A higher ADL score indicates that the resident is more independent in ADLs. The behavioural symptoms score and psychiatric symptoms score are based on 25 and 14 items, respectively, that are rated on a 3-point scale (35 daily, 15 some times per week, and 05 never). The indexes range from 0 to 75 and from 0 to 42, respectively, with higher scores indicating more symptoms. The internal consistency values (Cronbach alpha) of the scales in this sample were 0.79 for the behavioural index and 0.69 for the psychiatric index. Wandering behaviour, hitting others, and making aggressive threats were dichotomized into displaying the behaviour daily or on some occasions per week and not at all and were used separately in the analyses. The residents' cognitive levels were measured using a scale developed by Gottfries and Gottfries that comprises 27 items relating to the person's ability to orient herself or himself and ranges from 0 to 27, higher score indicating a

Bibliographic reference	**Pellfolk, T. J., Gustafson, Y., Bucht, G. and Karlsson, S. (2010). Effects of a restraint minimization program on staff knowledge, attitudes, and practice: a cluster randomized trial. Journal of the American Geriatrics Society, 58, 62–69.**
	higher cognitive level. A cutoff (24/27) on the Gottfries cognitive scale has been validated against the cut-off point of 24 out of 30 traditionally used in the Mini-Mental State Examination (MMSE), with a sensitivity of 90% and a specificity of 91%. The raw score and the cognitively impaired (score 0–24) variable are used in the analysis. Staff rated the residents' fall risks on a 100-mm visual analogue scale ranging from low risk (0) to high risk (100). Staff judgments of fall risk have been found to be as good a predictor of falls as more-objective measures. Staff registered every fall and the circumstances surrounding it on a special form throughout the study period, including 1 month before and after the intervention. The data on falls were supplemented with a survey of the unit's compulsory incident reports. The use of benzodiazepines and neuroleptics were dichotomized into having one or more and no ongoing treatments.
Study dates	Not provided. This study was published in 2010
Study location	Sweden
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? No • Can the results be applied to the local population? Unclear. Difficult to compare residential care homes in Sweden to the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Robison, J., Curry, L., Gruman, C., Porter, M., Henderson, C. R. J. and Pillemer, K. (2007). Partners in caregiving in a special care environment: cooperative communication between staff and families on dementia units. The Gerontologist, 47, 504–515.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Family members of people living with dementia in residential care homes. Exclusion criteria: None
Sample characteristics	N= 388 family members n= 169 experimental intervention: Intensive residential care staff and nurse training on effective communication,

Bibliographic reference	**Robison, J., Curry, L., Gruman, C., Porter, M., Henderson, C. R. J. and Pillemer, K. (2007). Partners in caregiving in a special care environment: cooperative communication between staff and families on dementia units. The Gerontologist, 47, 504–515.**
	empathy development, and conflict resolution. 63%=female; 37%=male; mean age (SD)= 56.9 years (11.4) n= 156 comparator: usual care 67%=female; 33%=male; mean age (SD)= 59 years (11.4)
Intervention	Researchers from the Cornell Gerontology Research Institute, the Foundation for Long Term Care, and the Center on Aging at the University of Connecticut Health Center developed a program to promote family and staff cooperation, called Partners in Caregiving. The PIC program fosters positive relationships between families and staff through intensive training on effective communication, empathy development, and conflict resolution. PIC trains both families and staff, and then it guides families, staff, and facility administrators in a collaborative examination of facility procedures and policies that have an impact on family–staff interactions. A randomized, controlled evaluation of the PIC program demonstrated improved attitudes for both groups, a reduced intention to quit for staff, and less family conflict with staff, specifically for families of residents with dementia. On the basis of the positive outcomes in the original PIC program for families of dementia residents, researchers adapted the PIC program for use on dementia special care units. Partners in Caregiving in the Special Care Unit Environment (PIC-SCU) draws heavily from the original program, utilizing the same structure and considerable overlap in curricular content. Program modifications in PIC-SCU include a new module on understanding behavioural symptoms as well as numerous case studies focused on residents with dementia. Like the original program, the PIC-SCU program has two primary sequential components. First, parallel training sessions are provided to both family and staff, designed to enhance communication techniques and develop conflict-resolution skills and empathy for the other group. Communication techniques focus on developing active listening skills and providing constructive feedback. The training includes a section on how cultural, racial, and other differences (e.g., socioeconomic status) can affect communication. Four primary training methods are used throughout the workshops: ‘‘mini-lectures,’’ case discussions, brainstorming sessions, and role plays. The program is detailed in a comprehensive training manual that contains directions for facilitating each of the sessions, descriptions of training activities, and master copies of handouts. The staff and family training sessions are between 4 and 5 hours in length. Finally, upon completion of the training, a meeting with families, staff, and nursing home administrators is held to set concrete goals for the unit and facility regarding procedures and policies that affect families. This 2-hour session brings staff and families together to discuss issues of concern with the facility administrators. The joint meeting is carefully structured and includes opportunities for sharing ideas, as well as prioritizing policy changes. **Components of Partners in Caregiving in a Special Care Environment Workshop:** A. Introduction to Partners in Caregiving (25 minutes): This introduces the theoretical background and goals of the program; it includes a brief warm-up introduction exercise for participants.

Bibliographic reference	**Robison, J., Curry, L., Gruman, C., Porter, M., Henderson, C. R. J. and Pillemer, K. (2007). Partners in caregiving in a special care environment: cooperative communication between staff and families on dementia units. The Gerontologist, 47, 504–515.**
	B. Dementia and Behavioural Symptoms (20 minutes): This gives basic information about dementia and how to approach behavioural symptoms that can be associated with it, with case examples from participants. C. Sharing Successful Family–Staff Communication (40 minutes): The group members participate in a brainstorming exercise in which they share concerns about communicating with the other group. A list of positive aspects of communication within the facility is also generated. D. Advanced Listening Skills (45 minutes): This is an interactive skill-building session in which participants learn active listening skills, feedback techniques, and how to avoid ‘‘communication blockers.’’ E. Saying What You Mean Clearly and Respectfully (30 Minutes): This explores the concept of ‘‘I-Messages,’’ using role-playing exercises to learn how to put them into practice. F. Cultural and Ethnic Differences (30 minutes): This introduces the concepts of cultural and ethnic diversity in the facility, with discussion of how it can affect good communication. G. Understanding Differences in Values (30 minutes): Participants explore differences in values of various groups in the nursing home (family, staff, administration, residents). Differences in values and their impact are discussed. H. Handling Blame, Criticism, and Conflict (45 Minutes): This provides a seven-step process for preventing and dealing with conflict with the other group. Techniques are practiced using role-play and case-study approaches. I. Planning a Joint Session for Families, Staff, and Administrators (15 minutes): Group members plan, organize, and develop an agenda for a joint meeting. Joint Session (1.5 to 2 hours): Both groups meet to share what they have learned and discuss their concerns with the administrator. A plan is developed for the groups to identify policy and procedural changes and address them as a team.
Comparison	Usual care
Outcome measures	Measurements were taken at baseline and at 6 months. The families responded to eight scales measuring their attitudes about staff and about their own well-being. The Interpersonal Conflict Scale asks how frequently the family member experiences arguments or conflicts with staff members over seven items such as laundry and administrative rules. The four response categories range from never to every day. On the Staff Provision to Residents Scale, families rate the care that the staff provides to their relatives by selecting never, rarely, sometimes, or almost always on three items. The Staff Behaviours Scale measures family perceptions of how often staff members provide them with news, encouragement, or suggestions using the same four answer choices as the previous scale. The Staff Empathy Scale asks families the degree to which they perceive staff as understanding, easy to talk to, or helpful (never, rarely, sometimes, almost always). A shortened version of the Nursing Home Hassles Scale assesses the frequency that families experienced seven negative staff behaviours, such as being rude or intolerant toward the resident (never, once in a while, often, or very often). The Family Involvement Scale asks families how often they engage in seven specific activities in the nursing home, from

Bibliographic reference	**Robison, J., Curry, L., Gruman, C., Porter, M., Henderson, C. R. J. and Pillemer, K. (2007). Partners in caregiving in a special care environment: cooperative communication between staff and families on dementia units. The Gerontologist, 47, 504–515.**
	providing direct care to attending social activities (never, 1 to 2 times a month, 3 to 4 times a month, 2 or more times a week, or almost every day). Research staff measured caregiver burden by using a shortened version of the Zarit Burden Interview with six items from the scale that relate to nursing home caregivers (never, rarely, sometimes, quite frequently, or nearly always). Families also responded to a seven-item version of the Center for Epidemiologic Studies–Depression (CES-D) scale. In addition, a single item assesses how easy it is for family members to talk to nursing staff (very difficult, somewhat difficult, somewhat easy, or very easy).
Study dates	Not provided. This study was published in 2007.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation was not given. • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all family members accounted for? Yes • Can the results be applied to the local population? Unclear. Residential care homes might be different to care homes in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Sloane, P. D. et al. (2004). Effect of person-centered showering and the towel bath on bathing-associated aggression, agitation, and discomfort in nursing home residents with dementia: a randomized, controlled trial. Journal of American Geriatric Society, 52, 1795–1894.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Aged 55 and older; receive assistance in bathing; have a diagnosis of Alzheimer's disease or a related dementia on the medical record; have moderate or severe cognitive impairment, as determined by an Minimum Data Set cognition score (MDS-COGS) of 5 or greater; demonstrate agitation or aggression during bathing; and be able to be showered. Exclusion criteria: dementia due to alcoholism, Huntington disease, or acquired immune deficiency syndrome; had a psychosis as a primary diagnosis; were anticipated to be discharged or to die within 6 months; or did not speak English.

Bibliographic reference	**Sloane, P. D. et al. (2004). Effect of person-centered showering and the towel bath on bathing-associated aggression, agitation, and discomfort in nursing home residents with dementia: a randomized, controlled trial. Journal of American Geriatric Society, 52, 1795–1894.**
Sample characteristics	N= 73 people living with dementia with agitation in residential care homes. n= 49 experimental intervention: shower group or towel bath group (there were two interventions) n= 24 towel bath intervention n= 25 shower intervention 74%=female; 26%=male; mean age (SD)= 86.0 years (8.6); mean MMSE (SD)= 2.2 (4.0) n= 24 comparator: usual care 96%=female; 4%=male; mean age (SD)= 86.9 years (6.1); mean MMSE (SD)= 2.1 (4.1)
Intervention	As operationalized in the study, person-centred bathing focused on resident comfort and preferences, viewed behavioural symptoms as expressions of unmet need, employed communication techniques appropriate for the resident's level of disease severity, applied problem-solving approaches to identify causes and potential solutions, and regulated the physical environment to maximize resident comfort. Person-centred showering sought to individualize the experience for the resident by using a wide variety of techniques, such as providing choices, covering with towels to maintain resident warmth, distracting attention (e.g., by providing food), using bathing products recommended by family and staff, using no-rinse soap, and modifying the shower spray. The towel bath is an in-bed method in which the caregiver uses two bath blankets, two bath towels, a no rinse soap, and 2 quarts of warm water; keeps the resident covered at all times; and cleanses the body using gentle massage. Training in person-centred bathing was included as a component of the towel-bath method. Further details on the principles used in the study interventions are available in the book Bathing Without a Battle. Showering (without person-centred training) was used as the control condition; this was done to standardize the conditions of observation and because showering is the predominant bathing method in nursing homes nationally. Recruited facilities were randomly assigned to three groups of five facilities each. One treatment group received the towel bath during the first 6-week intervention period and person-centred showering during the second intervention period. The other treatment group received the same interventions in the reverse order. A clinical nurse specialist or psychologist who worked alongside the CNAs 2 days a week for 4 weeks introduced the interventions (averaging approximately 8 hours per study subject per intervention). Training methods employed included short didactic training sessions, use of videotapes to identify behavioural symptoms and their antecedents, and hands-on supervision during subsequent baths to try out potential solutions. In the control facilities, consent and data collection occurred as in the treatment facilities, but no intervention took place; staff received training in person-centred bathing of study residents after all data collection in the facility had been completed.
Comparison	Usual care.
Outcome measures	The primary outcome measures were agitation, aggressive behaviours, and discomfort, coded by blinded raters from digitalized videotapes. Videotaping was conducted during the 2 weeks after completion of the intervention training; study research assistants who were otherwise uninvolved in the intervention conducted the videotaping.

Bibliographic reference	**Sloane, P. D. et al. (2004). Effect of person-centered showering and the towel bath on bathing-associated aggression, agitation, and discomfort in nursing home residents with dementia: a randomized, controlled trial. Journal of American Geriatric Society, 52, 1795–1894.**
	Undergraduate and graduate students who underwent intensive training and reliability studies before rating and who had periodic reliability spot-checks rated the videotaped baths. Each entire bath was rated, with bathing defined as starting when wetting or washing began and ending when drying was completed. Videotapes were presented to raters in random order, and the raters were blinded to the study aims, the assignment of subjects, and the pre- or post-intervention status of the tapes they rated. Secondary measures of effect included bath duration, bath completeness, skin condition, and skin microbial flora. Agitated and aggressive behaviours were evaluated using The Care Recipient Behaviour Assessment (CAREBA), a system for rating behavioural symptoms in real time that had been developed by the study's research team. The CAREBA coding system employs a modification of the definitions in the Cohen-Mansfield Agitation Inventory to rate individual behaviours. Ratings were conducted using an observational methods software package, The Observer Video-Pro, in which discrete behaviours were rated as events or states. The following variables were rated using the CAREBA: • overall agitation and aggression • physically aggressive behaviours: biting and attempted biting, hitting and attempted hitting, grabbing and attempted grabbing, kicking and attempted kicking, pushing, scratching, spitting, and throwing objects • nonaggressive physical agitation: resistiveness and attempts to exit during the bath • negative verbal events, including verbal aggression: complaints, threats, and swearing • verbal agitated states: weeping, crying, moaning, screaming, yelling, and unintelligible utterances that are obvious expressions of distress Resident discomfort during bathing was measured using a modification of the discomfort scale for dementia of the Alzheimer type. The scale contains six items (negative vocalization, content facial expression, sad facial expression, relaxed body language, tense body language, and fidgeting body language), each of which is rated on a 4-point scale.
Study dates	Not provided. This study was published in 2004.
Study location	USA
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation is not given. • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? No • Aside from the experimental intervention, were the groups treated equally? Unclear. Difficult to ascertain because different residential care homes were used.

Bibliographic reference	**Sloane, P. D. et al. (2004). Effect of person-centered showering and the towel bath on bathing-associated aggression, agitation, and discomfort in nursing home residents with dementia: a randomized, controlled trial. Journal of American Geriatric Society, 52, 1795–1894.**
	• At the end of the trial, were all patients accounted for? No. The numbers of patients who dropped out for each separate intervention arm are not given. • Can the results be applied to the local population? Unclear. Difficult to compare residential care homes in the USA to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Testad I., Aasland A.M., Aarsland D. (2005) The effect of staff training on the use of restraint in dementia: a single-blind randomised controlled trial. International Journal of Geriatric Psychiatry, 20, 587-590.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: People living with dementia in residential care homes. Exclusion criteria: None.
Sample characteristics	N= 142 people living with dementia. Living in residential care homes. n= 55 experimental intervention: staff training, including nurses, to reduce the use of physical restraints. 67%=female; 33%=male; mean age (SD)= 84.9 years (5.6); Clinical Dementia Rating (SD) = 2.0 (1.0) n= 87 comparator: usual care 72%=female; 28%=male; mean age (SD)= 84.0 years (6.3); Clinical Dementia Rating (SD) = 2.2 (0.9)
Intervention	The intervention consisted of two element received by staff and carried out over a seven-month period. First a six-hour seminar focusing on dementia, aggression, problem behaviour, decision making process and alternatives towards use of restraint was presented to the entire staff. The topics covered in the seminars were based on recent research and literature. A manual for the seminar was developed to ensure that the same topics were covered in all staff care groups. Then, each group was given guidance for one hour every month, for six months. Information on patients was systematically collected. Each patient was considered individually based on the topics in the seminar and an individual care plan based on the specific information on the patient made. The control group received treatment as usual.
Comparison	Usual care.
Outcome measures	The two main outcome measures were the Brief Agitation Rating Scale (BARS), and the frequency of use of restraints assessed by a standardised interview.
Study dates	Study dates were not provided. This study was published in 2005.
Study location	Norway

Bibliographic reference	**Testad I., Aasland A.M., Aarsland D. (2005) The effect of staff training on the use of restraint in dementia: a single-blind randomised controlled trial. International Journal of Geriatric Psychiatry, 20, 587-590.**
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation is not given. • Were clinicians and investigators blinded? No. Outcomes were measured by interviewing the staff. • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? No. Details of the numbers who dropped out for the intervention group and the control group are not given separately. • Can the results be applied to the local population? Unclear. The residential care homes in Norway might be different to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Very high

Bibliographic reference	**Testad, I., Ballard, C., Brønnick, K. and Aarsl, D. (2010). The effect of staff training on agitation and use of restraint in nursing home residents with dementia: a single-blind, randomized controlled trial. The Journal of Clinical Psychiatry, 71, 80–86.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Diagnosis of dementia. Exclusion criteria: None.
Sample characteristics	N= 90 people living with dementia in residential care homes. n= 44 experimental intervention: staff training, including nurses, 75%=female; 25%=male; mean age (SD)= 86.0 years (9); Functional Assessment Staging median (interquartile range) = 6 (1) n= 46 comparator: usual care 73%=female; 27%=male; mean age (SD)= 86.0 years (11.25); Functional Assessment Staging median (interquartile range) = 6 (3.25)
Intervention	Two-day educational seminar and monthly group guidance for 6 months. The aim is to reduce agitation and use of restraint. It involves lectures, written information (including a specifically developed manual), issuing treatment guidelines, feedback and peer support. The guidance group includes tools to implement and reinforce new skills. All staff were trained, regardless of whether they had a formal education. This included leaders and domestic staff.
Comparison	Usual care.

Bibliographic reference	**Testad, I., Ballard, C., Brønnick, K. and Aarsl, D. (2010). The effect of staff training on agitation and use of restraint in nursing home residents with dementia: a single-blind, randomized controlled trial. The Journal of Clinical Psychiatry, 71, 80–86.**
Outcome measures	These were measured at baseline and at 6 months follow-up (i.e. at the 12 month point because the programme lasted 6 months). Structural restraints. For example, locked doors, electronic surveillance and bed rails. Interactional restraints. For example, force or pressure in a medical examination or treatment. Agitation using the CMAI. Use of antipsychotics.
Study dates	2003 to 2004
Study location	Norway
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation was not given. • Were clinicians and investigators blinded? No. Outcomes were measured by interviewing the staff. • Were the groups similar at the start of the trial? No. At baseline, physical (structural) restraint use was 13% for the control group and 60% in the intervention group. The differences in antipsychotic drug use at baseline very different as well. • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. The residential care homes in Norway might be different to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Very high

Bibliographic reference	**Van De Ven, G. et al. (2013). Effects of dementia-care mapping on residents and staff of care homes: a pragmatic cluster-randomised controlled trial. PLoS One, 8, e67325.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Dementia diagnosed by an elderly-care physician according to the Diagnostic and statistical manual of mental disorders-IV criteria for dementia, approval of the elderly-care physician for inclusion, age of 65 years or more, at least one neuropsychiatric symptom (NPS), informed consent from the family of the resident, and the ability of the resident to use the common areas, such as the shared living room, for at least 4 hours a day.

Bibliographic reference	Van De Ven, G. et al. (2013). Effects of dementia-care mapping on residents and staff of care homes: a pragmatic cluster-randomised controlled trial. PLoS One, 8, e67325.
	Exclusion criteria: Residents with an estimated life expectancy of 6 weeks or less and those who were physically unable to spend time in common areas of the unit were not included in the study.
Sample characteristics	N= 192 people living with dementia in residential care homes. n= 73 experimental intervention: Nursing staff in residential care homes trained in dementia care mapping (DCM). 75%=female; 25%=male; mean age (SD)= 84.6 years (6.1); mean severity of dementia not provided. n= 119 comparator: Usual care. 74%=female; 26%=male; mean age (SD)= 83.5 years (6.6); mean severity of dementia not provided.
Intervention	The managers of the units of care homes allocated to the intervention selected staff members who were competent and interested in becoming certified dementia-care mappers. DCM Netherlands provided a guideline specifying the required competences. Ten staff members, two from each intervention care home, attended the basic and advanced training given by DCM Netherlands and became certified dementia-care mappers. Advanced users are able to observe, report, provide feedback to the staff, and instruct and support them in drawing up action plans. After the training, a member of DCM Netherlands and the researchers gave the intervention care homes a DCM organisational briefing day. After completing the DCM training and attending the organisational briefing day, the trained mappers were to carry out at least two DCM cycles. Each DCM cycle consists of observation, feedback, and action plans.
Comparison	The control group residents received usual care during the trial. They defined usual care as the continuation of daily care practices without implementation of DCM. The control care homes were offered the DCM training after the trial.
Outcome measures	The study outcome measures were assessed at the resident level. The primary outcome measure was agitation, assessed with the CMAI. This assessment instrument consists of 29 items about agitation and aggression and has been validated for use in care homes in the Netherlands. The CMAI measures the frequency (on a seven-point scale from never to several times an hour) of agitation during the preceding 2 weeks (total score range: 29–203). They also assessed NPSs and quality of life as secondary outcome measures. They assessed the neuropsychiatric symptoms (NPSs) with the Neuropsychiatric Inventory – Nursing Home (NPI-NH) version, a comprehensive assessment scale including the following symptoms: delusions, hallucinations, agitation, depression, anxiety, euphoria, apathy, disinhibition, irritability, aberrant motor behaviour, night-time disturbances, and eating change. The frequency (F) is rated on a four-point (1–4) Likert scale and the severity (S) is rated on and a three-point (1–3) Likert scale, yielding an F times S score. When a symptom is not present, the F and S scores are both zero. The F times S score thus contains information about prevalence, frequency, and severity (range: 0–12 for each symptom). They used the Global Deterioration Scale (GDS) to assess the severity of dementia. The residents' quality of life was measured with the Qualidem and the EuroQol 5D. The Qualidem includes 37 items and is a multidimensional scale specifically designed for institutionalised residents with dementia. The authors of the Qualidem state that, in case of severe dementia (GDS 7), 18 instead of 37 items can be applied. Therefore, patients in GDS 7 and those in GDS 1–6 are frequently analysed separately. They decided to use only the subscales that

Bibliographic reference	**Van De Ven, G. et al. (2013). Effects of dementia-care mapping on residents and staff of care homes: a pragmatic cluster-randomised controlled trial. PLoS One, 8, e67325.**
	were applicable to patients in all stages of dementia. Because not all items were applicable to patients with GDS 7, the maximum score would differ on some subscales for patients in GDS 7 and patients in GDS 1–6. Therefore, they determined the maximum scores for both groups with the applicable items, and converted the original scores into percentages of the maximum score (scale 0–100). This way, they could analyse the data for both groups together. Furthermore, they collected the following demo- graphic data at baseline: age, gender, marital status, and country of birth.
Study dates	October 2010 to April 2012.
Study location	Denmark
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? No • Were the groups similar at the start of the trial? Unclear. The mean severity of dementia for each group was not recorded. • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Uncertain as to how similar residential care homes in Denmark are to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**van Weert, J.C.M., van Dulmen, A.M., Spreeuwenberg, P.M.M., Ribbe, M.W., Bensing, J.M. Effects of snoezelen, integrated in 24 h dementia care, on nurse-patient communication during morning care. Patient Educ. Couns. 2005;58:312–326**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria for residential care homes: (1) the presence of two comparable units (one experimental ward and one control ward); (2) the willingness to create the conditions to implement snoezelen in the daily care of the experimental ward; (3) the promise to refraining from snoezelen training during the study period on the control ward; and (4) no substantial organisational changes (e.g., removal, reorganisation) during the study period. Inclusion criteria for residents: (1) moderate to severe dementia according to DSM-III-R, diagnosed by a physician; (2) moderate to severe nursing care dependency; (3) sense-organs completely or partially unimpaired; and (4) not

Bibliographic reference	van Weert, J.C.M., van Dulmen, A.M., Spreeuwenberg, P.M.M., Ribbe, M.W., Bensing, J.M. Effects of snoezelen, integrated in 24 h dementia care, on nurse-patient communication during morning care. Patient Educ. Couns. 2005;58:312–326
	bedridden. Exclusion criteria: (1) an additional psychiatric diagnosis; (2) bedridden.
Sample characteristics	N= 121 people living with dementia in residential care homes. n= 60 experimental intervention: Certified Nursing Assistants who had been trained to use snoezelen. 88%=female; 12%=male; mean age (SD)= 85.8360 years (6.1); mean memory impairment (BIB7; 0-21) (SD)= 13.41 (3.8) n= 61 comparator: usual care. 76%=female; 24%=male; mean age (SD)= 82.54 years (7.9); mean memory impairment (BIB7; 0-21) (SD)= 13.84 (3.9)
Intervention	Snoezelen, or Multi-Sensory Stimulation (MSS), is supposed to be an appropriate tool to communicate with severely demented persons, because there is no appeal to intellectual capabilities. Snoezelen in 24 hour dementia care combines a resident-oriented approach with stimulation of the senses by light, sound, feeling, smell and taste. It is a means of making contact and aims for pleasurable sensory experiences, tailored to the needs of demented elderly. The final goal is to increase or maintain the well-being of the demented person. Snoezelen was developed in the Netherlands, and quickly gained a significant following in Europe and later in America and Canada. It is a contraction of two Dutch words, the equivalent in English being 'sniffing and dozing'. In daily care, aspects of snoezelen are used at the bedside, in the bathroom and in the living room. The six experimental wards received the training 'snoezelen for caregivers' and implemented snoezelen in 24 hour care. The CNAs were trained in snoezelen by a qualified and experienced professional trainer of the Bernardus Expertise Center/Fontis. The training consisted of four, weekly, 4 hour in-service sessions and homework. The main objectives of training were to motivate team-members and to improve knowledge and practical skills. The underlying philosophy of snoezelen is compatible with developments in dementia care to 'person-centred' care, which aims to maintain personhood in the face of failing mental powers, by gaining knowledge of each individual and showing affective involvement. During the training, attention was paid to CNAs attitude towards verbal and non-verbal communication and the need for verbal and nonverbal attentiveness. With regard to communication, the training focused in particular on: • the development of CNAs awareness of the residents' physical, social and emotional needs (e.g., by paying attention to residents' verbal and nonverbal behaviours and learning how these can be interpreted), • making contact with demented residents and showing affection and empathy (e.g., by gazing, affective touch, smiling or showing verbal affection), • supporting demented residents in responsiveness (e.g., by waiting for a response), • avoiding to correct the residents' subjective reality (e.g., by validation), • avoiding the spread of useless cognitive information and testing the residents' remaining cognitive knowledge

Bibliographic reference	van Weert, J.C.M., van Dulmen, A.M., Spreeuwenberg, P.M.M., Ribbe, M.W., Bensing, J.M. Effects of snoezelen, integrated in 24 h dementia care, on nurse-patient communication during morning care. Patient Educ. Couns. 2005;58:312–326
	Furthermore, the training paid attention to practical skills needed for the application of multi-sensory stimulation, such as taking a life style history interview with family members, arranging a stimulus preference screening to find out which sensory stimuli the resident likes most and writing a snoezel care plan describing how to approach the resident and how to integrate multi-sensory stimuli in 24 hour care. An extensive manual of snoezelen was available with specific instructions, methodology observation forms, and examples on the integration of snoezelen in 24 hour care. In total, 59 CNAs and six head nurses attended the training program. During the 18-month implementation period, the caregivers were offered three in-house supervision meetings under the guidance of the same professional trainer. In addition, there were two general meetings, attended by three representatives of each nursing home (e.g., head nurses, care managers) to support the implementation of snoezelen at the organizational level. Details about the intervention have been described elsewhere.
Comparison	In the six control wards, usual care without snoezelen continued.
Outcome measures	Measurements were performed at baseline and after 18 months. The effectiveness of snoezelen was studied by video recordings of morning care. Morning care is given on every ward in every nursing home, and allows a nonbiased comparison between treatment and control groups: both groups deliver care on a one-to-one basis to the resident (individual attention with snoezelen versus individual attention without snoezelen) and they both have the same final objective (of getting the resident washed and dressed). Morning care is a suitable care moment to stimulate the senses (tactual, visual, auditory, olfactory) and to integrate elements of the snoezel methodology (e.g., nice smelling soap, soft towels). Video assessment of communicative behaviour during morning care was done by three independent observers, who were blinded as to whether the resident was included in the experimental or the control group, using the OBSERVER computer system. The assessors were trained and guidelines were followed to minimize observer bias and reactivity. Every video-recording was observed three times (twice to code nonverbal behaviour and once to code verbal behaviour). Indicators of nonverbal communication: nonverbal affective behaviours were selected that appeared to be particularly important for the establishment of the nurse–elderly relationship. The observation scheme contains the following indicators of rapport-building nonverbal communication: three nonverbal affective categories for CNAs (eye-contact, affective touch, smiling) and two nonverbal affective categories for residents (eye-contact, smiling). Eye-contact, affective touch and smiling convey involvement, closeness, friendliness and attentiveness. They are not necessary in performing nursing tasks, but do facilitate interaction between nurses and patients. In addition, instrumental touch was measured. Instrumental touch is inherent to nursing and does not play a role in building rapport, but has to be observed to distinguish it from affective touch. Indicators of verbal communication: Verbal nurse–patient communication was analysed using an adapted version of the Roter Interaction Analysis System (RIAS). The RIAS gives the opportunity to code both CNA and resident communication. The scheme uses verbal utterances as a unit of analysis. Each utterance, which is defined as the smallest distinguishable speech segment to which a coder can assign a classification, was allocated to one of 19

Bibliographic reference	van Weert, J.C.M., van Dulmen, A.M., Spreeuwenberg, P.M.M., Ribbe, M.W., Bensing, J.M. Effects of snoezelen, integrated in 24 h dementia care, on nurse-patient communication during morning care. Patient Educ. Couns. 2005;58:312–326
	categories, which are mutual exclusive. In the RIAS, a distinction is made between affective communication and instrumental communication, both essential in nursing care. Positive affective communication is needed to establish a trusting relationship between the CNA and the resident (e.g., social conversation that has no particular function in nursing activities, showing agreement and understanding). Instrumental communication includes communication that structures the encounter, stimulates autonomy and exchanges information. In addition, some study-specific adaptations were made to tailor the observation system to nurse–patient interaction in dementia care. Within the affective domain, 'negative affective communication' was distinguished, including disapproval and anger, which is expected to have a negative influence on the CNA-resident relationship instead of a positive. Furthermore, two sub-categories were specified within the cluster 'positive affective communication', because of their value within the concept of snoezelen. First, the category 'conversation about sensory stimulation', such as talking about the smell of soap or the colour of clothes. Second, the category 'validation' or 'emotion-oriented communication', meaning that the conversation is adapted to the (subjective) perceived reality of the resident, whether the resident is confused or not. Within the instrumental domain, the cluster 'negative instrumental communication' was distinguished, containing 'cognitive communication'. 'Cognitive communication' includes the provision of factual knowledge, which is useless in the context of the present situation, checking the residents' knowledge of facts or correcting verbal facts expressed by the resident. As snoezelen does not aim to make an appeal to the residents' intellectual capabilities, the active use of cognitive communication might confuse the resident and has to be avoided. We distinguished open and closed questions about factual knowledge, because closed questions are considered less confusing for dementia patients than open questions.
Study dates	The implementation period lasted 18 months per ward in the period between January 2001 and February 2003.
Study location	The Netherlands
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different locations were used. • At the end of the trial, were all patients accounted for? No. Half of the patients dropped out and were substituted by new patients. However, this may not be relevant to the intervention. • Can the results be applied to the local population? Unclear. Difficult to gauge the similarity of residential care homes in the Netherlands to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Moderate

Bibliographic reference	**Verkaik, R., Francke, A. L., Van Meijel, B., Spreeuwenberg, P. M., Ribbe, M. W. and Bensing, J. M. (2011). The effects of a nursing guideline on depression in psychogeriatric nursing home residents with dementia. International Journal of Geriatric Psychiatry, 26, 723–732.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: (1) Diagnosis of dementia (all types); (2) Severity of dementia from ‘‘age associated memory impairment’’ to ‘‘moderately severe dementia’’ (Global Deterioration Scale stages 2–6. (3) Diagnosed with depression in dementia according to the Provisional Diagnostic Criteria for depression of Alzheimer’s Disease (PDC-dAD). Because the diagnosis of dementia was established but not the type (see inclusion criterion 1), criterion B of the PDC-dAD ‘‘All criteria are met for dementia of the Alzheimer type’’ was not considered. Exclusion criteria: Residents with severe dementia (Global Deterioration Scale stage 7) were excluded from the study because the intervention was aimed at residents who were still able to verbally communicate.
Sample characteristics	N= 97 people with dementia with depression living in residential care homes n= 62 experimental intervention: Nurses trained to use a depression guideline for people living with dementia. 84%=female; 16%=male; mean age (SD)= 83.4 years (7.2); Mode Global Deterioration Scale = 5 n= 35 comparator: usual care 80%=female; 20%=male; mean age (SD)= 84.1 years (7.1); Mode Global Deterioration Scale = 6
Intervention	Nursing teams were trained in applying the depression guideline to their own residents diagnosed with depression in dementia. Content of the introduction of the nursing guideline on the wards: (1) Training and home work: At each participating ward the training was provided by one of three trainers of the Centre for Training and Expertise Osira/Bernardus from Amsterdam. Although the training was focused on CNAs, the nursing team manager and activity therapist were also invited to attend all three training sessions. This was considered important for sufficient support of the CNAs in using the guideline. The training consisted of: three hours of training in week 1 (first training session); home work in week 2 and 3; three hours of training in week 4 (second training session); home work in weeks 5 to 10; a three hour follow-up training in week 11 (follow-up training); First training session: Core elements of the first training session, in line with the key elements of the guideline, were (1) how to increase individualized pleasant activities, and (2) how to decrease unpleasant events. Additionally, attention was paid to recognition of comorbid depression in dementia and the importance of a person centred and systematic way of working. At the end of the first training session CNAs learned which of their current residents were diagnosed by the nursing home physician or psychologist with comorbid depression in dementia. During the training session, groups of three to five CNAs were formed around each diagnosed resident. In the following weeks each group had to develop a Pleasant-Activities-Plan for their resident.

Bibliographic reference	**Verkaik, R., Francke, A. L., Van Meijel, B., Spreeuwenberg, P. M., Ribbe, M. W. and Bensing, J. M. (2011). The effects of a nursing guideline on depression in psychogeriatric nursing home residents with dementia. International Journal of Geriatric Psychiatry, 26, 723–732.**
	Pleasant-Activities-Plans (homework): As a first step, data about the life history, personality and preferred and disliked activities were collected from the resident and his or her family. Also information was gathered about present depressive symptoms and the contexts in which these occur. Based on the collected information, the Pleasant-Activities-Plans had to contain written information on depression symptoms and the purposes, planning and evaluation of individualized and tailor-made pleasant activities. Activities in the plan could be conducted by CNAs themselves during regular care (e.g. play preferred music or make jokes during morning care) or during additional care (e.g. go outside into the garden). Activities could also be performed by activity therapists or relatives of the resident (e.g. take the resident to a riding school if he loves horses or to the local pub), but the CNAs are responsible for developing, facilitating and evaluating the activities. 2nd and follow-up training sessions: In the second training session the formulated Pleasant-Activities-Plans were discussed in the group. After the necessary adaptations were made, the plans were integrated into daily care and evaluated as described in the plan. In the follow-up training the experiences of the CNAs were discussed for each participating resident and plans were made for further introduction of the guideline onto the ward. (2) Promotion group: A “promotion group” consisting of the nursing team manager, activity therapist and two CNAs was installed, with a view to encouraging and supporting the team in following the guideline. This group could consult the trainer between weeks 1 and 11.
Comparison	Usual care
Outcome measures	Primary outcome: The primary outcome is depression severity. Instruments used to assess depression severity are the Cornell Scale for Depression in Dementia (Dutch version) and the Depression Rating Scale (DRS) of the Minimum Data Set (MDS) of the Resident Assessment Instrument (Dutch version). The Cornell scale contains nineteen depressive symptoms in five domains (Mood-related signs, Behavioural Disturbance, Physical Signs, Cyclic Functions, and Ideational Disturbance). Each item is rated on a scale from ‘‘absent,’’ ‘‘mild,’’ to ‘‘severe.’’ The DRS is an observational scale, based on seven items (negative statements, persistent anger, expressions of what seem to be unrealistic fears, repetitive health complaints, repetitive anxious complaints/concerns, sad/pained/worried facial expressions, crying/tearfulness) which are rated on a scale from ‘‘indicator not exhibited in last 30 days,’’ ‘‘indicator of this type exhibited up to 5 days a week,’’ to ‘‘indicator of this type exhibited daily or almost daily.’’ Secondary outcome: As secondary outcome to the severity of depression, the variable ‘‘mood’’ is assessed. Observed mood concerns the emotional consequences of depression and is assessed with the instrument FACE that was proved to be reliable in a severely demented and institutionalized population. FACE consists of three face diagrams with different mouth shapes. Mood is rated as if smile pre-dominates; if the expression is neutral; if frown pre-dominates. Scores range from 1 (happy) to 3 (sad). The Intraclass Correlation Coefficient (ICC) for the average FACE measures during morning care.
Study dates	November 2005 to May 2007

Bibliographic reference	**Verkaik, R., Francke, A. L., Van Meijel, B., Spreeuwenberg, P. M., Ribbe, M. W. and Bensing, J. M. (2011). The effects of a nursing guideline on depression in psychogeriatric nursing home residents with dementia. International Journal of Geriatric Psychiatry, 26, 723–732.**
Study location	The Netherlands
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Yes • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Unclear. Difficult to gauge the similarity of residential care homes in the Netherlands to those in the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

Bibliographic reference	**Visser, S. M., Mccabe, M. P., Hudgson, C., Buchanan, G., Davison, T. E. and George, K. (2008). Managing behavioural symptoms of dementia: effectiveness of staff education and peer support. Aging and Mental Health, 12, 47–55.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: Residents of a residential care home for people living with dementia. Exclusion criteria: None.
Sample characteristics	N= 76 people living with dementia in residential care homes. n= 21 experimental intervention: Staff from residential care homes received training on how to handle behavioural symptoms. 3 male, 18 female; mean age (SD)= 87.15 years (4.37) n= 23 experimental intervention: Staff from residential care homes received training on how to handle behavioural symptoms. They also received peer support. 4 male, 19 female; mean age (SD)= 87.64 years (7.67) n= 32 comparator: usual care 8 male, 24 female; mean age (SD)= 83.13 years (6.99) Mean MMSEs etc. were not provided.
Intervention	The Directors of Nursing (DON) from three residential care facilities were approached by a member of the Aged

Bibliographic reference	Visser, S. M., Mccabe, M. P., Hudgson, C., Buchanan, G., Davison, T. E. and George, K. (2008). Managing behavioural symptoms of dementia: effectiveness of staff education and peer support. Aging and Mental Health, 12, 47–55.
	Persons Mental Health Service (Victoria, Australia) and were given the opportunity to participate in the study. All three facilities approached agreed to participate, and they were randomly allocated to one of three groups (wait-list control, education-only, and education and peer support). Randomisation could not occur at the individual level (staff or residents) because of possible treatment effects if the same facility functioned as both intervention and control sites. Staff members involved in the study voluntarily agree to participate (this occurred after the facilities were randomly allocated to a group). The DON was asked to select residents who may be appropriate for involvement in the study, because they regularly displayed at least one of the 29 behaviours listed in the CMAI. Plain language statements and consent forms were provided to the DON, who forwarded them to prospective participants' next of kin. Consent among residents' next of kin was approximately 50% across each facility. The participation of staff members was voluntary and no payments or inducements were offered for participation in the study. Staff members from each of the three groups completed the SAQ and MBI at pre-intervention, post-intervention and at 3- and 6-month follow-up. Each staff member also selected one resident they were familiar with to complete the ADRQL, and two residents for the CMAI. Staff members assigned to an intervention group participated in education and/or peer support in the eight weeks between pre- and post-intervention measures. Education programme: The education programme consisted of eight units that were run twice a week for 1–1½ hours. Staff members who agreed to participate in the study were requested to attend one of the units each week. The first three units were primarily didactic and were designed to provide staff with information about dementia and behavioural symptoms. The following five units were facilitated workshops that were based on the behavioural model. During the workshops staff members developed individualised care plans for residents by monitoring the antecedents and consequences of behaviour and modifying them appropriately. Staff members engaged in group discussion and used specially designed worksheets to facilitate this process. One of the strengths of the behavioural model is that it has the potential to help staff to develop skills and knowledge that can be applied to a variety of situations and behaviours. Therefore, the workshops were designed to reflect this by encouraging staff members to develop their own strategies for managing behaviours, as well as the opportunity to implement their skills during the education programme, and to develop strategies to continue using once the training ceased. Peer support: The peer support programme was run for 30 minutes after the education units, starting at unit five (i.e. for four weeks). The group was facilitated by a member of the research team but aimed to address the concerns of staff members (e.g. work-related stressors). The sessions involved developing group aims and guidelines, provision of information and discussion about recognising and managing stress, and examination of issues affecting the resident care and how these issues can be better managed by staff members. Staff members were given the option of continuing the peer support programme on their own after the intervention was complete. However, staff felt they lacked the time and resources to continue with the peer support programme unassisted.

Bibliographic reference	**Visser, S. M., Mccabe, M. P., Hudgson, C., Buchanan, G., Davison, T. E. and George, K. (2008). Managing behavioural symptoms of dementia: effectiveness of staff education and peer support. Aging and Mental Health, 12, 47–55.**
Comparison	Usual care
Outcome measures	Cohen-Mansfield Agitation Inventory: The Cohen-Mansfield Agitation Inventory (CMAI) is a caregiver-rated scale that can be used to assess behaviours among nursing-home and community residing older people. The scale measures the frequency of 29 behaviours (e.g. screaming) as observed by the caregiver over the previous two weeks. Responses are rated on a seven-point likert scale from 1 (never) to 7 (several times a day). Scores can be calculated according to four subscales: Physically Aggressive (PA) behaviour, Physically Non-Aggressive (PNA) behaviour, Verbally Aggressive (VA) behaviour and Verbally Non- aggressive (VNA) behaviour. Alzheimer Disease Related Quality of Life: (ADRQL) scale is a instrument designed to assess health-related quality of life among people with Alzheimer's disease. The ADRQL consists of 47 items that are answered by carers responding with 'agree' or 'disagree' for each of the items, according to how the resident has behaved over the previous two weeks, as observed by staff members. The higher the score the better. The ADRQL assesses quality of life across five domains: Social Interaction (SI), Awareness of Self (AS), Feeling and Mood (FM), Enjoyment of Activities (EA) and Response to Surroundings (RS). The ADRQL is intended to be administered in an individual interview format. However, due to the number of staff participants involved in this study, it was not feasible to interview each staff member individually. Staff members individually completed the ADRQL for a single resident. The researcher was available to provide staff with guidance about how to correctly complete the questionnaire.
Study dates	Not provided. This study was submitted in 2006.
Study location	Australia
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method of randomisation was not given. • Were clinicians and investigators blinded? No. Staff recorded outcomes. • Were the groups similar at the start of the trial? Unclear. There are some differences. This could be due to the relatively small number of participants. • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? Unclear. The attrition rate of residents is not given. • Can the results be applied to the local population? Unclear. It is difficult to compare residential care homes in Australia to the UK. • Were all clinically relevant outcomes reported? Yes Overall risk of bias: High

Bibliographic reference	**Wenborn, J. et al. (2013). Providing activity for people with dementia in care homes: a cluster randomised controlled trial. International Journal of Geriatric Psychiatry, 28, 1296–1304.**
Study type	Cluster randomised controlled trial
Participants	Inclusion criteria: 60 years or older, have lived in the care home for at least 2 months and be intending to stay, meet the DSM-IV criteria for dementia and score less than 25 on the Mini Mental Status Examination. Exclusion criteria: Residents were excluded if they had other serious physical/mental health problems.
Sample characteristics	N= 159 n= 79 experimental intervention: Residential care staff training in activity provision. 64%=female; 36%=male; mean age (SD)= 84.2 years (7.6); mean MMSE (SD)= 30.3 (5.9) n= 80 comparator: usual care 71%=female; 29%=male; mean age (SD)= 84.2 years (7.6); mean MMSE (SD)= 32.2 (5.8)
Intervention	The intervention consisted of the following: • Assessment of the care home physical environment: This included making recommendations as to how it may be adapted and enhanced to enable residents' engagement in activity. • Education programme: Based on the principles of experiential learning, it aimed to enhance staff knowledge, attitude and skill. A range of techniques were utilised during the sessions including didactic teaching, group discussions and practical exercises. The programme was provided to the staff participant group and comprised the following: ○ Five 2 hours education sessions covering getting to know a resident's interests and abilities; identifying, planning and carrying out activities; and reviewing and recording the outcomes. The care home manager joined the fifth session to agree an Activity Action Plan for continued implementation of the programme. Progress with this was reviewed at two follow-up sessions. ○ Staff completed work-based learning tasks in between the sessions, with two residents each, to put the new knowledge and tools into practice. Tasks included compiling the resident's life story to identify personally meaningful activities and completing the Pool Activity Level Checklist to identify the individual's level of ability to engage in activity. This information enabled personally meaningful activities to be planned and provided at an appropriate level to each resident participant. Feedback and reflection on completing the tasks was shared at the beginning of the following group session, and potential strategies to improve implementation discussed. ○ The one-to-one coaching sessions enabled skill acquisition through practical implementation of activities previously demonstrated in the sessions and role modelling through observation of the researcher interacting and providing activities to individual residents. This combination of activities was aimed at increasing staff skills and changing their attitudes as they came to know residents more as individuals and recognise their potential to engage, regardless of the severity of dementia experienced. A workbook containing the sessions' content and tools was provided to enable the work-based learning tasks to be completed. A Trainers Manual outlined the programme content and delivery. The researcher provided the 16-week

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	programme to the eight intervention homes. The eight control homes continued to provide usual care with no limitation on training or introducing new activity provision and were offered an abbreviated intervention once data collection was complete.
Comparison	Usual care
Outcome measures	Quality of Life in Alzheimer's Disease - Patient and Caregiver Report (QOL-AD) (primary outcome): This is a self-rated and caregiver-rated scale of 13 items covering physical and mental health, relationships, finances and overall life quality. Higher scores reflect higher quality of life. Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale (CAPE-BRS): This assesses behaviour and functional ability, rated through observation and interviewing informant with higher scores indicating higher dependency. Challenging Behaviour Scale (CBS): This is a caregiver-rated, 25-item checklist that identifies the incidence, frequency and severity of behaviours that care home staff find difficult to manage. Higher scores indicate higher levels of challenging behaviour. Cornell Scale for Depression in Dementia: This is a 19-item scale that assesses depression in older people with dementia on the basis of self and caregiver reports and rater observation. A score of 8 or more indicates depression. Rating Anxiety in Dementia: This is a scale that assesses anxiety in people with dementia on the basis of self and caregiver reports, case notes and rater observation. Scores of 11 and above indicate clinical anxiety. Total number of medications.
Study dates	Not provided. This study was submitted in 2012
Study location	UK
Comments **Risk of bias**	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatment randomised? Unclear. The method or randomisation is not given. • Were clinicians and investigators blinded? Yes • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear. Different residential care homes were used. • At the end of the trial, were all patients accounted for? Yes • Can the results be applied to the local population? Yes • Were all clinically relevant outcomes reported? Yes Overall risk of bias: Low

E.13 Needs of younger people living with dementia

E.13.1 The specific needs of younger people living with dementia

Review question

- What are the specific needs of younger people living with dementia?

Full citation	Chaplin R, and Davidson I (2016) What are the experiences of people with dementia in employment?. Dementia 15, 147-61
Study details	Country/ies where the study was carried out: UK Study type: interviews Aim of the study: to focus on the experiences of people developing a dementia while still in employment in the UK Study dates: not provided Source of funding: a National Institute of Health Research grant
Participants	• Sample size: 5 younger people living with dementia • Inclusion criteria: Diagnosed with a dementia and under the care of a Consultant Psychiatrist, currently in employment or having left employment in the last 12 months, able to give informed consent to take part. • Exclusion criteria: none • Sample characteristics: mean age 64.6 years (range 60 to 74). Mean MMSE 26.5 (range 25 to 28)
Methods	Interviews
Thematic analysis	• Theme 1: PWD: An awareness of changes in their functioning in the work place as they developed dementia. For three participants, the Engineer, the Businessman and the Schools Meals Assistant, the first signs were poor short-term memory and a difficulty in remembering names and adjusting to new tasks. ○ Finding 1: The School Meals Assistant (58 years old) said: “They went on computers and I found I couldn’t keep up with it, I got all mithered, everything seemed confused to me and I couldn’t understand why.” ○ Finding 2: For the HGV Driver (60 years old) the first and only difficulty he was aware of was a word finding problem: “It was one particular place really that I could never remember the name of even though I was there, I spent six hours getting there but I couldn’t remember the name of it…” • Theme 2: PWD: A reluctance to acknowledge the signs. All of the participants described how they did not initially think that these difficulties in specific areas of functioning were the first signs of something more serious. At this stage, they tended to ascribe the changes to pressure of work, new work roles, life-long traits, such as poor memory or declining physical skills such as poor eyesight. ○ Finding 1: The Businessman (71 years old), for whom English is a second language, described how his firm had been through a big expansion over the last few years and that he thought that this had contributed to his poor health: “It was very interesting to see, unfortunately I overlooked one item, I wasn’t anymore 25, consequently it had a very detrimental effect on my health, it came to breakdown.”

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- Finding 2: The participant who was a Nursing Assistant (60 years old) initially put his visuospatial problems down to poor eyesight but then noticed other changes: “All through my life I had been a good speller and I even got to the point one day that I spelled my own name wrong and at that point I did become concerned.”

- Theme 3: PWD: Sharing the fears. They then began to suspect it was something more serious and all discussed their difficulties with their partners and were encouraged to seek further help.
  - Finding 1: The School Meals Assistant (58 years old) confided in her partner about the difficulties she was having in using the new computer system: “He thought it was just the computers that I’d not been used to and put it down to that but then I could tell, I wasn’t feeling right.”
  - Finding 2: The Businessman (71 years old) described how he had tried to dismiss his wife’s concerns and how: “One day she lost her patience and consequently she wanted a little bit more… you must remember this you must remember that you asked me three times and slowly sinks in something is wrong.”
  - Finding 3: At this stage, only one of the participants openly discussed their difficulties with their manager, the rest preferring to try to manage their difficulties themselves. The Nursing Assistant (60 years old) went to the Sister on his ward: “I did at one point realise that I had put a gentleman’s pyjama top on inside out and that to me was a siren to say this is not good enough and very quickly after that, after talking to the Ward Sister, we went together to Occupational Health.”
- Theme 4: PWD: Self-management. Three of the participants were able to discuss strategies for managing the symptoms of their illness in the workplace. They all spent more time and effort in planning and organising tasks and acknowledged how difficult it could be even with these strategies in place.
  - Finding 1: The Nursing Assistant would spend more time preparing his trolley for patient care duties: “…when I was going to a patient I knew who I was going to, what I was going to do and had everything set up not to leave that patient again until that work was complete.”
  - Finding 2: For the Businessman, his wife, who is also a part owner of the company, started to come into work more to assist him in the tasks he was struggling with: “It was quite convenient for me that Sylvia has an excellent memory, birthdays anything like that and when we went to meetings she would whisper the name of the person particularly if it is someone who is a client of the company.” He would also spend more time planning for meetings.
  - Finding 3: The Engineer (74 years old) said: “Well I write it down, use my diary and I have files of things, I don’t remember what I’ve got so I keep looking through things but I get there in the end.”
- Theme 5: PWD: Feeling under scrutiny. The three participants who worked more closely with others described how their managers or colleagues had noticed that they were having difficulties in some tasks. They mainly tried to manage this by increased observation of the employee but did not discuss this with the employee. Consequently, the participants felt that they were being watched covertly and they would have preferred to have been consulted about this.
  - Finding 1: The Nursing Assistant described how he was taken off ‘main duties’ on the ward such as supervising medication, putting in cannulas and writing in notes and was assigned to work in a pair with another nursing assistant. While he agreed that this was a reasonable adjustment to make to his duties, the way in which it was covertly done had a negative effect on his performance: “What Sister had actually done was to get one or two people to observe me when I didn’t know. Well let’s put it this way, I did know I was being observed some of the time and I did become apprehensive when I knew people were watching me.”
  - Finding 2: For the School Meals Assistant who could not use the new computer system, another member of staff was put by her side to

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do that part of the job for her. She was aware of some resentment from colleagues who she thought put it down to her being lazy: "Some of them was funny at first but I think it was because they didn't think I was pulling my weight, which I was, I just wasn't doing it right." She would have preferred for the reasons for this assistance to be discussed openly with her and her colleagues so that they knew that her difficulties were genuine.

- Finding 3: In the case of the Businessman, though he did not have a management structure above him to scrutinize his abilities, he was very aware that his son was moving to take more control of the business and that he needed this help: "I felt I had no choice, any decision I felt I was going to make, and the chances of them being wrong decisions well in my opinion up to 70% if not 80%."

- Theme 6: PWD: A lack of consultation about management decisions. Though two of the participants were given some adjusted duties when their employers became aware that they were having difficulties, none of the participants said that they were offered any 'reasonable adjustments' to their work role under the Equality Act (2010) after diagnosis. None of the participants were referred to a Disability Employment Advisor by their workplace. The HGV Driver and the School Meals Assistant were advised to take sickness leave when their employers became aware of the extent of their difficulties at work. They were advised to seek further assessment of their difficulties from their GP. Both of their GP's did make referrals on, one to a Neurologist and one to a Psychiatrist. Both these participants were then on sickness leave for the full six months and never returned to work.
  - Finding 1: The Nursing Assistant stayed in work with slightly adjusted duties until he was given his diagnosis a few weeks later by a Neurologist. He was then summoned to a meeting with Occupational Health and his Ward Sister. This meeting was held on the ward he worked on and his employment was terminated at once: "I feel the situation was taken behind closed doors and I don't believe that there were people around those closed doors, it was a case of yes he's got it and we're not prepared to even look for anything."
- Theme 7: PWD: A belief in continued competence despite the realisation of impairment. Three of the participants felt that they would have been able to carry on with an adjusted work role when they were diagnosed with dementia, while the School meals Assistant and the Businessman believed that they were no longer competent.
  - Finding 1: For the Nursing Assistant, though he was able to acknowledge that he had some difficulties in direct nursing tasks with patients, he felt that he retained many valuable skills on the ward: "I ended up as being a well-known person at being able to get someone down from that level of wanting to punch you to sitting down for a cup of tea. I could still do that."
  - Finding 2: The HGV Driver continued to feel that he was a competent driver and there was no evidence that his word finding problem affected his ability to drive. He was frustrated by the fact that his employers had asked Driver and Vehicle Licensing Agency (DVLA) to remove his licence without giving him the opportunity to have a Driving Safety Test at his Regional Driving Centre: "I'd love to drive to get my HGV back, I know I can still drive 'cos I feel like something like that, I've been doing it for 36 years it's instilled into you."
  - Finding 3: The Engineer described how he did his first lecture after the onset of his illness: "The lecture was about the tsunami and in terms of what is going on with me now, the interesting thing was many of my slides were pictures, there were no words on it, the words had to come from here and I had absolutely no problems at all."
- Theme 8: PWD: Feeling abandoned by the workplace and consequent feelings of resentment towards the workplace. Three of the participants expressed feelings of abandonment in how their employment situation was managed by their workplace. They felt that when they received their diagnosis and informed their workplace, no real attempt was made to find any adjusted work role for them. None of the participants was a member of a Trade Union and they did not have any formal representation at their meetings with Human Resource Departments. The two participants who went onto sickness leave for six months both said that they were rarely contacted by their work place or Human Resources and they were not warned when their sickness pay was ending. Both experienced financial hardship when this

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happened. In addition, none of them was given the opportunity to go back to the workplace to say goodbye to their colleagues when there employment was eventually terminated and they expressed regret about this. They all felt that there was no real will in the workplace to find a more suitable role or acknowledge their remaining skills. The two participants who went on extended sickness leave were not invited to meet with Human Resources until they had been away from work for a year and they felt this meeting was a formality and not a real opportunity to address their needs. Both were formally dismissed on grounds of incompetence.

- Finding 1: The School Meals Assistant said: "I did think they were trying to get rid of me, no one called me."
- Finding 2: The HGV Driver said: "I had to keep phoning them… they just forgot me I phoned them up at one stage and they didn't know who I was."
- Finding 3: When the Nursing Assistant asked about other jobs in his workplace he was told that they did not have insurance for him now that he had a diagnosis of Alzheimer's disease, which is an incorrect statement: "…Occupational Health said no one would give me insurance so at that point I thought well there's no point in trying to work myself into something when no one would be able to employ me."
- The HGV Driver said: "They said there were no jobs I could do, safety wise, in the depot, the will wasn't there really was it?"

- Theme 9: PWD: An acceptance of the final outcome. Four of the participants expressed an acceptance of the final outcome of their employment.
  - Finding 1: The HGV Driver said: "I was quite happy with the outcome, for my health, but it was a bit long, 12 months, I think it should have been sooner but never mind."
  - Finding 2: The Businessman now keeps a financial interest in the company along with his wife and son and is consulted about major decisions.
  - Finding 3: The Engineer still lectures and organizes conferences with the assistance of international colleagues: "That sort of activity will continue until I'm told I have to retire or they find someone else, well I hope they do, I can't go on indefinitely."
- Theme 10: PWD: Coming to terms with their situation. Two of the participants are now on Employment Support Allowance, one has taken early retirement and two classed themselves as semi-retired. Four of the participants said that their work was a big part of their life and that they had enjoyed it and taken a pride in doing it well.
  - Finding 1: Two participants, the Businessman and the Engineer had chosen to work beyond retirement age because they loved their work so much. The Businessman said: "Work was my 80% hobby, you have a hobby on the golf course and I have my work."
- Theme 11: PWD: Financial hardship and consequent worry. All of the participants said that leaving work had affected their family and their relationships. The Nursing Assistant and the HGV Driver both had partners who are still working and they had taken on more domestic roles to help them. For the HGV Driver and the School Meals Assistant, leaving work had meant some financial hardship and consequent worry.
  - Finding 1: The HGV Driver said: "We always had plenty of money… then suddenly we had no money and you start thinking about the future. We've still got a mortgage and I worry about that."
- Theme 12: PWD: A positive outlook for the future. Despite their difficult experiences all of the participants were determined to be positive about their future. All of the participants said that they had taken up new hobbies or restarted old ones since leaving or reducing their work. The three participants who are under the age of 65 had been referred to the Young Onset Dementia Service in their local area and had become involved in the various social and leisure activities facilitated by this service.

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	○ Finding 1: The Businessman said: "My wife is happy, I am at home more. We live a settled life now, go visiting people." ○ Finding 2: The School Meals Assistant said: "I'm probably happier now because I do different things, there's no day when I don't do anything even if I just go to town and I go to the gym and do stuff with Kath [Young Onset Dementia Worker]." ○ Finding 3: The Nursing Assistant said: "Well I've put my name down to do as much as I can because after being in work all my life just being stuck at home is not good enough for me, I need to do something, I'm not going to be sat down here and be moaning because my wife's working shifts and my sons are all out working, I want to be doing something everyday." ○ Finding 4: The Engineer was still planning future conferences: "One of the things I assume and still do assume is that I can do everything."
Author's comments	There is no doubt that with the rise in the age of retirement, the numbers of people developing a dementia while still in employment will also rise. Though this is a small sample and the interpretation of events is that of the participant, the findings of this study seem to show that support for workers who have a dementia and who are employed in lower ranked occupations is, at best, poor and at worst unlawful. Consultation appeared non-existent and referral to statutory agencies or adherence to the Equality Act (2010) appears to bear no regard to the wishes of the worker. This study highlights the need for staff working in services for people with dementia to have some knowledge of Employment Law and to build up relationships with useful agencies in the field of employment. One simple and effective way of doing this is through Trades Unions who would be able to give an expert view of the legislation and give insights into the particular working roles of individuals. Most importantly, they could encourage the employer to engage in a dialogue which takes into account the employees' wishes when considering future plans and utilization of residual skills in the workplace. However, union density is currently running at 25% of the UK workforce (Brownlie, 2011) which means that this solution is only partial. It is clear that this is a growing and imminent problem augmented by the removal of the statutory retirement age in 2012. Although this small study limits the extent to which the results can be applied to the general population, it is clear that further research is needed to gauge scale of the ostensible problem and to assess the experiences of a larger sample of people who have undergone similar (or different) scenarios as those described in this current study. Distinction should be made between the experiences of those from different occupational groups. Only then will it be possible to plan for the inevitable problems that face people who develop a dementia while still in employment.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Very valuable

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	Overall quality: High

Full citation	Clayton-Turner, and et al (2015) Approaching an unthinkable future: understanding the support needs of people living with young onset dementia. Wolverhampton: DEMENTIA PATHFINDERS
Study details	Country/ies where the study was carried out: UK Study type: interviews Aim of the study: to understand the support needs of people living with young onset dementia Study dates: 2014 and 2015 Source of funding: Department of Health's Workforce Advisory Group
Participants	• Sample size: 28 younger people living with dementia and 15 carers • Inclusion criteria: people involved with a young onset dementia training course • Exclusion criteria: none • Sample characteristics: not provided
Methods	With funding from the Department of Health's Workforce Advisory Group, Dementia Pathfinders ran a training project on young onset dementia. The project was informed at every stage by active involvement of people with young onset dementia and those in family caring roles who told their stories. They began by listening in detail to their experiences which were then translated into a two-day training course, co-delivered with people with young onset dementia and carers. The listening process generated the interview data. Twenty three people gave detailed reflections; fifteen were primary carers and eight were people with a diagnosis of dementia. These conversations lasted between one and three hours. Briefer contacts were made with another 20 people affected by young onset dementia.
Thematic analysis	• Theme 1: PWD: Relief at getting the diagnosis confirmed. ○ Finding 1: Rose, a younger person living with dementia said: "In some ways I was pleased when my diagnosis of dementia was confirmed. I didn't know and couldn't understand why I was having such problems." ○ Finding 2: Chris N, a younger person living with dementia said: "The last five years have certainly caused me to view my life in a very different way and learn to live for, and in, the moment. In 2012 I was diagnosed with frontotemporal dementia. As a result of the diagnosis and there being no cure, I was forced to retire from work as a driving examiner. Although it is never good to get a diagnosis of dementia, it was a great relief to finally establish the cause of the challenges that I was having in everyday functioning. I was now able to explain to family and friends the reasons why my demeanour and behaviour was different from the person they all knew well." • Theme 2: PWD: Telling children about the diagnosis is difficult. ○ Finding 1: Rose, a younger person living with dementia said: "The children were very good; I mean they had to be told. I did find this difficult, and made sure my husband was with me when we told them, because I knew we all had to be together to do it." • Theme 3: PWD: Dementia Service User Network (otherwise known as the 'Forget-Me-Nots') provide social comradeship and are a useful resource.

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- Finding 1: Keith, a younger person living with dementia said: “Until April 1st 2011, I was head teacher of a very large primary school, was studying for an MA, and was advising other Canterbury schools on behalf of Kent County Council. All that stopped with my diagnosis of Alzheimer’s disease at the age of fifty-five. After devoting five months to my dementia assessment, and then five more months to come to terms with that, I decided that I needed to continue to try and play a useful role in society and utilise some of the skills which, although waning a little, were still available to me, in order to raise awareness about what living well with dementia is really like.

  Quickly I was offered a voluntary role of ‘Dementia Envoy’ with the Kent and Medway NHS Social Partnership Trust, and then became a very busy person. I felt a greater impact could be had if others shared carrying the baton with me. Consequently in November 2012, six people with dementia and two clinical psychologists met to form what professionals called a “Dementia Service User Network”, but which we insisted should be called the “Forget-Me-Nots”. The function is partly social comradeship and partly to be a useful resource to the NHS Trust in the area. Four regular elements within our commitment are: being on interview panels for posts connected to dementia care; we analyse and comment upon dementia related literature being generated by the NHS; we have participated in a number of worthwhile projects with DEEP (Dementia Engagement and Empowerment Project) and are active supporters of this very important venture; we speak at conferences and at post-diagnosis groups where often people in the audience have not long been diagnosed and are coming to terms with this and welcome hearing our experience and positive advice.”
- Finding 2: Chris R, a younger person living with dementia said: “After my diagnosis of frontotemporal dementia, I thought we just had to get on with our lives and that’s it. How wrong was I?! After attending some coffee morning groups, which were not for me, I was invited to join the Forget-Me-Nots group in Canterbury. This has opened a whole new life for me. We are a really great mix, and we like to get everybody’s view. This is very important as everybody’s experience of dementia is different. I have sat on interview panels for different grades to work with dementia. I have spoken at memory clinics about how I cope with living with dementia, and about what support is available.

  Who would have thought it?! Here is me with a diagnosis of dementia and I’m involved in all these things. Now, I know this might sound strange, but there are benefits to having dementia: all the things we are doing for the future for people with dementia, all the great people I have met in our group and at meetings and interviews; letting people know about dementia, and that it’s not a death sentence, and there are lots of things out there for you. Certain things become more difficult. Simple things are not so easy anymore, but you have got to do your best to get on with your life as best you can.”
- Finding 3: Chris N, a younger person living with dementia said: “joined the Forget-Me-Nots group. I find this group very stimulating and the feeling of friendship and community goes a long way to reassure all our group members that they are not alone in the strange, and sometimes confusing, world of dementia.

- Theme 4: PWD: Making the most of life. Receiving a diagnosis of a life-limiting condition tends to concentrate the mind. It helps you recognise what is important, clarifying life goals and helping you identify things you want to do. Dementia forces you to make the most of every day, to live in the moment and cherish times of fun, intimacy and discovery. You find a new strength within and a depth to some relationships which become closer through the hard times.
  - Finding 1: Rose, a younger person living with dementia said: “I certainly still enjoy life and my husband and I do a lot together. I’m still looking after the house; I enjoy doing our wonderful garden and allotment, which takes up a large proportion of our time, but keeps us busy! I still love reading. We enjoy walking together, particularly walks along the beach which is very close to us. When it comes to dementia, you just have to take it a day at a time.”

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	○ Finding 2: Rose, a younger person living with dementia said: "'After his diagnosis, Jerry and I felt strongly that we had to make the most of every day, doing normal things that others our age would do. We spent a lot of time visiting National Trust properties and museums as we have both always enjoyed history and architecture. As dementia progressed we went to some places so often we did not even need to present our membership cards as we were so well known. They were a great source of gentle outing suitable to the needs of the person while enabling us both to get something out of the trip at an appropriate level. There was always tea and cake too!" ○ Finding 3: Chris N, a younger person living with dementia said: "As a result of my diagnosis, I decided to live life to the full and went back to playing my Tenor Horn. Most weekends I can be found on a bandstand somewhere in Kent, or further afield. I have adopted the daily mantra 'I may have dementia, but dementia doesn't have me!'" • Theme 5: PWD: Younger people living with dementia find YoungDementia UK very helpful. ○ Finding 1: Nic, a younger person living with dementia said: "Jen and Simon are my support workers from YoungDementia UK. They are people I can trust and rely on and I've never had that before. It's really nice having someone coming around each week, which is really the highlight of my week, and I'm glad to have someone to chat to. I wish people were more patient and understanding. They make judgements about me based on my appearance. But they should realise that just because people don't fit the stereotype doesn't mean they can't have dementia." • Theme 6: PWD & carer: Having dementia is frustrating, concerning and induces fear. ○ Finding 1: Keith, a younger person living with dementia said: "A key factor for me is frustration: frustration with the impact dementia has on me as a relatively young person; frustration around the lack of appropriate care both now and as the condition progresses; frustration around the lack of understanding, bordering at times on disbelief that I have dementia from people I meet. I live with constant concerns. There are concerns around the fact that physically (thankfully) I am well but mentally and emotionally I am much more affected. Also, there are concerns around how my progressing dementia makes those close to me – wife, grown-up children and grandchildren – view me." ○ Finding 2: Peter, a husband of a younger person living with dementia said: "'I used to help Brenda to bed each night and then go back downstairs for my daily respite, which usually included a glass of wine I'm afraid. Then one night she just wouldn't get into bed. She seemed frightened about something. After a lot of gentle cajoling (I'd become a lot more patient and caring since the diagnosis) I got her to tell me what was wrong. She said that she'd seen someone on top of the wardrobe. Then they were underneath it and then inside. After a lot of explaining that there was nobody there, I managed to persuade her to get into bed." • Theme 7: Carer: Life unravelling before diagnosis ○ Finding 1: Peter, a husband of a younger person living with dementia said: "As far as the GP and I were concerned, my wife was suffering from depression. In my naivety I just thought depression meant you were unhappy all the time. She was pretty low but there seemed to be more to it than that. She used to love taking the neighbour's dog for a walk. One day she didn't come back. It had started to rain and I searched the village with no luck and called friends to see if she was with them. I was about to call the police when an RAC van turned up with a drenched Brenda and dog on board. The RAC Man had found them cowering by the side of a main road looking lost. There are good Samaritans around! She got lost when driving too. Once I was out searching and found her on the hard shoulder of a motorway frightened to drive further. She was very house-proud but things went downhill despite her insisting she'd 'spent hours cleaning'! We had a new cooker installed and however hard I tried to teach her how to use it, she just couldn't. I'm afraid I was rather impatient which didn't help. This depression was very strange. We tried all sorts of remedies including going to someone who dangled a crystal over her head. It

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	didn't work. Life was beginning to get very difficult and we were both unhappy all the time." • Theme 8: Carer: Caring for a younger person living with dementia is stressful. ○ Finding 1: Suzy, a daughter of a younger person living with dementia said: "The emotional impact of caring is huge for us all as a three generational household. We are losing Mum. Her dementia means things are slipping faster than ever. We have to think through whether involving Mum in activities away from the home, and out of her routine, will have a positive effect. The children understand that creating memories is important, that their grandma might not remember but they will. The mix of emotions is difficult to balance. Sometimes I feel so grateful to be able to care for someone who cared for me. Sometimes I feel exhausted, like doing my best is never good enough. I often feel frustrated that services don't fit us. We are allocated four hours of support for Mum a week, we care for her 24/7. I find myself in conflict situations with health and social care professionals who don't understand what it means to care for someone with a dementia. Sometimes I just want my Mum back, as she was, for one day, just to check in that I am doing my best for her." • Theme 9: Carer: There is a lack of support for younger people living with dementia and their carers. ○ Finding 1: Keith, a husband of a younger person living with dementia said: "Elaine and I have been married for 35 years now. Elaine was adventurous and sporty, and we spent our holidays walking and camping. We couldn't have children, but I think that made us even more reliant on each other. In 2006 I started noticing subtle changes in Elaine: alterations in her behaviour patterns and character, some so small they are hard to describe. She would be a bit repetitive. She said she kept being told off for making mistakes at work, but didn't know why. In 2009 we eventually got a diagnosis of Pick's disease. There are few services available for younger, mobile people. Despite this terrifying diagnosis, we received no counselling. I became a full-time carer. I have to watch out for her 24 hours a day. For me it's very lonely. Your life shrinks. Our families live quite far away and Elaine can't hold a conversation anymore. The worst time is in the evening, especially in winter. We rarely socialise now because she gets agitated in new places or with other people in the house. There is a desperate need for more support for people with early onset dementia, and counselling and training for their carers. My worst fear is that something will happen to me – because then who will look after Elaine? If I am not with her, she can get agitated and distressed. We are still as close as we can be in the circumstances. Of course I still love her. I know that her essence is there, even though the Elaine that was has gone." • Theme 10: Carer: When caring for a younger person living with dementia, key to coping and staying well is to carve out time for self. ○ Finding 1: Sue, a wife of a younger person living with dementia said: "I am still working as an adult education tutor and decided it was important to keep it up because it was a stimulating outlet for me. I had to be very resourceful in getting care, as it was impossible to use normal agencies as they would not guarantee times and I had to be in front of a group of students at specific times. We used relatives, friends, and people we got to know through dementia, even approaching the local day centre to see if members of staff would cover an evening while I was teaching. The money I earned went on care, but we both benefitted by being apart for a couple of hours. Now Jerry is in care my earnings make a difference to my life, as without them I would not to be able to keep a car or go on holiday. Teaching also allows me to be myself and forget the limbo I continue to live in, being neither a widow nor a wife. This is a particular problem with young onset dementia, as often those affected live for very long periods with the disease. It is now 11 years since Jerry was diagnosed, but probably 15 years since it started. He has now needed fulltime care for four years." • Theme 11: Carer: Caring for a younger person living with dementia increases the closeness of relationships. ○ Finding 1: Peter, a husband of a younger person living with dementia said: "This is going to sound very strange, but I wouldn't have

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	missed those years I was caring for my wife at home for anything. Of course I wish her dementia had never happened. But it did, and it brought us closer together. I'd led a busy business life with lots of travelling. She'd had her own interests including being a Samaritan. Her dementia forced us to spend much more time together, appreciate each other more, and despite all the difficulties we laughed a lot. For several years our focus was on one another – I was there for her and she was there with me. Then I just couldn't cope anymore and she went to live in a care home. I was lost with no Brenda to look after, no work, most friends had become remote, and all my interests had fallen by the wayside. The lack of day to day dementia in my life left a void that took a very long time to fill." • Theme 12: Carer: Support groups for carers relieve stress. ○ Finding 1: Peter, a husband of a younger person living with dementia said: "The Memory Service wasn't particularly helpful after Brenda's diagnosis in 2006. However her condition rapidly worsened and they allocated me a mentor from within their team. She was the Speech and Language Therapist. She persuaded me to try a support group she ran but their loved-ones all seemed to be about 30 years older than Brenda (she was diagnosed at age 59). We had virtually no problems in common. She then suggested I try a support group she ran for carers of people with rarer dementias. They all turned out to be around my age and despite the differences, we all seemed to be suffering from the same sort of problems. We met every month under her gentle guidance. We talked together, listened together, laughed together, cried together. We helped one another through desperate times. It seems that men find opening their hearts to others very difficult – I know I did. But after a while all of us, men and women alike, were talking openly about what was happening in our lives. I discovered that just talking with others in my position was such a stress relieving therapy. That Speech and Language Therapist deserves a medal!" • Theme 13: Carer: Informal networks and the wider family are important. ○ Finding 1: Sue, a wife of a younger person living with dementia said: "Jerry and I had always enjoyed walking and initially he went walking on his own. Fairly soon he began to get lost on paths he had known well. Family members and friends set up support to allow him to go walking, although distances became shorter and walking much slower. For each of us the benefits were huge, allowing healthy exercise and time out of the house observing nature instead of four walls. Spatial awareness was something that went quickly, so this type of help was invaluable as Jerry was unsafe on his own and knew it, so would not go out unless accompanied." • Theme 14: Carer: Carers can receive support online at Talking Point, a peer support community run by Alzheimer's Society. ○ Finding 1: 'L', a daughter of a younger person living with dementia: "My mum has dementia – I'm new to this and I'm in my 20s. I finally plucked up the courage to google 'young people who have a parent with dementia' and I found this site. Everything is so hard – yeah I have loads of people to support me but they don't really understand what it's like to have a parent with dementia. She's just in her 50s and they live hours away from me. My dad is a hero and he's doing so well but I feel it's really hard for him. Does anyone else know what this is like – feeling sorry for their parents like this? It'd be great to chat to someone." • Theme 15: Carer: A diagnosis of dementia should be made before stopping work. ○ Finding 1: Angela, a wife of a younger person living with dementia said: "Ted decided to slip into full retirement because of his memory problems but before he had his diagnosis. This meant that he missed out on having his pension made up to 65 as would have happened if he had left through sickness. It also meant that he gave himself no opportunity to discuss remaining at work doing less hours and/or a simpler role." • Theme 16: Carer: There is booklet of advice for employers about dementia.

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	○ Finding 1: Angela, a wife of a younger person living with dementia said: "I think employment issues are only beginning to be considered. I have seen that there is now an Alzheimer's Society booklet with guidelines for employers; the need will grow as the retirement age rises." • Theme 17: Carer: Driving should be discussed. ○ Finding 1: Angela, a wife of a younger person living with dementia said: "…nobody discussed driving with us or reminded us that we should inform the DVLA and his insurance of his diagnosis. This meant that, had he had an accident, he would have been driving illegally and without insurance. Fortunately Ted decided to stop driving before any accidents happened." • Theme 18: Carer: Becoming involved with research is advantageous for younger people living with dementia and their carers. ○ Finding 1: Angela, a wife of a younger person living with dementia said: "Ted and I derived much benefit through becoming involved in research. It was stimulating and widened our group of friends, giving opportunities to attend events. We were participants in a research project and were keen to know of anything which might slow down or stop the progress of the disease. Since Ted's death my research activities have widened and are a major source of stimulation, activity and friendship. You can register your interest in research at joindementiaresearch.nihr.ac.uk" • Theme 19: Carer: Younger people living with dementia benefit from having relationships that are allowed to develop. ○ Finding 1: Gillian, the wife of a younger person living with dementia said: "Because of his age, my husband David did not really fit into the standard day care setting and so we were given a "sitter". Right from the start I made it clear that I did not want him sitting whatsoever and eventually, after a few changes, we came across a wonderful lady who was happy to engage in activities with David. This entailed walking from our home across the local country park to our local bowling alley, where they had a couple of games of bowling, and then went on to a nearby café where they had lunch. Then they had a nice stroll home along the sea front. This continued for quite a few years and was amended as his condition deteriorated. Small changes were made, such as turning off the line on the bowling lane when David could no longer keep his feet behind it [this stops the scoring]. Other customers at the café would save his regular table for him, and eventually staff would cut up his food before delivering it to the table. He soon had quite a few new friends who would always stop to talk when he was out with me. They also went to the pub once a week for a few games of dominoes, and once again were well received by the regulars, again saving him his usual table and having a little chat. In fact, on one such afternoon the wake of a regular was being held in the pub. The family were insistent that David had his usual table and even brought over a plate of sandwiches. Such kindness shown by complete strangers!"
Author's comments	The impact of being diagnosed with dementia at a young age is huge and can be deeply painful. There is greater potential than with later diagnosis for life to be disrupted and confidence lost following the common experience of having to give up work and other roles that provide meaning and significance in life. People with young onset dementia are determined to continue with 'normal life' as long as possible and require a dementia friendly world of work, leisure, commerce and community if this is going to be possible. Occupational health services could enable the person with dementia and their carer to leave work in a way that is dignified and of their own choosing. The shock waves of a diagnosis at a young age reverberate. The lives of partners, children, parents and friends are touched, and a new way of being together must be found. The primary carer is at risk of physical and mental stress because of the many competing demands on their time and energy. Keeping relationships strong is a priority, as it is the informal networks on which younger people with dementia rely most heavily for support.

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	People with young onset dementia struggle to find a diagnosis, and when they do receive one it is more often of a rarer condition. They and their families need specialist advice and support in learning how to understand and cope with the symptoms and live life to the full. Because young onset dementia has been considered rare, there has been little impetus to provide specialist services, but being in services for older people can have a detrimental effect on a younger person. There is a pressing need for more age appropriate help. The severe emotional and psychological consequences of a diagnosis of young onset dementia require a range of effective sources of support. This includes specialist one to one counselling and advice, from those who understand young onset dementia, but also ideally a range of settings where people can meet others in their situation and gain mutual support. Conventional day care and domiciliary services tend not to meet the needs of younger people with dementia. New models of support could be developed that are acceptable which would involve opportunities to be active and outdoors, pursuing interests and engaging in purposeful activities. They would encompass long enough periods of funded help to allow the family carer to continue with paid work if they so wish. It is not unusual to live with young onset dementia for many years, meaning a large proportion of the carer's life is shaped by their support role. Carers need long-term help to negotiate the stages of dementia, make decisions and maintain their own health and well-being. This may include support in finding full-time and end of life care. Help should not stop when the person dies, as it takes years to work through the grief and find a new way of life. Pioneering organisations across the UK have developed innovative ways of supporting younger people that can provide ideas and inspiration for new projects to fill gaps in provision. We hope that others will follow their lead.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? No. This study is written as a report rather than as a published study with a methods section. • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: Moderate

Full citation	Clemerson Gemma, Walsh Sue, and Isaac Claire (2014) Towards living well with young onset dementia: An exploration of coping from the perspective of those diagnosed. Dementia: The International Journal of Social Research and Practice 13(4), 451-466
Study details	Country/ies where the study was carried out: UK

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	Study type: semi-structured interviews Aim of the study: The aim of this study was to provide an exploration of the individual's subjective experiences of young-onset Alzheimer's dementia Study dates: not provided Source of funding: The investigators received no financial support for the research and authorship. The investigators were staff at the University of Sheffield
Participants	• Sample size: 8 younger people living with dementia • Inclusion criteria: participants were recruited if they were under 65 years old, had a medical diagnosis of AD and were British. Mild–moderate stages of AD (according to their clinician's judgement) • Exclusion criteria: individuals with a co-existing learning disability or neurological conditions were excluded from the study • Sample characteristics: mean age = 55.6 years (range 35 to 63). Mean MMSE = 18.9 (range 17 to 21). All participants were living in their own homes; five lived with a partner, one with their daughter and two lived alone. None of the participants were actively working at the time of interview.
Methods	Semi-structured interviews
Thematic analysis	• Theme 1: PWD: Experiences of feeling 'too young'. ○ Finding 1: Don, a younger person living with dementia said: "At my age I never thought I would ever get anything." ○ Finding 2: Emma, a younger person living with dementia said: "because people usually get it in their sixties and seventies…" ○ Finding 3: George, a younger person living with dementia said: "The Doctor says 'you are too young to have this' and I said 'I am?' LAUGH" ○ Finding 4: Malcolm, a younger person living with dementia said: "I feel older and I haven't before at all and it's not so old but then people keep saying I'm old. I'm 58, yes 58 and I feel really old, I suppose I am but I have never thought about age before at all." ○ Finding 5: John, a younger person living with dementia said: "At least I am 73, I mean 63." ○ Finding 6: Pat made contradictory references to his age, first identifying himself as young: 'I prefer younger [people], about my own age' and then switching to an older self-view: 'I prefer younger people than, you know, old fogies like me'. • Theme 2: PWD: People coped by normalising the situation. Creating an identity as an older person, even transiently, allowed people to make sense of developing AD by normalising the life-cycle. ○ Finding 1: Mark, who spoke of himself as "…not so young now…" commented: "…everybody gets older and nearer to dementia anyway." ○ Finding 2: John, who appeared to have a more fluid sense of age, said: "…you see you expect to forget a few things don't you when you get to 63." • Theme 3: PWD: Developing dementia forced people to contemplate death. ○ Finding 1: George said: "When I first got it I thought I was going to be dead soon…" and: "'I worry that I won't be here one day, you know, that I'll die." ○ Finding 2: Malcolm said: "I don't expect to live that long."

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- Finding 3: Emma said: "[. . .] the only thing that what worries me is my future and what is going to happen to me."

- Theme 4: PWD: Shock at losing their expected future. For many, this included loss of employment as they were forced to take early retirement.
  - Finding 1: Mark said: "'I was in a position where I should have been trundling along and getting on with it… Then I was told that I wasn't going to work anymore which was a bit of a shock."
- Theme 5: PWD: Loss of adult competency. Loss of adult competency represents another sub-theme in the disruption to the life-cycle. This emerged through people's experience of either feeling more 'childlike' due to a loss of skills or being treated this way by others.
  - Finding 1: Don said: "You know when I am trying to get my coat on and then my wife is trying to get it on for me and I feel like a baby."
  - Finding 2: Malcolm said: "[. . .] there is a couple a couple of doors away who seem to treat me, I don't know, maybe a little bit childlike perhaps."
  - Finding 3: George said: "Like when they took me on holiday our granddaughter had to take me to the room every day because I would get lost. She was only five and taking this bulk home."
  - Finding 4: Pat said: "'[when] I can't get my trousers on… it makes you angry, really really angry because you know you can do it… but you can't do it this day."
- Theme 6: PWD: Some people tried to prevent themselves from thinking about the future.
  - Finding 1: Don said: "I don't think about it long term, I just take it, take each day by day…"
- Theme 7: PWD: Some people tried to stay positive, which for a few meant denying further significant decline.
  - Finding 1: John said: "I think my future will be as basically as what it is now. I shall just get up and take the dog for a walk and I suppose we will have the odd good thing happening and we will have the odd bad thing happening."
- Theme 8: PWD: With further reflection it seemed that some participants were working towards resolving concerns through comparing their situation to others who were more impaired or died younger than themselves.
  - Finding 1: John said: "[. . .] but then again you think 'why has that poor little kid got cancer?' At least I am 73, I mean 63, so I have had a little bit of an innings."
  - Finding 2: Malcolm said: "There is no point in worrying [about the future], I have nursed people who have died younger than what I am now and I know people who have had cancer younger than me and died so I am sort of thinking 'well, you know, if it is 10 years more I am going to be late sixties by then, that is not too bad' sort of thing."
- Theme 9: PWD: Redefining self. For some, the impact of developing dementia was so significant that it was viewed to change their fundamental core or personality.
  - Finding 1: Malcolm said: "'I think I thought it [dementia] was mainly to do with forgetting but it is a lot more than that. I think it changes you as a person, in fact I am sure it does."
  - Finding 2: Pat said: "'I was forgetting things I should have known. I used to be quite clever then all of a sudden it just seemed to disappear."
  - Finding 3: For Peter, this process began with a purposeful cutting off from the old self: "Your past life is past. That is gone now – just forget it." And: "It is part and parcel of who I am now."

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- Finding 4: George spoke of beginning to adjust his view that only 'old' people develop dementia, saying: "I said [to the neighbours] 'it's Alzheimer's'. He said 'you are joking'. I said 'there are young kids getting it and all sorts, it's not just for old people any more'".

- Theme 10: PWD: A reduced sense of self-worth also contributed to the threat to self. Simply having the disease made some individuals question their worth.
  - Finding 1: Malcolm said: "'I don't feel as confident perhaps. I feel lesser, smaller because of it in a way.'
  - Finding 2: Pat said: "[. . .] you feel like, well I must be useless because I can't even write my name and I used to do it regularly, you know, three months ago."
  - Finding 3: Emma said: "I think people might not want to talk to me because they might think I am thick but I am not."
- Theme 11: PWD: Most participants who disclosed their condition had positive responses from others, which helped them to accept their diagnosis as part of who they were.
  - Finding 1: Don said: "I didn't want to tell anybody, I don't know why… but it was getting bad and people were reporting me for doing things wrong… then the men at work, the nurses and everybody, when they knew what I had got they were all rallying around. They were quite good."
- Theme 12: PWD: Holding on to their existing self-concept. One way in which participants aimed to regain a stable sense of self was by holding on to their existing self-concept.
  - Finding 1: Malcolm said: "[. . .] the past becomes more important because you want to cling on to who you are…"
- Theme 13: PWD: Disconnection and isolation. A shared phenomenon of feeling isolated or disconnected from others emerged.
  - Finding 1: Pat summed this up, saying: "The sound of silence. There is a lot of silence."
  - Finding 2: For some, isolation and disconnection were experiences enforced on them because of others: "We have lost some friends to be honest, well people who I thought were [friends]. I don't know, maybe they can't handle it." (Malcolm)
  - Finding 3: "I just avoid people I don't like who are being negative towards me." (Emma)
- Theme 14: PWD: There is a lack of age-appropriate services. This heightened feelings of isolation.
  - Finding 1: Don felt particularly let down and neglected by services: "I think people with this complaint, it seems to me like they say 'We have just put them over in that basket over there and just leave them on their own.'"
  - Finding 2: George, a younger person living with dementia said: "I just thought of things there could be for my age and stuff but all I saw was old people, old men."
- Theme 15: PWD: Re-engaging in life following people's initial experience of disconnection and isolation. Although disconnection was identified as a way of managing the sense of difference to others, it was recognised that this could not be sustained long term.
  - Finding 1: George implied the importance of reconnecting and continuing with life when he metaphorically discussed his walks in the wood: "When I go in the woods, I have got to make sure that I come back out…"
  - Finding 2: Emma said: "I am never going to be the quiet one in the corner! LAUGH"
  - Finding 3: Don commented: "I'm just going to give it my best shot, you know. I am not going to go and lock myself in."
  - Finding 4: "Well you have got to make something of your life. If you don't you are just like cabbage and I don't want to become a

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	cabbage, I want to be doing something." (Peter) • Theme 16: PWD: As people began to reconnect with others, their focus shifted. Their focus shifted from concern with how they cope to concern with how their loved ones cope. Others focussed their attentions on contributing to the community and helping other people with dementia. ○ Finding 1: "My wife. She's had so much to deal with. I just want to protect her and make sure she's alright." (George) ○ Finding 2: "…if I could help somebody else then I will do it because that will make me feel like I have had some part of things." (Emma) • Theme 17: PWD: A feeling of powerlessness. ○ Finding 1: "It has just taken over my life…" (Don) ○ Finding 2: "There is nothing I can do about it and that hurts a lot." (Pat) And: "Basically, there is nothing I can do about it is there? Unless someone comes up with a miracle cure for it." ○ Finding 3: "I don't bother about the future, let that come to me." (George) ○ Finding 4: "You have to play the cards that you have been dealt, end of story." (John) • Theme 18: PWD: The intention to regain control emerged as a common coping strategy in response to the experience of loss of agency. ○ Finding 1: "Coping is important because if you are coping you feel that you are on top of it rather than it being on top of you. You feel that you have got some control over it in a way rather than being led along by it. Learning to cope with it is sort of putting it in its place rather than it just taking over." (Malcolm) ○ Finding 2: "…I am the one that is going to carry on and deal with the rest of my life in the best way I possibly can." (Mark) ○ Finding 3: George argued: "If it gets tough, I get tougher than that". And: "Yes, you can't just give in. Never give in, keep going." ○ Finding 4: "I have just had to tell myself that I have got to get better and I have got to get on with it and every day just keep smiling." (Emma)
Author's comments	In terms of influencing clinical practice, the findings support the need to develop specialist services for younger people with dementia to help address the feelings of difference and isolation. Group-based interventions may be particularly useful. Self-help groups may provide a channel through which young people with dementia can continue to contribute to wider society. It may also facilitate individuals' natural attempts to cope with the disease through allowing them to take control and regain a sense of agency.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. Saturation of themes was not mentioned. The number of people recruited is relatively small. The investigators wrote that "Purposive sampling was employed to develop a suitably homogeneous sample." Therefore, presumably more participants could have been recruited. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes

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	• Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Very valuable Overall quality: Moderate

Full citation	Hegarty, Ackermann, and Evans (2014) Walking side by side. Journal of Dementia Care 22(2), 18-19
Study details	Country/ies where the study was carried out: UK Study type: focus group interview for younger people living with dementia. A questionnaire for their carers. Aim of the study: to report on the gains for younger people with dementia of being involved in a memory clinic's weekly walking group Study dates: 2012 Source of funding: not stated. The investigators were a student at the University of South Wales in Cardiff, an occupational therapist at Pembrokeshire's Memory Clinic and the Heath Board-wide Young Onset Dementia service, and a consultant clinical psychologist for Pembrokeshire Older People's Mental Health Service who was also the Hywel Dda Health Board Lead for young onset dementia services.
Participants	• Sample size: 4 men and 2 women who were younger people living with dementia, and their spouses. • Inclusion criteria: younger people living with dementia (who are under the age of 65 years) and their carers who are members of a memory clinic's weekly walking group. The dementia had been diagnosed by the memory clinic. • Exclusion criteria: none • Sample characteristics: not provided
Methods	The walking group was established in 2008 by an occupational therapist. The group aimed to: • Provide ongoing monitoring and age-appropriate specialist support. • Provide a peer group for people. • Provide community-based opportunities for recreational and physical activity. • Engage with clients efficiently by offering group intervention and thus direct limited resources cost-effectively. • Provide some opportunity for carer respite. Over 5 years, membership has varied between 5 and 7 people. The core membership has been stable with a couple of members leaving as their mobility has become impaired and a couple of new members joining. The group is led weekly by an occupational therapist with input from occupational therapy support workers acting as co-facilitators. The group meets weekly for outings of around 2 hours. The venue is selected according to prevailing weather conditions and people's preferences. The National Park Coastal Path was around the centre, the centre being situated in west Wales. Walking in this region is a normal and sought-

Full citation	Hegarty, Ackermann, and Evans (2014) Walking side by side. Journal of Dementia Care 22(2), 18-19
	after activity in the local community. People wanted continuity for the group and proposed alternative activities for when weather conditions resulted in cancelled walks.
Thematic analysis	• Theme 1: PWD: The walking group created supportive and positive relationships, bringing closeness, friendship and compassion. ○ Finding 1: "It's just nice to be with a crowd of people that we all know. We do get challenged as well when we are out walking. It's good to see how everybody gets together to make sure that everything is alright. There is no competitive input to what we do – it's caring, it's friendly and it's supportive." (younger person living with dementia) ○ Finding 2: "We're all in the same boat." (younger person living with dementia) ○ Finding 3: "We're all on the same level." (younger person living with dementia) • Theme 2: PWD: Group members were clear about the benefits to partners. ○ Finding 1: "Well, it's not just for us because with the walking group, it allows our spouse time – to have their own time." (younger person living with dementia) ○ Finding 2: "You're out of the way and safe. Gives them a chance to draw breath." (younger person living with dementia) • Theme 3: PWD: Some talked about the disadvantages of having a large walking group. ○ Finding 1: "When you have large groups of people, they have internal groups and it breaks off and you get conflict." (younger person living with dementia) • Theme 4: PWD: The group was a social network. ○ Finding 1: "If someone knew somebody who's not right, and you could say, 'Do you like doing what we are doing?' We could bring them to our group as well." (younger person living with dementia) • Theme 5: Carer: Through the spouses' questionnaire, partners reported some positive impact on physical health and communication skills, and a substantial positive impact on mood. ○ Finding 1: "The feeling of being part of a social group – a group that gives confidence and help… just by walking and chatting with others in a similar situation." (spouse) ○ Finding 2: "Seems to stimulate memories of where was visited." (spouse) ○ Finding 3: "At the moment, as [name] can attend without me, the space this provides is a help to our relationship." (spouse)
Author's comments	There was a high level of agreement among members that the walking group had benefited them and partners. The group provided a supportive and accepting environment. These positive interpersonal relationships, based on perceived commonalities, enabled, enabled people to communicate and express themselves with a confidence they did not feel in other social settings. The ongoing support from the memory clinic team in both 'keeping an eye' on how people were doing and in offering a peer-group network were also seen as strengths, and this group met service drivers and objectives in a cost-efficient and age-appropriate way.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes

Full citation	Hegarty, Ackermann, and Evans (2014) Walking side by side. Journal of Dementia Care 22(2), 18-19
	• Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Extremely valuable Overall quality: High. Saturation of themes was not mentioned but this may not have been possible.

E.14 Assessing and managing comorbidities

E.14.1 Assessing and treating intercurrent illness in people living with dementia

- Are there effective methods for assessing intercurrent illness in people living with dementia that are different from those already in use for people who do not have dementia?
- Are there effective methods for treating intercurrent illness in people living with dementia that are different from those already in use for people who do not have dementia?

E.14.1.1 Assessment of intercurrent illness

Pain assessment

Bibliographic reference	Mosele (2012)
Study type	Prospective cohort
Aim of the study	To assess the psychometric properties of the Pain Assessment in Advanced Dementia (PAINAD) scale in a sample of people with different degrees of cognitive impairment. To compare the PAINAD with the Numerical Rating Scale (NRS)
Country(ies) where study carried out	Italy
Study dates	January 2010 to February 2011

Bibliographic reference	Mosele (2012)
Source of funding	Not reported
Sample size	Total eligible = 700 participants Included = 600 people completed the pain assessment data. Mean age 83.2 ± 6.9 years (73.2% female; 26.8% male) Cognitively impaired (MMSE<24) n=310; cognitively intact (MMSE ≥ 24) n=290
Inclusion criteria	All participants were consecutively admitted to the acute geriatric section of the Department of Medicine at Padua University
Exclusion criteria	Patients unable to communicate their experience of pain by means of self-assessment scales (uncommunicative patients or with MMSE score ≤5, patients with delirium (delirium rating scale), acute psychiatric symptoms, end of life care and severe sensory impairment were excluded
Details	Pain assessment- Both NRS and PAINAD administered at same time and measured by same trained physician for all participants. Italian version of PAINAD was used **PAINAD criteria** Breathing: normal (score=0); laboured (score=1); noisy laboured (score=2) Negative vocalisation: none (0); occasional moans or muttering (1); repeated trouble calling out, load moaning or crying (2) Facial expression: smiling or inexpressive (0); frowning or sad (1); facial grimacing (2) Body language: relaxed (0); tense and pacing (1); rigid with fists clenching or striking out (2) Consolability: No need to be consoled (0); distracted or reassured (1); unable to be distracted or consoled (2) **NRS** Intensity of pain: ○ no pain (0); worst possible pain (10) Patients asked to say a number that best describes pain none to mild (score 1 to 3); moderate (score 4 to 6); severe (score 7 to 10)
Interventions	Geriatric assessment data was obtained on all participants' physical health, cognitive and functional status. Pain assessment was measured at least 48 hours after admission by the dame physician for all participants. Both

Bibliographic reference	Mosele (2012)
	NRS and PAINAD were administered at the same time. Each participant was observed for at least 5 minutes prior to administering the pain assessment.
Results	**Rates of accurately identified intercurrent illness in people living with dementia** • Pain characteristics ○ Prevalence of pain as assessed by NRS and PAINAD NRS for cognitively impaired = 50.3%; PAINAD for cognitively intact = 42.4% p= 0.02 PAINAD for cognitively impaired = 62.9%; NRS for cognitively intact = 45.1% p= 0.0007 ○ Presence of pain by cognitive function according to MMSE scores Identified by PAINAD cognitively impaired vs cognitively intact (62.9% vs 45.1%; mean score SD 2.5 ± 1.8 vs 1.8 ± 3.4) Identified by NRS cognitively impaired vs cognitively intact (50.3% vs 42.4%; mean score SD 2.2 ± 3.5 vs 1.9 ± 3.4 **Diagnostic test accuracy (including Sensitivity, Specificity, PPV, NPV etc.)** • PAINAD validation ○ Concurrent validity and inter-rater agreement was confirmed in patients with mild cognitive impairment (MMSE scores 24-18; Kendall's τ = 0.77, p <0.0001 κ = 0.76, p<0.0001) ○ Concurrent validity and inter-rater agreement was confirmed in patients with severe cognitive impairment (MMSE scores <18; Kendall's τ = 0.77, p <0.0001 κ = 0.77, p<0.0001) ○ Internal consistency in people with dementia = α = 0.90 Internal consistency in people without cognitive impairment = α = 0.94 ○ Observed mean (SE) score of PAINAD according to NRS class

	NRS class				
	none	mild	moderate	severe	p
PAINAD score[a]	0.38 (0.07)	1.93 (0.11)	4.74 (0.13)	8.61 (0.17)	<0.0001
PAINAD score[b]	0.43 (0.07)	1.79 (0.10)	5.08 (0.14)	8.73 (0.20)	<0.0001

(a) Crude observed mean score
(b) Mean score adjusted for MMSE, depression, CIRS,ADL and age

Clinical outcomes including cognitive, functional and behavioural ability

• Not reported

Health related quality of life of people living with dementia

• Not reported

Bibliographic reference	Mosele (2012)
	Resource use and cost • Not reported
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Unclear • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Unclear • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? n/a • Was the follow up of subjects long enough? n/a • How precise are the results? Unclear • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Bibliographic reference	Horgas (2007)
Study type	Cross sectional
Aim of the study	To evaluate the reliability and validity of an observational pain assessment tool (Non Communicative Patients Pain Instrument: NOPPAIN) versus a subjective pain assessment tool (Numeric Rating Scale; NRS and Verbal Descriptor Scale ;VDS) in patients with dementia. To compare NOPPAIN scores and self-reported pain in cognitively impaired and cognitively intact older adults.
Country(ies) where study carried out	USA
Study dates	Not reported
Source of funding	Grant awarded from National Institute for Nursing Research
Sample size	40 participants (31 (77.5%) female 9 (22.5%) male) (mean age 83 years (range 65-96 years); Participants with cognitive impairment (n=20; mean MMSE score= 17, range 10-23) cognitively intact (n=20; mean MMSE score = 27 range 24-30)

Bibliographic reference	Horgas (2007)
Inclusion criteria	Inclusion was based on criteria for a larger parent study (of which these participants were recruited as a subsample. Participants were 65 years or over, fluent in English language, able to stand up from a chair (with assistance if needed); diagnosed osteoarthritis in the lower body, adequate vision and hearing to complete the interview.
Exclusion criteria	Participants who were acutely ill, had abnormal vital signs relative to baseline or were on bed rest were excluded.
Details	Participants were recruited as a sub sample of those taking part in a larger pain assessment study, based upon a videotaped pain assessment protocol designed to elicit pain behaviours. The principal investigator randomly selected 20 cognitively impaired and 20 cognitively intact participants to be re-evaluated using NOPPAIN. **Self-reported pain:** Participants were asked to describe pain before and after a standardised activity by using a structured interview format: Participants reported if they were currently experiencing pain (yes/no) If they responded “yes” they were asked to rate pain using an NRS and VDS. Following the activity, participants rated presence and intensity of pain again. **Observed pain:** Participants took part in a standardised activity (asked to sit, stand lie on bed, walk in place and transfer between activities for 10 minutes). Activities were conducted in random order and all behaviour observed. Correlation analyses were used to examine relationship between NOPPAIN scores, self-reported pain intensity and observed pain behaviours.
Interventions	All raters were previously trained in using NOPPAIN. After watching the videotapes of participant’s pain experiences, the raters scored the participants pain behaviours using a NOPPAIN measure tool. All raters watched the videos, findings were not discussed and the raters were blind to participants cognitive status
Results	**Rates of accurately identified intercurrent illness in people living with dementia** • Differences between participants with cognitive impairment and cognitively intact participants were not reported. **Diagnostic test accuracy (including Sensitivity, Specificity, PPV, NPV etc.)** • Relationship between NOPPAIN scores and self-reported pain in cognitively intact and cognitively impaired participants:

NOPPAIN intensity	Self-reported intensity	Total sample *(r)*	Cognitive intact *(r)*	Cognitive impairment *(r)*
NRS	NRS	.39	.66 (p<0.001)	.16
VDS	VDS	.31	.66 (p<0.001)	.05
NOPPAIN: presence	**Behavioural observations: presence**			

Bibliographic reference	Horgas (2007)
	Total no. of observed pain indicators | Total no of observed pain indicators | 0.63 | 0.65 | 0.63 **Clinical outcomes including cognitive, functional and behavioural ability** • Not reported **Health related quality of life of people living with dementia** • Not reported **Resource use and cost** • Not reported
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Unclear • Was the outcome accurately measured to minimise bias? Unclear • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? n/a • Was the follow up of subjects long enough? n/a • How precise are the results? Unclear • Can the results be applied to the local population? Unclear

Bibliographic reference	De Waters (2008)
Study type	Correlational study
Aim of the study	To psychometrically evaluate PAINAD in cognitively impaired and cognitively intact older adult hip fracture patients. To compare data obtained from PAINAD scale to a standardised self-report measure
Country(ies) where study carried out	USA
Study dates	July 2004 to Feb 2005
Source of funding	Not reported
Sample size	25 participants; 21 (84%) female; 4 (16%) male 12 = cognitive impairment (MMSE≤23; N=10 (83%) female;N= 2 (17%) male; 13 = cognitively intact; (MMSE >24; N= 11 (85%) female; N=2 (15%) male

Inclusion criteria	Inclusion criteria: Age 65 years or older; hip fracture as a result of trauma; hospitalised for surgical repair; English speaking; able to use a 0-10 point self-report pain scale.
Exclusion criteria	Exclusion criteria: Underwent multiple surgeries during hospitalisation; nonverbal; unable to use the 0-10 point self-report pain scale; experienced a pathologic hip fracture due to malignancy
Details	Pain was assessed with the numeric rating scale (NRS) and PAINAD. NRS was rated from 0-10 (0 indicates no pain; 10 indicates worst imaginable pain) PAINAD consists of 5 items (breathing, negative vocalization, facial expressions, body language and consolability). Each item is rated from 0-2 and ratings summed for a total score ranging from 0-10.
Interventions	Scores on PAINAD were observed by direct observation during periods of likely pain (transfer from bed to chair or chair to bed) and unlikely pain (sitting or lying quietly). Each participant was observed on two occasions. Following PAINAD observation all participants were asked to self-report pain using the NRS.
Results	**Rates of accurately identified intercurrent illness in people living with dementia** • Table shows comparison of pain scores

	25th Percentile	50th (median) Percentile	75th Percentile
Total group (n=25)			
Likely pain			
○ NRS	5.50	8.00	10.00
○ PAINAD	5.00	7.00	8.00
Unlikely pain			
○ NRS	0.00	2.00	5.50
○ PAINAD	1.00	1.00	4.50
Impaired group (n=12)			
Likely pain			
○ NRS	7.25	9.00	10.00
○ PAINAD	7.00	7.50	8.75
Unlikely pain			
○ NRS	0.00	1.50	7.50
○ PAINAD	1.00	3.00	5.75
Intact group (n=13)			
Likely pain			
○ NRS	4.00	6.00	8.00

○ PAINAD	4.50	6.00	8.00
Unlikely pain			
○ NRS	0.00	3.00	4.50
○ PAINAD	1.00	.1.00	4.00

Diagnostic test accuracy (including Sensitivity, Specificity, PPV, NPV etc.)

○ Table shows correlation between PAINAD and NRS

	Correlation between PAINAD and NRS	Significance	Number of observations
All observations	0.834	0.01	50
Unlikely pain	0.639	0.01	25
Likely pain	0.764	0.01	25
Cognitively intact	0.735	<0.001	26
Cognitively impaired	0.915	<0.001	24

- Reliability of PAINAD: Internal consistency

Cronbach alpha for cognitively impaired group was α=0.847 and cognitively intact group α=0.846

Clinical outcomes including cognitive, functional and behavioural ability

- Not reported

Health related quality of life of people living with dementia

- Not reported

Resource use and cost

- Not reported

Overall risk of bias

Very low

Risk of bias further info

- Did the study address a clearly focused issue? Yes
- Was the cohort recruited in an acceptable way? Unclear
- Was the exposure accurately measured to minimise bias? Yes
- Was the outcome accurately measured to minimise bias? Yes
- Have the authors identified all confounding factors? Unclear
- Have they taken confounding factors into account in the design/analysis? Unclear
- Was the follow up of subjects complete enough? N/a
- Was the follow up of subjects long enough? N/a

	• How precise are the results? P values provided • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Bibliographic reference	**Van Herk (2009)**
Study type	Multi centre case control study
Aim of the study	To psychometrically evaluate the PAINAD alongside the NRS in participants with and without cognitive impairment
Country(ies) where study carried out	Netherlands
Study dates	Not reported
Source of funding	Grants from Laurens (an organisation incorporating nursing homes and residential homes in Rotterdam) and Pain Expertise Centre Rotterdam of Erasmus MC
Sample size	Total sample = 174 participants Case group N=124 84 (68%) female; 40 (32%) male; moderately to severe cognitive impairment (MMSE<18) Control group N=50 26 (52%) female; 24 (48%)male; cognitively intact to mild impairment (MMSE≥18)
Inclusion criteria	Inclusion criteria was a nurses rating of 4 and higher on the NRS. Case group also included residents who were verbally unable to communicate (unable to administer MMSE) Control group included cognitively intact residents who could report pain themselves
Exclusion criteria	Not reported
Details	Video recordings were made of participants experiencing a potentially painful activity (being washed or dressed) and a rest situation and pain observed using Rotterdam Elderley Pain Observation Scale (REPOS) • REPOS: a 14 item observational pain scale: 1: Tense face; 2: Grimace; 3: Eyes (almost) squeezed; 4: Raising upper lip; 5: Frightened/ fearful look; 6: Aggression/ anger; 7: Panicky/ panic attacks; 8: Not cooperating; 9: Seeking comfort; 10: Moving body part; 11: Crying softly; 12: Moaning/groaning; 13: Sounds of restlessness/ verbal expressions; 14: Holding breath/ faltering Scoring was on a four point scale (0=not present; 1=sometimes present; 2=often present; 3= always present) • Numeric rating scale (NRS) 0= no pain to 10= worst possible pain
Interventions	Both resident and nurses (NRS resident and NRS nurse) rated the pain experience. The recordings were observed and scored with REPOS and validity was estimated by correlating REPOS with NRS nurse and NRS resident ratings
Results	**Rates of accurately identified intercurrent illness in people living with dementia** • Only reports differences between case and control groups of REPOS activity score –

Bibliographic reference	Van Herk (2009)

Case group = 5 (IQR 3 to 6) Control group = 4 (IQR 3 to 5)

Diagnostic test accuracy (including Sensitivity, Specificity, PPV, NPV etc.)

- REPOS verification

Table shows Spearman Rank correlations between REPOS and other pain scales

	Case group r (95% CI)	Control group r (95% CI)
REPOS during painful activity	-	0.01 (-0.27 to 0.29)
NRS- resident	0.19 (0.01 to 0.35)	0.36 (0.09 to 0.58)
NRS-nurse	0.75 (0.66 to 0.82)	0.61 (0.40 to 0.76)
PAINAD		
REPOS at rest		
NRS- resident	-	0.40 (0.14 to 0.61)
NRS-nurse	-0.12 (0.01 to 0.35)	0.20 (-0.08 to 0.45)
PAINAD	0.64 (0.52 to 0.73)	0.66 (0.46 to 0.80)

Table shows logistic regression on scores of painful activity (case/ control is criterion and pain behaviours are independent variable s

Behaviour	OR	P (significance)	95%CI
Tense face	-	-	
Grimace	1.05	0.88	0.53 to 2.08
Frightened/fearful look	1.71	0.17	0.79 to 3.72
Eyes (almost) squeezed	1.21	0.65	0.53 to 2.73
Raising upper lip	0.94	0.87	0.48 to 0.186
Moving body part	1.56	0.27	0.71 to 3.41
Panicky/ panic attack	3.67	0.01	1.34 to 10.08
Not cooperating	3.76	0.09	0.87 to 17.05
Seeking comfort	1.25	0.63	0.51 to 3.04
Aggression/ anger	11.73	0.02	1.51 to 91.06
Moaning/ groaning	3.13	0.01	1.42 to 6.87
Sounds of restlessness/ verbal expressions	2.53	0.08	0.91 to 7.07
Holding breath/ faltering respiration	1.11	0.77	0.54 to 2.31

Bibliographic reference	Van Herk (2009)
	Clinical outcomes including cognitive, functional and behavioural ability • Not reported **Health related quality of life of people living with dementia** • Not reported **Resource use and cost** • Not reported
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Unclear • Did the authors use an appropriate method to answer their question? Unclear • Were cases recruited in an acceptable way? Unclear • Were controls recruited in an acceptable way? Unclear • Was exposure accurately measured to minimise bias? Unclear • Have the authors taken into account confounding factors? Unclear • How precise are the results? P values Cis provided • Can the results be applied to the local population? Unclear • Do the results fit with other evidence? Unclear

Bibliographic reference	Lukas (2013)
Study type	Retrospective cohort
Aim of the study	To determine whether observer-rated pain assessment tools can be used to determine presence of pain and evaluate pain intensity in older people with moderate to severe cognitive impairment
Country(ies) where study carried out	Australia
Study dates	Not reported
Source of funding	Supported by an Australian Government NHMRC Project Grant
Sample size	Out of a total of 206 people were eligible for inclusion, 125 participants were included in analysis Cognitively impaired participants with MMSE <20 (n=65 MMSE 13.57 ± 4.29; 47% female) Cognitively intact participants with MMSE ≥24 (n=60 MMSE 27.35 ± 2.10; 47% female)
Inclusion criteria	Inclusion criteria was set to ensure a representative heterogeneous sample of elderly institutionalised people.

Bibliographic reference	Lukas (2013)
Exclusion criteria	People who were unconscious or unresponsive (defined by Glasgow Coma scale) were excluded from participation. Participants who had mild cognitive impairment (MMSE 23-20) and residents unable to provide verbal response, and participants without an MMSE score were excluded from analysis.
Details	Participants were observed during a movement protocol or at rest, Pain status was established using self-report and observational information was collected immediately after each other • Self-report ○ Pain today (y/n); ○ Pain Now (y/n); ○ McGill Present pain verbal index rating (no pain, mild, discomforting, distressing, horrible, excruciating) • Observational measures ○ Abbey Pain scale (vocalization, facial expression, change in body language, behavioural, physiological and physical changes) Scored 0 to 3 (absence to severe) up to maximum 18 points ○ PAINAD ○ NOPPAIN
Interventions	Participants were observed completing a movement exercise with participants observed at rest and during movement (walking a minimum of 6 steps, returning to sitting). Observational measurements were taken followed by administration of questionnaires
Results	**Rates of accurately identified intercurrent illness in people living with dementia** Accuracy of multivariate behavioural scales when referenced to self-report was not assessed by cognitive status **Diagnostic test accuracy (including Sensitivity, Specificity, PPV, NPV etc.)** • Level of agreement regarding presence of pain Table shows level of agreement between self and observational reports of pain

	Self-rated pain yes/no[b]					
Observational rated pain (yes/no)[a]	**Normal cognition**			**Impaired cognition**		
	Agreement	False positive error	False negative error	Agreement	False positive error	False negative error
Abbey	78.3%	15.0%	6.7%	66.1%	30.8%	3.1%
PAINAD	73.3%	16.7%	10.0%	66.1%	30.8%	3.1%

Bibliographic reference	Lukas (2013)

NOPPAIN	80.0%	10.0%	10.0%	69.2%	24.6%	6.2%

(a) Receiver operating characteristic curve derived dichotomous proxy rating
(b) McGill: Pain yes/no self-report

- Correlations regarding pain intensity

  Table shows correlations between self-ratings and observational ratings of pain intensity

Self-rated pain[a]	Abbey		PAINAD		NOPPAIN	
	Intact (n=59)	Impaired (n=49)	Intact (n=59)	Impaired (n=49)	Intact (n=59)	Impaired (n=49)
r[b]	0.314	0.563	0.241	0.532	0.320	0.680
P	0.015	<0.001	0.066	<0.001	0.013	<0.001

*(a) Measured using McGill rating scale (0*5)*
(b) Spearman Rho correlation coefficient

Clinical outcomes including cognitive, functional and behavioural ability

- Not reported

Health related quality of life of people living with dementia

- Not reported

Resource use and cost

- Not reported

Overall risk of bias	Moderate

Risk of bias further info	

- Did the study address a clearly focused issue? Yes
- Was the cohort recruited in an acceptable way? Yes
- Was the exposure accurately measured to minimise bias? Yes
- Was the outcome accurately measured to minimise bias? Yes
- Have the authors identified all confounding factors? Unclear
- Have they taken confounding factors into account in the design/analysis? Unclear
- Was the follow up of subjects complete enough? n/a
- Was the follow up of subjects long enough? n/a
- How precise are the results? P values provided
- Can the results be applied to the local population? unclear
- Do results fit with other evidence? unclear

Falls assessment

Bibliographic reference	Kato-Narita et al (2010)
Study type	Case control study
Aim of the study	To analyse the correlation between falls and loss of functional capacity in people with Alzheimer's disease and those without cognitive impairment
Country(ies) where study carried out	Brazil
Study dates	Not reported
Source of funding	Not reported
Sample size	48 participants diagnosed with Alzheimer's disease (14 (29%) male; 34 (71%) female; mean age 77 years; mean MMSE 16.2 25 participants with CDR 1 mild Alzheimer's disease and 23 as CDR 2 moderate Alzheimer's disease) 40 participants without cognitive impairment were included as a control group (18 (45%) male; 22 (55%) female mean age 74.5 years; mean MMSE26.8).
Inclusion criteria	Participants aged 60 years or over with a diagnosis of Alzheimer's disease (according to NINCDS-ADRDA and classified according to Clinical Dementia Rating (CDR) scale were included. Participants in control group were not cognitively impaired and recruited according to the Mayo Older American Normative Studies criteria.
Exclusion criteria	Participants who had non-Alzheimer's disease, or other neurological disorders; severe dementia (CDR higher than 2); limited mobility due to pain or amputation; presence of vertigo or dizziness; signs of vestibular syndrome; episodes of loss of consciousness; on treated depression; visual impairment not corrected by glasses; severe hypoacusia were excluded.
Details	Participants answered a questionnaire addressing walking aids, history of falls in last 12 months
Interventions	Functional abilities were assessed through Disability Assessment for Dementia questionnaire (based on effective realization criteria- which explored whether participant had the functional capacity to complete the motor activity) Balance was assessed through Berg Balance Scale (BBS)
Results	**Rates of accurately identified intercurrent illness in people living with dementia** • Performance on scale Table showing mean (SD) and range of the sample and intergroup comparison for performance of Berg Balance Scale

Group	Controls	AD (total)	CDR1	CDR2	P (two tailed)	Multiple comparison
Total sample	53.1 (2.9)	51.3 (3.1)	51.8 (3.1)	50.7 (3)	0.001	CDR 0 ≠

Bibliographic reference	Kato-Narita et al (2010)

	46-56	43-56	43-56	44-56		CDR 2
Fallers	52.2 (3) 46-56	50.8 (3.2) 43-56	50.9 (3.4) 43-56	50.6 (2.9) 44-55	0329	N?A
Non fallers	53.8 (2.6) 47-56	51.7 (3) 44-56	52.7 (2.6) 47-56	50.7 (3.3) 44-56	0.015	CDR 0 ≠ CDR 2

- Number of falls

Table shows mean number of falls (SD) range and percentage of participants that had a fall in previous 12 months

Variable	Controls	AD	CDR1	CDR2	p (two tailed)
Number of falls					
Total sample	0.6 (0.9) 0-3	0.9 (1.2) 0-6	1.2 (1.5) 0-6	0.6 (0.8) 0-3	0.415
Fallers	1.4 (0.8) 1-3	1.7 (1.2) 1-6	2 (1.52) 1-6	1.3 (0.6) 1-3	0.662
Occurrence of falls (no of participants %)	18 (45%)	24 (50%)	13 (52%)	11 (47.8%)	0.772
Recurrence of falls (no of participants %)	5 (12.5%)	9 (18.7 %)	6 (25%)	3 (14.3%)	0.617

There was a negative correlation between number of falls and performance on Berg Balance scale among fallers and the moderate AD group (r=-0.383, p=0.015)

Diagnostic test accuracy (including Sensitivity, Specificity, PPV, NPV etc.)

- Not reported

Clinical outcomes including cognitive, functional and behavioural ability

- Functional capacity

Table shows mean (SD) and range for performance of sample and intergroup comparison for effective realisation

Group	Controls	AD	CDR1	CDR2	P (two tailed)	Multiple comparison
Total sample	100 (0)	73.1 (17.8)	80.9 (13.8)	64.6 (18)	<0.0001	CDR 0 ≠ CDR 1 and

Bibliographic reference	Kato-Narita et al (2010)

		17.6-100	46.6-100	17.6-100		CDR 2
Fallers	100 (0)	74.8 (18.1) 35.3-100	80.9 (15.4) 46.6-100	67.5 (19) 35.3-100	<0.0001	All groups differ
Non fallers	100 (0)	71.4 (17.6) 17.6-100	80.9 (12.5) 64.3-100	62 (17.4) 17.6-87.5	<0.0001	All groups differ

There was a negative correlation between number of falls and BBS scores in the moderate AD group (r=-0.613, p=0.045)

Health related quality of life of people living with dementia

- Not reported

Resource use and cost

- Not reported

Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Did the authors use an appropriate method to answer their question? • Were cases recruited in an acceptable way? Yes • Were controls recruited in an acceptable way? Yes • Was exposure accurately measured to minimise bias? Unclear • Have the authors taken into account confounding factors? Unclear • How precise are the results? P values provided • Can the results be applied to the local population? Unclear • Do the results fit with other evidence? unclear

Delirium assessment

Bibliographic reference	Sepulveda et al (2015)
Study type	Cross sectional study
Aim of the study	To assess Delirium rating scale- revised 98 against other assessment scales in people with dementia compared to those without cognitive impairment
Country(ies) where study carried out	Spain
Study dates	Not reported
Source of funding	No formal funding for the study

Bibliographic reference	Sepulveda et al (2015)
Sample size	125 participants eligible for participation A subsample of 85 participants were classified as having possible dementia (according to Spanish Informant questionnaire on Cognitive Decline in the Elderley score >85) (45 (56%) female; 40 (44%) male
Inclusion criteria	All newly admitted patients to a skilled nursing facility during a 6 month period and rated within 24*48 hours after admission were eligible
Exclusion criteria	Not reported
Details	Clinical data was obtained and charts were reviewed for a recent diagnosis of delirium. All participants were evaluated 24*48 hours after admission with the Spanish Dementia Rating Scale Revised 98 and other classification systems.
Interventions	The classification systems used to assess DRS-R98 against delirium diagnostic criteria were: DSM111-R; DSM-5 DSM-IV ICD-10 Receiver operating curve (ROC) analysis of Area under the curve for the whole sample and for those with dementia was reported
Results	**Rates of accurately identified intercurrent illness in people living with dementia** Patients with dementia had a significantly higher occurrence of delirium based on all 4 diagnostic criteria compared to those without dementia DSM-5 Dementia group = 30.6% non-dementia = 12.5% (χ^2 = 4.772, p=0.029) ICD-10 Dementia group = 21.2% non-dementia group = 5% (χ^2 = 5.296, p=0.021) DSM-III-R Dementia group = 35.3% non-dementia group = 10% (χ^2 = 8.788, p=0.003) DSM-IV Dementia group = 28.2% non-dementia group = 10% (χ^2 =5.203, p=0.023) **Diagnostic test accuracy (including Sensitivity, Specificity, PPV, NPV etc.)** • ROC analysis and AUC for diagnosis of delirium using DRS-R98 versus four different diagnostic criteria DSM III-R Dementia group (AUC 88.55% SE: 4.30) non dementia group (AUC 92.92% SE 2.69) DSM-IV Dementia group (AUC 88.29% SE: 4.22) non dementia group (AUC 92.43% SE 2.67) DSM-5 Dementia group (AUC 87.03% SE: 4.25) non dementia group (AUC 91.03% SE 2.77) ICD-10 Dementia group (AUC 86.69% SE: 3.80) non dementia group (AUC 90.50% SE 3.80) **Clinical outcomes including cognitive, functional and behavioural ability**

Bibliographic reference	Sepulveda et al (2015)
	• Not reported **Health related quality of life of people living with dementia** • Not reported **Resource use and cost** • Not reported
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Unclear • Was the exposure accurately measured to minimise bias? Unclear • Was the outcome accurately measured to minimise bias? Unclear • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? N/A • Was the follow up of subjects long enough? N/A • How precise are the results? P values provided • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

E.14.1.2 Management of intercurrent illness

Pain management

Bibliographic reference	Fuchs-Lacelle (2008), Pain assessment as intervention: a study of older adults with severe dementia, Clinical Journal of Pain
Study type	Cluster RCT
Aim of the study	To determine whether systematic pain assessment leads to improved pain management practices and decreases nursing stress in comparison with a control condition
Country(ies) where study carried out	Canada
Study dates	Not reported
Source of funding	Canadian Institute of Health Research
Sample size	21 units within 12 long-term care facilities 173 long-term care participants 61 carers
Inclusion criteria	Presence of dementia with severe communication impairment and over the age of 65
Exclusion criteria	None
Interventions	Intervention: • Completion of the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) every other day for 3 months Control: • Completion of an Activity Log every other day for 3 months
Results	See table below

Variable	Coefficient	Standard error	p value
PACSLAC scores			
Time	-0.01	0.00	0.03
Activity log scores			
Time	0.00	0.00	0.94
Sex	4.57	1.39	0.01
Physical condition	-4.33	0.76	0.00
PRN medication quantification score			
Time	0.00	0.00	0.00

Bibliographic reference	Fuchs-Lacelle (2008), Pain assessment as intervention: a study of older adults with severe dementia, Clinical Journal of Pain			
	Group	0.01	0.08	0.86
	Cognitive Impairment	0.05	0.004	0.00
	Physical condition	-0.02	0.55	0.97
	Group x time	0.01	0.001	0.00
	Nursing stress scale: total score			
	Time	-2.28	0.73	0.00
	Group	-6.10	2.84	0.04
	Registered nurse*	11.67	3.43	0.00
	Registered psychiatric nurse*	13.19	4.32	0.00
	Licensed practical nurse*	1.48	5026	0.78
	Nursing stress scale: inadequate preparation			
	Time	-0.15	0.09	0.12
	Group	-0.74	0.31	0.02
	Registered nurse*	0.12	0.37	0.76
	Registered psychiatric nurse*	0.39	0.47	0.41
	Licensed practical nurse*	-0.42	0.57	0.46
	Nursing stress scale: lack of support			
	Intercept	2.67	0.49	0.00
	Time	-0.03	0.12	0.83
	Group	-1.11	0.39	0.01
	Registered nurse*	0.92	0.47	0.06
	Registered psychiatric nurse*	0.65	0.59	0.28
	Licensed practical nurse*	-0.08	0.71	0.91
	Nursing stress scale: uncertainty concerning treatment			
	Time	-0.29	0.14	0.05
	Group	-1.30	0.42	0.00
	Registered nurse*	1.85	0.51	0.00
	Registered psychiatric nurse*	2.74	0.64	0.00

Bibliographic reference	**Fuchs-Lacelle (2008), Pain assessment as intervention: a study of older adults with severe dementia, Clinical Journal of Pain**
	Maslach Burnout Inventory: emotional exhaustion Time -1.04 0.58 0.08 Group -7.07 3.08 0.03 *Reference group is special care aid
Overall risk of bias	Moderate
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Unclear • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Yes • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Yes • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Bibliographic reference	**Husebo (2014), Efficacy of pain treatment on mood syndrome in patients with dementia: a randomized clinical trial, International Journal of Geriatric Psychiatry**
Study type	Cluster RCT (Secondary publication of Sandvik 2014)
Aim of the study	To determine whether a stepwise protocol for treating pain in nursing home residents with moderate to severe dementia is more effective than usual care
Country(ies) where study carried out	Norway
Study dates	October 2009-June 2010
Source of funding	Norwegian Research Council
Sample size	60 nursing units within 18 nursing homes 352 people with dementia
Inclusion criteria	• 65 years or older

<table>
<tr><td>Bibliographic reference</td><td>Husebo (2014), Efficacy of pain treatment on mood syndrome in patients with dementia: a randomized clinical trial, International Journal of Geriatric Psychiatry</td></tr>
<tr><td></td><td>• Residing in a nursing home for at least 4 weeks
• Diagnosis of Alzheimer’s disease or other dementia
• MMSE < 20</td></tr>
<tr><td>Exclusion criteria</td><td>• Expected survival of less than 6 months
• Severe psychosis
Allergy to any study drug</td></tr>
<tr><td>Interventions</td><td>Intervention:
• Stepwise protocol for treating pain – based on the 2009 recommendations of the American Geriatric Society Panel for pharmacological management of persistent pain in older adults
○ Acetaminophen
○ Morphine
○ Buprenorphine
○ Pregabalin
○ Combination therapy
Control:
• Usual care</td></tr>
<tr><td>Results</td><td>8 week follow-up:
<table>
<tr><th rowspan="2">Outcome</th><th colspan="2">Control</th><th colspan="2">Intervention</th><th>p value*</th></tr>
<tr><td>Baseline (SD)</td><td>Week 8 (SD)</td><td>Baseline (SD)</td><td>Week 8 (SD)</td></tr>
<tr><td>NPI-NH total score</td><td>31.9 (21.9)</td><td>26.6 (20.1)</td><td>33.8 (21.7)</td><td>18.9 (17.6)</td><td><0.001</td></tr>
<tr><td>Mood symptom factor group</td><td>16.9 (12.5)</td><td>14.7 (11.5)</td><td>18.3 (13.0)</td><td>9.9 (10.6)</td><td><0.001</td></tr>
<tr><td>Depression</td><td>2.9 (3.7)</td><td>2.1 (2.9)</td><td>2.5 (3.3)</td><td>1.6 (2.9)</td><td>0.025</td></tr>
<tr><td>Anxiety</td><td>3.2 (4.1)</td><td>2.5 (3.7)</td><td>3.3 (4.2)</td><td>1.8 (3.1)</td><td>0.125</td></tr>
<tr><td>Apathy</td><td>2.5 (3.6)</td><td>2.6 (3.7)</td><td>3.6 (4.3)</td><td>1.7 (3.3)</td><td>0.017</td></tr>
<tr><td>Irritability</td><td>3.7 (3.7)</td><td>2.9 (3.4)</td><td>4.2 (4.1)</td><td>2.3 (3.0)</td><td>0.092</td></tr>
<tr><td>Night-time behaviours</td><td>2.2 (3.3)</td><td>1.9 (3.1)</td><td>1.6 (2.7)</td><td>1.3 (2.6)</td><td>0.050</td></tr>
<tr><td>Appetite and eating disorders</td><td>2.5 (4.0)</td><td>2.7 (4.0)</td><td>2.4 (4.1)</td><td>1.3 (2.9)</td><td>0.005</td></tr>
</table></td></tr>
</table>

Bibliographic reference	Husebo (2014), Efficacy of pain treatment on mood syndrome in patients with dementia: a randomized clinical trial, International Journal of Geriatric Psychiatry
	*Mann-Whitney U-test
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? No • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Bibliographic reference	Sandvik (2014), Impact of a stepwise protocol for treating pain on pain intensity in nursing home patients with dementia: a cluster randomized trial, European Journal of Pain
Study type	Cluster RCT
Aim of the study	To determine whether a stepwise protocol for treating pain in nursing home residents with moderate to severe dementia is more effective than usual care
Country(ies) where study carried out	Norway
Study dates	October 2009-June 2010
Source of funding	Norwegian Research Council
Sample size	60 nursing units within 18 nursing homes 352 people with dementia
Inclusion criteria	• 65 years or older • Residing in a nursing home for at least 4 weeks • Diagnosis of Alzheimer’s disease or other dementia • MMSE < 20

Bibliographic reference	**Sandvik (2014), Impact of a stepwise protocol for treating pain on pain intensity in nursing home patients with dementia: a cluster randomized trial, European Journal of Pain**
Exclusion criteria	• Expected survival of less than 6 months • Severe psychosis • Allergy to any study drug
Interventions	Intervention: • Stepwise protocol for treating pain – based on the 2009 recommendations of the American Geriatric Society Panel for pharmacological management of persistent pain in older adults o Acetaminophen o Morphine o Buprenorphine o Pregabalin o Combination therapy Control: • Usual care

Results

Pain at 8 week follow-up:

Pain location	**Control**			**Intervention**			**p value***
	Baseline (SE)	Week 8 (SE)	Difference	Baseline (SE)	Week 8 (SE)	Difference	
Hands	0.8 (0.2)	1.0 (0.1)	0.161	1.1 (0.2)	0.8 (0.2)	-0.243	0.014
Arms	1.7 (0.2)	1.8 (0.2)	0.119	1.8 (0.2)	1.2 (0.2)	-0.677	0.004
Legs	2.6 (0.2)	2.2 (0.2)	-0.342	2.0 (0.2)	1.6 (0.2)	-0.375	0.859
Turn over	1.9 (0.2)	2.0 (0.2)	0.026	2.0 (0.2)	1.3 (0.2)	-0.739	0.008
Sit	1.6 (0.2)	2.0 (0.2)	0.398	2.1 (0.2)	1.2 (0.2)	-0.826	<0.001
Part 1 total score – musculoskeletal pain	8.7 (0.8)	8.9 (0.2)	0.393	9.0 (0.8)	5.8 (0.8)	-3.233	<0.001
Head, mouth, neck	1.0 (0.1)	0.9 (0.1)	-0.091	1.4 (0.2)	0.8 (0.1)	-0.627	0.011
Heart, lung, chest	0.8 (0.2)	0.8 (0.1)	0.049	0.8 (0.1)	0.4 (0.1)	-0.426	0.008
Abdomen	0.9 (0.1)	0.7 (0.1)	-0.143	1.0 (0.2)	0.4 (0.1)	-0.546	0.069

Bibliographic reference	Sandvik (2014), Impact of a stepwise protocol for treating pain on pain intensity in nursing home patients with dementia: a cluster randomized trial, European Journal of Pain

Pelvis, genital organs	1.6 (0.2)	1.6 (0.2)	-0.023	1.8 (0.2)	0.8 (0.2)	-0.944	0.001
Skin	1.7 (0.2)	1.4 (0.2)	-0.208	1.5 (0.2)	1.0 (0.2)	-0.570	0.145
Part 2 total score – internal organs, head and skin	5.9 (0.5)	5.4 (0.4)	-0.416	6.5 (0.5)	3.4 (0.4)	-3.113	<0.001
Overall pain intensity	3.7 (0.2)	3.4 (0.2)	-0.297	3.8 (0.2)	2.1 (0.2)	-1.655	<0.001

*Random-intercept model in a two-way repeated-measure configuration

Adverse events:
Six patients had treatment related adverse events (1 nausea, 1 rash, 2 reduced appetite, 2 somnolence)

Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? No • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Delirium

Bibliographic reference	Kolanowski (2011), Pilot study of a nonpharmacological intervention for delirium superimposed on dementia, Research in Gerontological Nursing
Study type	RCT
Aim of the study	To determine the clinical feasibility and potential for using cognitively stimulating activities in the treatment of

<table>
<tr><td>Bibliographic reference</td><td>Kolanowski (2011), Pilot study of a nonpharmacological intervention for delirium superimposed on dementia, Research in Gerontological Nursing</td></tr>
<tr><td></td><td>delirium superimposed on dementia</td></tr>
<tr><td>Country(ies) where study carried out</td><td>USA</td></tr>
<tr><td>Study dates</td><td>Not reported</td></tr>
<tr><td>Source of funding</td><td>Social Science Research Institute, Pennsylvania State University</td></tr>
<tr><td>Sample size</td><td>16 people with delirium superimposed on dementia</td></tr>
<tr><td>Inclusion criteria</td><td>• 65 years or older
• English speaking
• Community dwelling
• Diagnosis of mild to moderate dementia (chart review and 0.5-2.0 score on the Clinical Dementia Rating Scale)
• Presence of delirium (at least two features on the Confusion Assessment Method)</td></tr>
<tr><td>Exclusion criteria</td><td>• Neurological or neurosurgical disease associated with cognitive impairment other than dementia
• Nonverbal
• Severe hearing or vision impairment
• No family or caregiver to interview</td></tr>
<tr><td>Interventions</td><td>Intervention:
• Standard nursing care and prescribed rehabilitation therapies, plus 30 minutes per day of cognitively stimulating recreational activities for 30 days.
Control:
• Standard nursing care and prescribed rehabilitation therapies</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th rowspan="2">Variable</th><th colspan="2">Mean (SD)</th><th colspan="3">p values</th></tr>
<tr><th>Intervention</th><th>Control</th><th>Group</th><th>Time</th><th>Group by time</th></tr>
<tr><td>Barthel Index</td><td>47.74 (21.43)</td><td>43.41 (12.89)</td><td>0.9656</td><td><0.0001</td><td>0.001</td></tr>
<tr><td>Confusion Assessment Method</td><td>0.79 (0.47)</td><td>0.36 (0.52)</td><td>0.8482</td><td>0.018</td><td>0.1128</td></tr>
<tr><td>Delirium Rating Scale</td><td>6.71 (9.02)</td><td>8.51 (9.57)</td><td>0.6599</td><td>0.5802</td><td>0.0842</td></tr>
<tr><td>MMSE</td><td>16.84 (9.61)</td><td>16.25 (10.37)</td><td>0.5233</td><td>0.2495</td><td>0.0298</td></tr>
<tr><td>Digit Span</td><td>5.29 (1.55)</td><td>5.18 (1.70)</td><td>0.8703</td><td>0.1594</td><td>0.113</td></tr>
</table>
</td></tr>
<tr><td>Overall risk of bias</td><td>High</td></tr>
<tr><td>Risk of bias further info</td><td>• Did the study address a clearly focused issue? Yes</td></tr>
</table>

Bibliographic reference	Kolanowski (2011), Pilot study of a nonpharmacological intervention for delirium superimposed on dementia, Research in Gerontological Nursing
	• Was the cohort recruited in an acceptable way? Unclear • Was the exposure accurately measured to minimise bias? Unclear • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? No • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Unclear • How precise are the results? Small sample size so low precision • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Rehabilitation following hip fracture

Bibliographic reference	Smith (2015), Enhanced rehabilitation and care models for adults with dementia following hip fracture surgery, Cochrane Database of Systematic Reviews
Study type	Systematic review
Aim of the study	• To assess the effectiveness of models of care including enhanced rehabilitation strategies designed specifically for people with dementia following hip fracture surgery compared to usual care. • To assess the effectiveness for people with dementia of models of care including enhanced rehabilitation strategies which are designed for all older people, regardless of cognitive status, following hip fracture surgery compared to usual care.
Country(ies) where study carried out	N/A
Study dates	Search up to 1st June 2014
Source of funding	N/A
Inclusion criteria	Randomised and quasi-randomised controlled clinical trials (RCTs) evaluating the effectiveness for people with dementia of any model of enhanced care and rehabilitation following hip fracture surgery compared to usual care.
Exclusion criteria	None
Interventions	Intervention: • Enhanced models of care and/or rehabilitation: ○ Heightened surveillance for common postoperative complications following hip fracture in older people, namely, pressure sores, poor nutrition, embolic events, pneumonia and delirium.

Bibliographic reference	**Smith (2015), Enhanced rehabilitation and care models for adults with dementia following hip fracture surgery, Cochrane Database of Systematic Reviews**
	○ Staff training and strong communication across multidisciplinary teams ○ Care planning and discharge liaison Control: • Standard nursing, medical and therapy intervention
Results	Included five trials with a total of 316 participants. Four trials evaluated models of enhanced interdisciplinary rehabilitation and care, compared with usual rehabilitation and care: • Two for inpatients only • Two for inpatients and at home after discharge. The fifth trial compared outcomes of geriatrician-led care in hospital to conventional care led by the orthopaedic team. All papers analysed subgroups of people with dementia/cognitive impairment from larger RCTs of older people following hip fracture. Trial follow-up periods ranged from acute hospital discharge to 24 months post-discharge. All studies were considered to be at high risk of bias in more than one domain. As subgroups of larger studies, the analyses lacked power to detect differences between the intervention groups. Further, there were important differences in the baseline characteristics of the participants in experimental and control groups. The quality of the evidence for all outcomes to was rated as low' or 'very low'. No studies assessed cognitive function or quality of life. There was low-quality evidence that enhanced care and rehabilitation in hospital led to lower rates of some complications and that enhanced care provided across hospital and home settings reduced the chance of being in institutional care at three months post-discharge (Odds Ratio (OR) 0.46, 95% confidence interval (CI) 0.22 to 0.95, 2 trials, n = 184), but this effect was more uncertain at 12 months (OR 0.90, 95% CI 0.40 to 2.03, 2 trials, n = 177). The effect of enhanced care and rehabilitation in hospital and at home on functional outcomes was very uncertain because the quality of evidence was very low from one small trial. Results on functional outcomes from other trials were inconclusive. The effect of geriatrician-led compared to orthopaedic-led management on the cumulative incidence of delirium was very uncertain (OR 0.73, 95% CI 0.22 to 2.38, 1 trial, n = 126, very low-quality evidence).
Overall risk of bias	Low
Risk of bias further info	The risk of bias of the systematic review was rated low, but the risk of bias in many of the studies included in the review was high

Bibliographic reference	**Stenvall (2007), A multidisciplinary, multifactorial intervention program reduces postoperative falls and injuries after femoral neck fracture, Osteoporosis International**
Study type	Cluster RCT

Bibliographic reference	**Stenvall (2007), A multidisciplinary, multifactorial intervention program reduces postoperative falls and injuries after femoral neck fracture, Osteoporosis International**
Aim of the study	To evaluate whether a postoperative multidisciplinary, intervention program, including systematic assessment and treatment of fall risk factors, active prevention, detection, and treatment of postoperative complications, could reduce inpatient falls and fall-related injuries after a femoral neck fracture
Country(ies) where study carried out	Sweden
Study dates	May 2000-December 2002
Source of funding	Vårdal Foundation, The Joint Committee of the Northern Health Region of Sweden, the JC Kempe Memorial Foundation, the Dementia Fund, the Foundation of the Medical Faculty, the Borgerskapet of Umeå Research Foundation, University of Umeå, the County Council of Västerbotten and the Swedish Research Council
Sample size	199 (including 64 people with dementia)
Inclusion criteria	• 70 years or older • Femoral neck fracture
Exclusion criteria	• Severe rheumatoid arthritis • Severe hip osteoarthritis • Pathological fracture • Severe renal failure • Bedridden before fracture
Interventions	Intervention: • Comprehensive geriatric assessments, management and rehabilitation • Active prevention, detection and treatment of postoperative complications such as falls, delirium, pain and decubitus ulcers Control: • Specialist orthopaedic unit following conventional postoperative routines
Results	Incidence rate ratio for falls in full population: 0.38 (0.20, 0.76) Incidence rate ratio for falls in dementia sub-population: 0.07 (0.01, 0.57)
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Unclear • Was the outcome accurately measured to minimise bias? Yes

Bibliographic reference	Stenvall (2007), A multidisciplinary, multifactorial intervention program reduces postoperative falls and injuries after femoral neck fracture, Osteoporosis International
	• Have the authors identified all confounding factors? Yes • Have they taken confounding factors into account in the design/analysis? No • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Unclear • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Falls

Bibliographic reference	Chan (2015), Efficacy of physical exercise in preventing falls in older adults with cognitive impairment: a systematic review and meta-analysis, JAMDA
Study type	Systematic review
Aim of the study	To determine whether the current evidence supports that physical exercise is also efficacious in preventing falls in older adults with cognitive impairment
Country(ies) where study carried out	N/A
Study dates	Search up to July 2013
Source of funding	Not stated
Inclusion criteria	RCTs that compared the efficacy of physical exercise with routine medical care or other controlled activities in preventing falls in older people with cognitive impairment • Cognitive impairment defined by either a standardised cognitive assessment or a diagnosis of dementia
Exclusion criteria	Trials where exercise was part of a multifactorial program
Interventions	Intervention: • Group or home-based exercise Control: • Routine care or less intensive interventions
Results	Included RCTs

Authors	N	Mean age	mean MMSE	Study population	Intervention	Control
Toulette (2003)	20	81.4	16.3	People with dementia living at home or	Group exercise	Daily routine

Bibliographic reference	Chan (2015), Efficacy of physical exercise in preventing falls in older adults with cognitive impairment: a systematic review and meta-analysis, JAMDA

				institutions with at least 2 previous falls		
Pitkälä (2013)	210	78.0	18.0	Home-dwelling patients with AD living with spousal caregivers	Home or group exercise	Routine medical care
Rolland (2007)	134	83.0	8.8	Patients with AD living in nursing homes	Group exercise	Routine medical care
Zieschang (2013)	122	82.1	21.7	Patients with mild to moderate dementia	Group exercise	Motor placebo training group
Lord (2003)	141	81.0	22.8	Older People, MMSE 20-24 living in apartment villages or hostels	Group exercise	Flexibility and relaxation program
Rosendahl (2008)	100	84.2	16.0	Dementia (DSM criteria) living in residential care facilities	Group exercise	Activities performed while sitting
Moseley (2009)	54	85.9	N/A	Dementia (SPMSQ)	Group exercise	Tailored program of limited weight-bearing exercises

Relative risk for number of falls (7 studies): 0.68 (0.51, 0.91)
Relative risk for number of fractures (2 trials): 1.47 (0.56, 3.81)

Relative risks of falls found to be 0.71 for group-exercise and 0.68 for home-based exercise from a Cochrane review of older people who do not necessarily have cognitive impairment

Overall risk of bias	Low
Risk of bias further info	The risk of bias of the systematic review was rated low, but the risk of bias in many of the studies included in the review was high

Bibliographic reference	Oliver (2006), Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses, BMJ
Study type	Systematic review
Aim of the study	To evaluate the evidence for strategies to prevent falls or fractures in residents in care homes and hospital inpatients and to investigate the effect of dementia and cognitive impairment
Country(ies) where study carried out	N/A
Study dates	Search up to January 2005
Source of funding	Department of Health Accidental Injury Prevention Programme
Inclusion criteria	Studies of patients in hospitals or care homes that reported the number of rate of falls or fractures or people who fell. Data had to be reported in such a way it was possible to calculate log relative risks and their variances. Studies could be included if they were trials with individual or cluster randomisation, case-control studies or observational cohort studies.
Exclusion criteria	None
Interventions	Multiple intervention types: • In hospital multifactorial interventions • In care home multifactorial interventions • Hip protectors in care homes • Removal of physical restraint • Fall alarm devices • Exercise • Changes or differences in physical environment • Calcium and vitamin D in care homes • Medication review
Results	Meta-regression for effect of dementia prevalence on intervention effect size : Rate ratio for falls p value: 0.72 Relative risk for fallers: 0.87 Rate ratio for fractures: 0.18
Overall risk of bias	Moderate
Risk of bias further info	The risk of bias of the systematic review was rated moderate due to the heterogeneity of studies included in the review, but the risk of bias in many of the studies included in the review was high

Bibliographic reference	Pitkälä (2013), Effects of the Finnish Alzheimer Disease Exercise Trial (FINALEX), JAMA Internal Medicine
Study type	RCT
Aim of the study	To investigate the effects of intense and long-term exercise on the physical functioning and mobility of home-dwelling patients with AD and to explore its effects on the use and costs of health and social services.
Country(ies) where study carried out	Finland
Study dates	April 2008-August 2009
Source of funding	Social Insurance Institution of Finland, Central Union for the Welfare of the Aged, Sohlberg Foundation, King Gustaf V and Queen Victoria's Foundation.
Sample size	210 home-dwelling patients with Alzheimer's disease and their carers
Inclusion criteria	• An established diagnosis of Alzheimer's disease • A spouse living at the same address • Aged 65 or older • No diagnosed terminal illness • The ability to walk independently with or without a mobility aid • At least 1 of: o 1 fall during the past year o Decreased walking speed o Unintentional weight loss
Exclusion criteria	None
Interventions	• Home-based exercise o Physiotherapist led individually tailored training • Group-based exercise o Physiotherapist led group exercise consisting of endurance, balance and strength training, and exercise for improving executive functioning • Control group o Usual care provided by the Finnish healthcare system, plus oral and written advice on nutrition and exercise methods
Results	**6 month follow-up** Mean number of falls (SD): • Home-based exercise 1.22 (2.05) • Group-based exercise 1.68 (3.29)

Bibliographic reference	Pitkälä (2013), Effects of the Finnish Alzheimer Disease Exercise Trial (FINALEX), JAMA Internal Medicine
	• Control group 2.71 (3.26) Proportion of people falling: • Home-based exercise 30/63 • Group-based exercise 28/60 • Control group 43/63 Adjusted mean annual cost (95% CI): • Home-based exercise $25,112 ($17,642, $32,581) • Group-based exercise $22,066 ($15,931, $28,199) • Control group $34,121 ($24,559, $43,681) Hospital admissions (sample): • Home-based exercise 29/68 • Group-based exercise 30/61 • Control group 37/65
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Yes • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Yes

Bibliographic reference	Shaw (2003), Multifactorial intervention after a fall in older people with cognitive impairment and dementia presenting to the accident and emergency department: randomised controlled trial, BMJ
Study type	RCT
Aim of the study	To investigate the effects of intense and long-term exercise on the physical functioning and mobility of home-

<table>
<tr><td>Bibliographic reference</td><td>Shaw (2003), Multifactorial intervention after a fall in older people with cognitive impairment and dementia presenting to the accident and emergency department: randomised controlled trial, BMJ</td></tr>
<tr><td></td><td>dwelling patients with AD and to explore its effects on the use and costs of health and social services.</td></tr>
<tr><td>Country(ies) where study carried out</td><td>UK</td></tr>
<tr><td>Study dates</td><td>Not reported</td></tr>
<tr><td>Source of funding</td><td>Alzheimer’s Society, Northern and Yorkshire NHS Executive</td></tr>
<tr><td>Sample size</td><td>274 cognitively impaired older people presenting to the accident and emergency department after a fall</td></tr>
<tr><td>Inclusion criteria</td><td>• Aged 65 or older
• MMSE < 24
• Presenting to the accident and emergency department after a fall (an event reported by either the person who fell or a witness, resulting in the patient inadvertently coming to rest on the ground or at another lower level with or without loss of consciousness or injury)</td></tr>
<tr><td>Exclusion criteria</td><td>• Unable to walk
• Medical diagnosis that was a likely attributable cause of index fall (e.g. cerebrovascular accident)
• Unfit for investigation within 4 months
• Unable to communicate for reasons other than dementia
• Living outside a 15 mile radius of the site of recruitment
• No major informant (someone in contact with the patient at least twice a week)</td></tr>
<tr><td>Interventions</td><td>• Intervention
○ Multifactorial assessment and intervention
• Control
○ Usual care from all health professional who were involved in their management</td></tr>
<tr><td>Results</td><td>1 year follow-up
<table>
<tr><th>Outcome</th><th>Intervention group (n=130)</th><th>Control group (n=144)</th><th>Relative risk (95% CI)</th></tr>
<tr><td>Patients falling in 1 year</td><td>96 (74%)</td><td>115 (80%)</td><td>0.92 (0.81, 1.05)</td></tr>
<tr><td>Median number of falls (IQ range)</td><td>3 (0, 7)</td><td>3 (1, 8)</td><td>-0.02 (-0.32, 0.09)</td></tr>
<tr><td>Median time (weeks) to first fall (IQ range)</td><td>11 (2, 41)</td><td>11 (2, 33)</td><td>P=0.459</td></tr>
<tr><td>Major injury</td><td>37 (28%)</td><td>31 (21%)</td><td>1.32 (0.87, 2.00)</td></tr>
</table></td></tr>
</table>

Bibliographic reference	**Shaw (2003), Multifactorial intervention after a fall in older people with cognitive impairment and dementia presenting to the accident and emergency department: randomised controlled trial, BMJ**			
	Fractured neck or femur	6 (5%)	12 (8%)	0.55 (0.21, 1.43)
	Fall related A&E attendance	52 (40%)	46 (32%)	1.25 (0.91, 1.72)
	Fall related hospital admission	19 (15%)	19 (13%)	1.11 (0.61, 2.00)
	Mortality	27 (21%)	29 (20%)	1.03 (0.65, 1.64)
Overall risk of bias	Low			
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Unclear • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Yes • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear			

Bibliographic reference	**Suttanon (2013), Feasibility, safety and preliminary evidence of the effectiveness of a home-based exercise programme for older people with Alzheimer's disease: a pilot randomized controlled trial, Clinical Rehabilitation**
Study type	RCT
Aim of the study	To evaluate the feasibility and safety of a home-based exercise programme for people with Alzheimer's disease, and to provide preliminary evidence of programme effectiveness in improving balance and mobility and reducing falls risk
Country(ies) where study carried out	Australia
Study dates	Not reported
Source of funding	National Ageing Research Institute

Bibliographic reference	**Suttanon (2013), Feasibility, safety and preliminary evidence of the effectiveness of a home-based exercise programme for older people with Alzheimer's disease: a pilot randomized controlled trial, Clinical Rehabilitation**
Sample size	40 people with mild to moderate Alzheimer's disease
Inclusion criteria	• Diagnosis of Alzheimer's disease confirmed from specialist or Memory Clinic assessment • Alzheimer's symptoms of mild to moderate severity (MMSE≥10) • Could walk outdoors with no more support than a single-point stick • Living in the community
Exclusion criteria	• Serious orthopaedic condition (e.g. recent lower limb surgery, severe lower limb arthritis) • Major neurological disorder (e.g. stroke, Parkinson's disease) that could potentially restrict functional mobility
Interventions	• Home-based exercise programme ○ Six-month individualised home-based exercise programme supervised by a physiotherapist ○ Based on the Otago home-exercise programme • Control (education) programme ○ Education and information programme delivered by an occupational therapist ○ Designed to provide the same number of home visits and phone calls as the exercise programme
Results	**6 month follow-up** Proportion of people falling: • Home-based exercise 9/19 • Control group 7/21 Mean AQOL score (SD) • Home-based exercise 25.63 (4.50) • Control group 25.43 (6.31) Caregivers' mean AQOL score (SD) • Home-based exercise 25.12 (3.98) • Control group 21.53 (4.35) Caregivers' mean Zarit Burden score (SD) • Home-based exercise 28.19 (17.43) • Control group 26.50 (11.56)
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes

Bibliographic reference	Suttanon (2013), Feasibility, safety and preliminary evidence of the effectiveness of a home-based exercise programme for older people with Alzheimer's disease: a pilot randomized controlled trial, Clinical Rehabilitation
	• Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Yes • Have they taken confounding factors into account in the design/analysis? Yes • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Yes • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Yes

Bibliographic reference	Tchalla (2013), Preventing and managing indoor falls with home-based technologies in mild and moderate Alzheimer's disease patients: pilot study in a community dwelling, Dementia and Geriatric Cognitive Disorders
Study type	RCT
Aim of the study	To determine the effectiveness of home-based technologies coupled with teleassistance service in older people with Alzheimer's disease
Country(ies) where study carried out	France
Study dates	July 2009-June 2010
Source of funding	Corrèze Téléassistance, Fondation Caisse d'Épargne
Sample size	96 people with Alzheimer's disease
Inclusion criteria	• 65 years or older • Diagnosis of Alzheimer's disease • Living at home • Registered in the frail elderly people register
Exclusion criteria	• Severe dementia (MMSE < 10) • Already in a falls rehabilitation program
Interventions	• Intervention o Fall reduction program following an initial Comprehensive Gerontological Assessment. Participants were

Bibliographic reference	Tchalla (2013), Preventing and managing indoor falls with home-based technologies in mild and moderate Alzheimer's disease patients: pilot study in a community dwelling, Dementia and Geriatric Cognitive Disorders
	equipped with an HBTec-TS system ○ HBTec was a nightlight path with a wire sensor installed on the floor. The device turns on automatically when the person sets foot on the ground, showing the right path and improving awareness ○ Teleassistance service with a remote intercom, an electronic bracelet and a central hotline providing telephone support at all times • Control ○ Fall reduction program following an initial Comprehensive Gerontological Assessment. No HBTec-TS system was implemented
Results	**1 year follow-up** Proportion of people falling: OR 0.37 (0.15, 0.88)
Overall risk of bias	Low
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Unclear • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? Yes • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Unclear

Bibliographic reference	Toulotte (2003), Effects of physical training on the physical capacity of frail, demented patients with a history of falling: a randomised controlled trial, Age and Ageing
Study type	RCT
Aim of the study	To develop a physical training programme to improve balance in dependent, demented, people with a history of falling, and so decrease falls and increase autonomy.
Country(ies) where study carried out	France

Bibliographic reference	**Toulotte (2003), Effects of physical training on the physical capacity of frail, demented patients with a history of falling: a randomised controlled trial, Age and Ageing**
Study dates	Not reported
Source of funding	Institut Regional de Recherche sur le Handicap, Conseil Regional du Nord-Pas de Calais, Direction Régionale de la Recherche et de la Technologie
Sample size	20 elderly dementia patients with a history of falling
Inclusion criteria	• Diagnosis of dementia • MMSE < 20 • Fallen at least twice, either at home or in an institution • Fallen in the 3 months preceding the study • Could walk at least 10 meters with or without the assistance of a cane, frame or another person
Exclusion criteria	• Unstable medical condition
Interventions	• Training group o Two supervised 1 hour exercise sessions per week for 16 weeks o Exercises to develop muscular strength, proprioception, static and dynamic balance and flexibility • Control (education) programme o Routine care
Results	**Number of falls during 16 week training** Intervention: 0 Control: 6 **Falls in intervention group post-training** First month: 2 Second month: 2 Third month: 1 Sixth month: 7
Overall risk of bias	Moderate
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Unclear • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear

Bibliographic reference	Toulotte (2003), Effects of physical training on the physical capacity of frail, demented patients with a history of falling: a randomised controlled trial, Age and Ageing
	• Was the follow up of subjects complete enough? Yes • Was the follow up of subjects long enough? No (differential follow-up between arms) • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Yes

Bibliographic reference	Wesson (2013), A feasibility study and pilot randomised trial of a tailored prevention program to reduce falls in older people with mild dementia, BMC Geriatrics
Study type	RCT
Aim of the study	To test the feasibility and acceptability of a home hazard reduction and balance and strength exercise fall prevention program.
Country(ies) where study carried out	Australia
Study dates	June 2010-December 2010
Source of funding	Alzheimer's Association USA, Alzheimer's Australia Research
Sample size	22 person with dementia and carer dyads
Inclusion criteria	• Aged over 65 years • A specialist diagnosis of dementia or an Addenbrooke's Cognitive Examination score of ≤82 • A non-paid carer with a minimum of 3.5 hours per week of face to face contact • English speaking
Exclusion criteria	• Delirium or an acute medical condition • Severe psychiatric or progressive neurological disorder (except dementia) • MMSE < 12 • Severe visual impairment • Residents of aged care facilities

Interventions	• Home-based exercise program
	  ○ Strength and balance training exercises
	  ○ Home hazard reduction
	  ○ Six occupational therapist and five physiotherapist visits over 12 weeks

Bibliographic reference	Wesson (2013), A feasibility study and pilot randomised trial of a tailored prevention program to reduce falls in older people with mild dementia, BMC Geriatrics
	• Control group ○ Usual care
Results	**12 week follow-up** Mean number of falls (SD): • Home-based exercise 0.45 (1.03) • Control group 1.00 (1.48) Proportion of people falling: • Home-based exercise 2/11 • Control group 4/11 Caregivers' mean Zarit Burden score (SD) • Home-based exercise 19.14 (12.27) • Control group 11.64 (11.48)
Overall risk of bias	Moderate
Risk of bias further info	• Did the study address a clearly focused issue? Yes • Was the cohort recruited in an acceptable way? Yes • Was the exposure accurately measured to minimise bias? Yes • Was the outcome accurately measured to minimise bias? Yes • Have the authors identified all confounding factors? Unclear • Have they taken confounding factors into account in the design/analysis? Unclear • Was the follow up of subjects complete enough? No • Was the follow up of subjects long enough? Yes • How precise are the results? Sufficiently • Can the results be applied to the local population? Unclear • Do results fit with other evidence? Yes

E.14.2 Management strategies for people living with dementia and co-existing physical long term conditions

- What are the optimal management strategies (including treatments) for people living with dementia with co-existing physical long term conditions?

Bibliographic reference	**Adrait A, Perrot X, Nguyen M, Gueugnonc M, Petitota C, Collet L et al (2017) do hearing aids influence behavioural and psychological symptoms of dementia and quality of life in hearing impaired Alzheimer's disease patients and their caregivers? Journal of Alzheimer's Disease, 58, pp 109-121**
Study type	Multicentre double blind randomised controlled semi-crossover study
Aim	To examine the efficacy of fitting binaural HAs to patients with age related hearing loss and Alzheimer's disease
Patient characteristics	N= 48 Intervention group n= 22, mean age 83 years; 63.6% female, 36.4% male; mean MMSE=19.8 Control group m=26, mean age =82.3 years; 57.7% female, 43.3% male; mean MMSE=19.3
Inclusion/ exclusion criteria	Community dwelling participants with a probable diagnosis of Alzheimer's disease (DSM-IV); NINCDS-ADRDA) Inclusion criteria: Aged 65 years or over; MMSE 10-28 Bilateral sensorineural hearing loss between 21 and 80 dB) Had not benefitted from hearing aids in last 2 years Exclusion criteria Non Alzheimer's disease (based on medical history, clinical elements or medical imaging data) Recent introduction of cognitive behavioural treatment prior to study Recent changes in dosage for AChEIs or memantine or psychotropic medication
Intervention	Binaural active hearing aids
Comparison	Control intervention – placebo hearing aids (switched to active after 6 months)
Length of follow up	Data collected at baseline, 6 months and 1 months follow up
Outcomes measures and effect size	• **Clinical progression of comorbidity and associated symptoms** Treatment efficacy: Table shows change in scores at 6 and 12 months

	Active HAs Mean (SD)	**Placebo HAs (Mean (SD)**	**P value**
NPI 6 months	**23.6 (22.6)**	**26.1 (14.7)**	**0.3**
NPI 12 months	**20.1 (20.0)**	**24.4 (27.8)**	**0.1**

Bibliographic reference	**Adrait A, Perrot X, Nguyen M, Gueugnonc M, Petitota C, Collet L et al (2017) do hearing aids influence behavioural and psychological symptoms of dementia and quality of life in hearing impaired Alzheimer's disease patients and their caregivers? Journal of Alzheimer's Disease, 58, pp 109-121**
	IADL 6 months | **3.2 (2.0)** | **3.0 (2.3)** | **0.6** **IADL 12 months** | **3.0 (1.9)** | **2.7 (2.5)** | **0.3** **ZBI 6 months** | **22.4 (14.7)** | **26.3 (15.2)** | **0.5** **ZBI 12 months** | **20.3 (12.3)** | **25.7 (13.5)** | **0.3** **ADRQL 6 months** | **452.0 (88.4)** | **446.4 (45.8)** | **0.2** **ADRQL 12 months** | **474.5 (56.3)** | **431.3 (69.5)** | **0.0496**
Authors conclusion	This study did not find that fitting binaural hearing aids to people with hearing impairment and Alzheimer's disease improved neuropsychiatric symptoms, ADL or quality of life
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes, randomised chronological order • Were patients, health workers and study personnel blinded? Controlled cross over • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? How precise was the estimate of treatment effect? Cross over element, MD (SD) reported • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	**Kume K, Hanyu H, Sakurai, H, Takada Y (2012) Effects of telmisartan on cognition and regional cerebral blood flow in hypertensive patients with Alzheimer's disease, Geriatrics & gerontology international 12 1444-1586**
Study type	Prospective randomised open label trial
Aim	To compare the effects of telmisartan and amlodipine on cognitive function and regional cerebral blood flow (rCBF) and to determine whether telmisartan has beneficial effects for elderly hypertensive patients with Alzheimer's disease (AD).
Patient	Participants were enrolled from a memory clinic

<table>
<tr><td>Bibliographic reference</td><td>Kume K, Hanyu H, Sakurai, H, Takada Y (2012) Effects of telmisartan on cognition and regional cerebral blood flow in hypertensive patients with Alzheimer's disease, Geriatrics & gerontology international 12 1444-1586</td></tr>
<tr><td>characteristics</td><td>Telmisartan group (n=10; mean age= 78.8 ± 5.1 years 50% female; 50% male; amlodipine group (n=10; mean age = 79.0 ± 6.6 years; 60% female; 40% male)</td></tr>
<tr><td>Number of Patients</td><td>20 patients with mild AD (clinical dementia rating score = 1) (Diagnosis based on a diagnosis using the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer’s Disease and Related Disorders Association criteria for probable AD) and hypertension. Hypertension was defined as a systolic blood pressure (SBP) of at least 140mm Hg or a diastolic blood pressure (DBP) of at least 90mm Hg.</td></tr>
<tr><td>Inclusion/ exclusion criteria</td><td>Inclusion:
Participants with mild AD and hypertension enrolled from the memory clinic. Patients taking a stable (unchanged dose of donepezil in last 6 months) were also eligible.
Exclusion:
Any evidence of other neurological or psychiatric disorders sufficient to cause memory impairment, including depression or anxiety disorder, (based on a score ≥ 5 on the Geriatric Depression Scale).
Other exclusions included clinically significant medical problems, including cancer in the last 3 years, chronic renal or heart failure, severe pulmonary disease, or poorly controlled diabetes.</td></tr>
<tr><td>Intervention</td><td>An initial dose of 40 mg/day increasing to 80 mg/day</td></tr>
<tr><td>Comparison</td><td>An initial dose of 5 mg/ day increasing to 10 mg/ day</td></tr>
<tr><td>Length of follow up</td><td>6 months</td></tr>
<tr><td>Location</td><td>Japan</td></tr>
<tr><td>Outcomes measures and effect size</td><td>• Clinical progression of comorbidity and associated symptoms
Table showing mean changes in BP and pulse rate at baseline and at 6 months
<table>
<tr><th></th><th>Telmisartan (n=10)</th><th>Amlodipine (n=10)</th></tr>
<tr><td>BP & PR changes</td><td></td><td></td></tr>
<tr><td>SBP</td><td></td><td></td></tr>
<tr><td>Baseline</td><td>150 ± 12</td><td>153 ± 9</td></tr>
<tr><td>6 months</td><td>136 ± 11 p<0.01</td><td>134 ± 11 p<0.01</td></tr>
<tr><td>DBP</td><td></td><td></td></tr>
<tr><td>Baseline</td><td>81 ± 10</td><td>82 ± 7</td></tr>
<tr><td>6 months</td><td>72 ± 8 p<0.05</td><td>74 ± 6 p<0.05</td></tr>
<tr><td>PR</td><td></td><td></td></tr>
<tr><td>Baseline</td><td>78 ± 4</td><td>75 ± 4</td></tr>
<tr><td>6 months</td><td>77 ± 5</td><td>75 ± 3</td></tr>
</table>
• Clinical outcomes including cognitive, functional, behavioural ability</td></tr>
</table>

Bibliographic reference	**Kume K, Hanyu H, Sakurai, H, Takada Y (2012) Effects of telmisartan on cognition and regional cerebral blood flow in hypertensive patients with Alzheimer's disease, Geriatrics & gerontology international 12 1444-1586**

Table showing mean (SD) changes in cognitive function at baseline to 6 months

	Telmisartan (n=10)	Amlodipine (n=10)
Neuropsychological changes		
MMSE		
Baseline	21.1 ± 2.5	22.4 ± 3.6
6 months	21.6 ± 2.2	21.6 ± 4.5
ADAS-cog		
Baseline	18.1 ± 4.5	15.0 ± 5.6
6 months	16.7 ± 5.1	17.8 ± 6.7 p<0.05
WMS-R (logical memory-I)		
Baseline	5.4 ± 3.7	4.4 ± 3.3
6 months	6.9 ± 2.8	3.9 ± 4.3

- **Change in prevalence of appropriate polypharmacy**
  Not reported
- **Intervention related problems such as potentially avoidable adverse effects**
  Not reported
  Intervention related outcomes including concordance, compliance, satisfaction of person living with dementia and their carers

Authors conclusion	Telmisartan may have additional benefits and be useful for the treatment of elderly hypertensive patients with AD.
Source of funding	Not reported

Risk of bias

- Did the trial address a clearly focused issue? Yes
- Was the assignment of patients to treatments randomised? Study describes ‘subjects were randomly assigned’ but does not report method of randomisation used/ how
- Were patients, health workers and study personnel blinded? Not clear
- Were the groups similar at the start of the trial? Yes
- Aside from the experimental intervention, were the groups treated equally? Not clearly reported
- Were all of the patients who entered the trial properly accounted for at its conclusion? Yes
- How large was the treatment effect? How precise was the estimate of treatment effect? Small sample, limited between group analysis
- Can the results be applied to the population of interest? Yes
- Were all clinically important outcomes considered? Yes

<table>
<tr><td>Bibliographic reference</td><td>Plichart M, Seux ML, Caillard L et al (2013) Home based blood pressure measurement in elderly patients with cognitive impairment: comparison of agreement, Blood pressure monitoring, 18, 208-214</td></tr>
<tr><td>Study type</td><td>Randomised Open comparative crossover study</td></tr>
<tr><td>Aim</td><td>To assess the agreement, mean difference, direction and control rates between hypertension blood pressure monitoring (HBPM) by a relative and 24-h ambulatory blood pressure monitoring (ABPM) in cognitively impaired elderly participants.</td></tr>
<tr><td>Patient characteristics</td><td>Inclusion criteria:
Participants were consecutive adults diagnosed with dementia (according to DSM-IV criteria) with office hypertension (≥ 140/90 mmHg at two or more visits), aged 75 years or over and unable to perform self- HBPM but had a relative able to perform HBPM.
Exclusion criteria:
Not reported</td></tr>
<tr><td>Number of Patients</td><td>60 participants (mean age 80.8 years; 47% male 53% female; mean MMSE score =20.1)</td></tr>
<tr><td>Intervention</td><td>24 hour ABPM readings were taken at half-hourly intervals during the day (0700- 2300h) and hourly at night (2300-0700h)</td></tr>
<tr><td>Comparison</td><td>For relative HBPM the caregiver took 18 home readings (6 readings a day – 3 in morning, 3 in the evening) for 3 consecutive days. The mean value of the 18 measurements defined the r-ABPM.
The order of r-HBPM or ABPM was randomised</td></tr>
<tr><td>Length of follow up</td><td>3 day duration</td></tr>
<tr><td>Location</td><td>France</td></tr>
<tr><td></td><td>• Clinical progression of comorbidity and associated symptoms
Comparison of BP measurements (mmHg) between relative HBPM and ABPM
<table>
<tr><td>Mean (SD)</td><td>r-HBPM</td><td>24-h ABPM</td><td>P value comparison r-HBPM & 24h ABPM</td><td>Daytime ABPM</td><td>P value comparison r-HBPM & daytime ABPM</td></tr>
<tr><td>Systolic BP</td><td>146.9 (19.9)</td><td>135.6 (17.4)</td><td><0.001</td><td>137.2 (17.0)</td><td><0.001</td></tr>
<tr><td>Diastolic BP</td><td>78.7 (11.5)</td><td>77.7 (9.4)</td><td>0.38</td><td>78.7 (9.4)</td><td>0.99</td></tr>
<tr><td>Hypertension (%)</td><td>71.7 (43)</td><td>63.3 (38)</td><td>0.06</td><td>56.7 (34)</td><td>0.003</td></tr>
<tr><td>White coat hypertension (%)</td><td>28.3 (17)</td><td>36.7 (22)</td><td>0.06</td><td>43.3 (26)</td><td>0.003</td></tr>
</table>
Correlation coefficients between r-HBPM and 24-hABPM
SBP r=0.75 (p<0.001)
DBP r= 0.64 (p<0.001)</td></tr>
</table>

Correlation coefficients between r-HBPM and daytime ABPM
SBP r=0.74 (p<0.001)
DBP r= 0.64 (p<0.001)

Mean difference in measurements between r-HBPM and 24-h ABPM
SBP measurements r-HBPM was 11.5mmHg higher than 24-h ABPM (95%CI -37.8 to 14.7mmHG (mean spearmans r = -0.13, p=0.29)
DBP measurements r-HBPM was -1.0mmHG lower than 24-h ABPM (95%CI -17.9 to 16.0 mmHG (mean spearmans r = -0.24, p=0.06)

Hypertension diagnosis

	Relative HBPM N (%)	
	No hypertension	Hypertension
24 h ABPM		
No hypertension	17 (77.3)	5 (22.7)
Hypertension	0 (0)	38 (100)
Daytime ABPM		
No hypertension	17 (65.4)	9 (34.6)
Hypertension	0 (0)	34 (100)

BP cut offs for defining hypertension: 24-hABPM BP ≥ 130/80 mmHg; daytime ABPM BP ≥ 135/85 mmHg; r-HBPM ≥ 135/85 mmHG

Agreement between methods for diagnosis of hypertension and white coat hypertension
Overall agreement r-HBPM and 24-h ABPM= 92% k = 0.81 (95%CI 0.61—0.93)
sensitivity = 100%; specificity = 77%

Overall agreement r-HBPM and daytime ABPM = 85% k= 0.68 (95%CI 0.49-0.85)
Sensitivity = 100%; specificity = 65%

- **Clinical outcomes including cognitive, functional, behavioural ability**
  Not reported
- **Change in prevalence of appropriate polypharmacy**
  Not reported
- **Intervention related problems such as potentially avoidable adverse effects**

	Not reported • **Intervention related outcomes including concordance, compliance, satisfaction of person living with dementia and their carers** Feasibility of use of relative-HBPM = 97% (defined by ≥12/18 measurement- n=60) • **Costs:** Undiscounted costs in VC group = 41,729 euros; SC group = 39,702 euros (diff= 2,026 euros (11,688 to 15,587 euros)
Bibliographic reference	**Sato T, Hanyu H, Hirao K, Kanetaka H, Sakurai H, Iwamoto T (2011) Efficacy of PPAR-y agonist pioglitazone in Alzheimer disease, Neurobiology of Aging, 32, 1626 -1633**
Study type	Randomised open label controlled trial
Aim	To determine whether pioglitazone is effective for treatment of Alzheimer's disease and Type II Diabetes
Patient characteristics	Participants with mild AD (CDR score 0.5 or 1) and type II Diabetes mellitus (NINCDS and ADRDA) Diabetes defined as use of oral hypoglycaemic drug or non-fasting plasma glucose level of 200 mg/dl or more ; a fasting plasma glucose level of 126 mg/dl or more
Number of Patients	42 patients (treatment group- n=21; mean age = 77.4 ± 6.2 52% male, 48% female) (no treatment group) n= 21; mean age = 77.6 ± 6.5; 43% male; 57% female
Inclusion/ exclusion criteria	Inclusion: Participants with mild AD (CDR score 0.5 or 1) and type II Diabetes mellitus (NINCDS and ADRDA) Diabetes defined as use of oral hypoglycaemic drug or non-fasting plasma glucose level of 200 mg/dl or more ; a fasting plasma glucose level of 126 mg/dl or more Exclusion: Any evidence of neurologic or psychiatric disorders sufficient to cause memory impairment (including depression or anxiety disorder- a score of 5 or more on Geriatric Depression Scale) Clinically significant medical problems including cancer within previous 3 years, chronic renal or heart failure, severe pulmonary disease or poorly controlled diabetes or use of insulin
Intervention	15mg (n=19) 30mg (n=2) pioglitazone daily
Comparison	No treatment
Length of follow up	6 months
Location	Japan
Outcomes measures and effect size	• **Clinical progression of comorbidity and associated symptoms** Table showing mean (SD) changes in metabolism and plasma from baseline to 6 months

	Pioglitazone (n=21)	control (n=21)

	Baseline	Month 6	P value	Baseline	Month 6	P value
Metabolic changes						
Fasting plasma glucose (mg/dl)	137 ± 41	121 ± 27		148 ± 40	131 ± 29	
HBA1C (%)	6.8 ± 1.2	6.4 ± 1.1	<0.05	6.9 ± 1.0	6.5 ± 0.8	<0.05
Fasting immunoreactive insulin µU/ml)	7.4 ± 3.6	5.7 ± 2.3	<0.01	6.6 ± 4.8	6.5 ± 2.7	<0.05
HOMA-R	2.4 ± 1.2	1.6 ± 0.8	<0.05	2.2 ±1.5	1.9 ± 0.8	
			<0.01			
Plasma Aβ40 and Aβ42 changes						
Aβ40 (pmol/L)						
Aβ42(pmol/L)	54.8 ± 18.9	53.5 ± 19.7		54.9 ± 21.6	53.6 ± 27.1	
Aβ40/Aβ42	6.2 ± 2.0	6.3 ± 2.2		7.7 ± 4.2	6.0 ± 2.6	
	9.3 ± 3.2	9.1 ±3.5		7.6 ± 2.2	9.5 ± 3.9	<0.05

- **Clinical outcomes including cognitive, functional, behavioural ability**
  Table showing mean (SD) changes in cognitive function at baseline to 6 months

	Pioglitazone (n=21)			control (n=21)		
	Baseline	Month 6	P value	Baseline	Month 6	P value
Neuropsychological changes						
MMSE	22.1 ± 3.5	23.1 ± 4.1	<0.05	21.9 ± 3.4	21.6 ± 3.0	
ADAS-cog	15.5 ± 5.9	142 ± 6.5	<0.05	15.3 ± 4.7	17.5 ± 5.2	<0.01
WMS-R logical memory I	6.5 ± 4.1	7.8 ± 4.7	<0.01	5.7 ± 3.2	5.4 ± 3.6	
Frontal assessment battery	11.8 ± 3.0	11.8 ± 3.0		10.9 ± 2.1	10.2 ± 2.6	
Category fluency	20.2 ± 6.4	21.0 ± 6.4		19.6 ± 3.8	19.5 ± 3.9	

- **Change in prevalence of appropriate polypharmacy**
  Not reported
- **Intervention related problems such as potentially avoidable adverse effects**
  Adverse events
  3 patients in pioglitazone group had mild peripheral edema
  Intervention related outcomes including concordance, compliance, satisfaction of person living with dementia and their carers

Not reported

Authors conclusion Pioglitazone treatment resulted in improvements in cognition , fCBF and stabilisation of Type II diabetes in patients with

	Alzheimer's disease and type II diabetes
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes, full clear reporting of method applied • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Unclear • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? How precise was the estimate of treatment effect? Predominant within group changes from baseline reported only • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? No, further analysis undertaken to identify between group differences

Bibliographic reference	**Richard E, Kuiper R, Dijkgraaf MG, van Gool MD (2009) Vascular care in patients with Alzheimer's disease with cerebrovascular lesions – a randomised clinical trial, Journal of the American Geriatrics Society, 5 pp 797-805**
Study type	Randomised open label controlled trial
Aim	To investigate whether a multicomponent intervention aimed at many vascular risk factor could have a clinical benefit for people with Alzheimer's disease
Patient characteristics	130 eligible for inclusion. 123 included (vascular care group- n=65; mean age = 76.7 ± 5.6; 53.8% male, 46.2% female) (standard care group) n= 58; mean age = 76.2 ± 4.8; 39.7% male; 60.3% female
Inclusion/ exclusion criteria	Inclusion: Aged 65 years or over and diagnosis of probable Alzheimer's disease –CEMDE schedule and white matter lesions of vascular origin Exclusion: Epilepsy, focal neurological deficits other than cognitive deficits, any condition that would preclude follow up at 24 months
Intervention	Vascular care multicomponent intervention Standardised protocol approach: Acetylsalicylic acid 38 to 100 mg , pyridoxime 50 mg and folic acid 0.5 mg per day. If total blood cholesterol > 5.0 mmol/L = 40mg pravastatin If SBP > 140mmHg or DBP >90 mmHg antihypertensive treatment started

<table>
<tr><td>Bibliographic reference</td><td>Richard E, Kuiper R, Dijkgraaf MG, van Gool MD (2009) Vascular care in patients with Alzheimer's disease with cerebrovascular lesions – a randomised clinical trial, Journal of the American Geriatrics Society, 5 pp 797-805</td></tr>
<tr><td></td><td>Visits to outpatients every 3 months</td></tr>
<tr><td>Comparison</td><td>Standard care
No specifications about vascular care
Attend follow up scheduled at 1 and 2 years
Treated according to general guidelines for vascular risk factors in elderly people</td></tr>
<tr><td>Length of follow up</td><td>2 years</td></tr>
<tr><td>Location</td><td>Netherlands</td></tr>
<tr><td>Outcomes measures and effect size</td><td>• Clinical progression of comorbidity and associated symptoms
Table showing mean (SD) changes of comorbid outcomes
<table>
<tr><td></td><td colspan="3">Standard care</td><td colspan="3">Vascular care</td><td>Difference in change score</td><td></td></tr>
<tr><td>Clinical measures</td><td>1 year (n=48)</td><td>2 year (n=44)</td><td>Change score Over 2 years</td><td>1 year (n=57)</td><td>2 year (n=50)</td><td>Change score over 2 years</td><td>95%CI</td><td>P</td></tr>
<tr><td>SBP mmHg</td><td>146.4 ± 20.7</td><td>142.4 ± 17.8</td><td>-18.65 ± 25.3</td><td>143.1 ± 21.3</td><td>136.2 ± 22.8</td><td>-14.53 ± 24.0</td><td>-4.12 (-14.75 to 6.16)</td><td>0.86</td></tr>
<tr><td>DBP mmHg</td><td>82.8 ± 10.6</td><td>82.4 ± 10.6</td><td>-5.64 ± 15.9</td><td>79.9 ± 9.3</td><td>77.1 ± 9.7</td><td>-3.67 ±12.8</td><td>-1.97 (-8.21 to 4.26)</td><td>0.65</td></tr>
<tr><td>HBA1c (%)</td><td>5.9 ± 0.6</td><td>5.8 ± 7.1</td><td>0.05 ± 0.5</td><td>5.9 ± 0.6</td><td>5.9 ± 0.7</td><td>0.25 ± 0.5</td><td>0.20 (-0.08 to0.48)</td><td>0.16</td></tr>
<tr><td>Homocystein µmol/L</td><td>15.4 ± 5.6</td><td>15.0 ± 5.4</td><td>0.14 ± 4.0</td><td>12.5 ± 5.1</td><td>12.5 ± 5.2</td><td>-4.54 ± 8.8</td><td>-4.68 (0.53 to8.82)</td><td>0.003</td></tr>
</table></td></tr>
</table>

Bibliographic reference	Richard E, Kuiper R, Dijkgraaf MG, van Gool MD (2009) Vascular care in patients with Alzheimer's disease with cerebrovascular lesions – a randomised clinical trial, Journal of the American Geriatrics Society, 5 pp 797-805

Folic acid nmol/L	15.5 ± 9.8	15.8 ± 7.9	0.18 ± 8.9	39.2 ± 13.5	42.2 ± 9.7	24.40 ±10.8	24.22 (-18.97 to -29.47)	<0.001
Vitamin B12 pmol/L	311.2 ±127.3	279.8 ± 86.8	3.40 ± 95.8	314.8 ± 146.8	293.9 ± 168.6	-35.47 ±146.2	-38.87 (-102.77-25.03)	0.63
Triglycerides mmol/L	1.6 ± 0.8	1.44 ± 0.9	0.15 ± 0.87	1.5 ± 0.7	1.4 ±0.6	-0.34 ± 0.81	-0.49 (-0.94 to -0.04)	0.20
Total cholesterol mmol/L	5.6 ± 1.4	5.4 ± 1.2	-0.12 ± 0.90	5.0 ± 1.1	4.88 ± 1.0	-1.06 ± 1.05	-0.94 (1.43 to -0.45)	0.001
HDL cholesterol mmol/L	1.6 ± 0.7	1.5 ± 0.5	-0.02 ± 0.23	1.8 ± 0.8	1.6 ± 0.5	-0.04 ± 0.31	-0.02 (-0.17 to 0.13)	0.99
LDL cholesterol mmol/L	3.3 ± 1.1	3.3 ± 1.0	-0.09 ± 0.80	2.7 ± 0.8	2.7 ± 0.8	-0.98 ± 1.00	-0.90 (-1.44 to -0.36)	0.002

- **Clinical outcomes including cognitive, functional, behavioural ability**
  Table showing mean (SD) changes in cognitive outcomes

Clinical measures	1 year (n=48)	2 year (n=44)	Change score Over 2 years	1 year (n=57)	2 year (n=50)	Change score over 2 years	95%CI	P

Bibliographic reference	**Richard E, Kuiper R, Dijkgraaf MG, van Gool MD (2009) Vascular care in patients with Alzheimer's disease with cerebrovascular lesions – a randomised clinical trial, Journal of the American Geriatrics Society, 5 pp 797-805**

IDD in daily activities for Dementia	15.2 ± 10.9	22.8 ± 13.4	11.04 ± 13.1	10.9 ± 7.4	17.9 ± 13.5	13.75 ± 10.3	2.71 (-3.14 to 8.56)	0.26
MMSE	19.5 ± 5.2	17.0 ± 6.4	-5.23 ± 6.0	19.7 ± 5.1	16.8 ± 8.1	-5.78 ±6.4	-0.55 (-3.12 to 2.02)	0.65
Revised memory and behavioural problems checklist	31.9 ± 12.5	37.3 ± 15.4	6.63 ± 12.8	30.3 ± 13.6	31.1 ± 14.7	11.7 ± 13.1	4.54 (-1.39 to 10.49)	0.35

- **Change in prevalence of appropriate polypharmacy**
  Not reported
- **Intervention related problems such as potentially avoidable adverse effects**

	Standard care (n=58) N(%)	Vascular care (n=65) N (%)	Odds ratio (95%CI)	P value
Personal situation				
Living at home	28 (48.3)	36 (55.4)	1.13 (0.48 to 2.63)	0.78
Institutionalisation	24 (41.4)	23 (35.4)	0.96 (0.42 to 2.20)	0.91
Death	6 (10.3)	6 (9.2)	1.38 (0.35 to 5.46)	0.65
Severe clinimetric decline	12 (27.3)	17 (34.0)	1.46 (0.58 to 3.72)	0.42

- **Intervention related outcomes including concordance, compliance, satisfaction of person living with dementia and their carers**

Authors conclusion	No benefits were found in daily functioning, cognitive deficits or behavioural abnormalities as a result of multi component vascular care
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes

Bibliographic reference	Richard E, Kuiper R, Dijkgraaf MG, van Gool MD (2009) Vascular care in patients with Alzheimer's disease with cerebrovascular lesions – a randomised clinical trial, Journal of the American Geriatrics Society, 5 pp 797-805
	• Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Yes, clearly and fully reported methods of randomisation and concealment • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? How precise was the estimate of treatment effect? Effect sizes fully reported, clear interpretation of outcomes • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Ostaskiewicz J, Johnston L, Roe B (2010), Timed oiding for the management of urinary incontinence in adults, Cochrane Database of Systematic Reviews
Study type	Systematic review
Aim of the study	• To assess the effects of timed voiding for the management of people with urinary incontinence who cannot participate in independent toileting
Country(ies) where study carried out	N/A
Study dates	Assessed as up to date 2009, edited version published 2010
Source of funding	N/A
Inclusion criteria	Randomised and quasi-randomised controlled clinical trials (RCTs) evaluating the effectiveness of timed voiding for adults delivered alone or in combination with another intervention compared to usual care or no timed voiding.
Exclusion criteria	None
Interventions	Intervention: Timed voiding combined with other modalities (one trial combined TV delivered by nursing home staff with a medical assessment and individualised medical intervention- including propantheline & flavoxate for unstable bladder and /or ethinyloestradiol combined with pelvic floor exercises for women with urodynamic stress incontinence and./or antibiotic therapy for UTI; The other trial combined a schedule of toileting assistance (5x a day) combined with stepped use of continence products , bedside commodes, staff education and administration of low dose oxybutynin) Control:

Bibliographic reference	Ostaskiewicz J, Johnston L, Roe B (2010), Timed oiding for the management of urinary incontinence in adults, Cochrane Database of Systematic Reviews
	• Usual care or no advice
230	Included two trials with a total of 298 participants. One trial n= 20 (mean age 91.3 years primarily demented and frail elders- other demographic info not reported) One trial n= 278 (mean age 82.2 years; 17% male, 83% female majority with chronic brain failure • **Clinical progression of comorbidity and associated symptoms** **Number of incontinent episodes at outcome** Number of studies = 1 – N=20 Intervention = 20% wet Control = 80% wet (NB review paper reports limited data analysis due to absence of reporting of standard deviation. **Number of patients with reductions in incidence of daytime incontinence** Number of studies = 1 Intervention = 40/102 Control = 26/89 RR 1.34 [0.90, 2.01] **Number of patients with reductions in incidence of night time incontinence** Number of studies = 1 Intervention = 39/95 Control = 18/79 RR 1.80 [1.12, 2.89] **Number of patients whose pad test indicates reduction in the volume of incontinence** Number of studies = 1 Intervention = 16/65 Control = 11/45 RR 1.01 [0.52, 1.96] • **Clinical outcomes including cognitive, functional, behavioural ability** Not reported • **Change in prevalence of appropriate polypharmacy** Not reported • **Intervention related problems such as potentially avoidable adverse effects**

Bibliographic reference	Ostaskiewicz J, Johnston L, Roe B (2010), Timed oiding for the management of urinary incontinence in adults, Cochrane Database of Systematic Reviews
	Not reported • **Intervention related outcomes including concordance, compliance, satisfaction of person living with dementia and their carers** Not reported
Authors conclusion	There is insufficient evidence to recommend timed voiding for the management of urinary incontinence in an adult population
Overall risk of bias	High-quality systematic review but studies were of low quality. Effect measures only able to be presented for one paper
Risk of bias further info	• Did the review address a clearly focused question? Yes • Did the authors look for the right type of papers? Yes • Do you think all the important, relevant studies were included? Yes • Did the review's authors do enough to assess the quality of the included studies? Yes • If the results of the review have been combined, was it reasonable to do so? Yes • What are the overall results of the review? Yes • How precise are the results? Dichotomous data- RRs and CIs presented • Can the results be applied to the local population? Yes

Bibliographic reference	Jirovec M M, Templin T (2001) Predicting success using individualised scheduled toileting for memory-impaired elders at home, Research in Nursing and Health, 24, pp1-8
Study type	Randomised controlled trial
Aim	To evaluate the effectiveness of an individualised scheduled toileting (IST) program for incontinent, memory impaired elders being cared for at home
Patient characteristics	118 patients Patient demographics (mean age 79.89 years; 31% male; 69% female; mean baseline cognitive impairment – all sample not reported but measured by Short portal mental status questionnaire; (SPMSQ* higher score = greater cognition) Composite mobility score (higher score= greater mobility) Intervention group – 6.64; control group = 6.73
Inclusion/ exclusion criteria	Inclusion: Volunteers were recruited as caregivers of people with memory impairment Exclusion:

<table>
<tr><td>Bibliographic reference</td><td>Jirovec M M, Templin T (2001) Predicting success using individualised scheduled toileting for memory-impaired elders at home, Research in Nursing and Health, 24, pp1-8</td></tr>
<tr><td></td><td>Not reported</td></tr>
<tr><td>Intervention</td><td>Caregivers of patients taught an IST providing toileting reminders to memory impaired patients scheduling developed in consultation with caregiver and voiding patterns identified– voiding approx. every 2 hrs.</td></tr>
<tr><td>Comparison</td><td>Control group (precise details not reported)</td></tr>
<tr><td>Length of follow up</td><td>6 months</td></tr>
<tr><td></td><td>USA</td></tr>
<tr><td>Outcomes measures and effect size</td><td>

Clinical progression of comorbidity and associated symptoms

Mean (SD) of incontinent episodes- analysis based on 74 participants;
Intervention group (n=44)
Baseline incontinence frequency = 0.43 (0.23); 6 month incontinence frequency = 0.37 (0.28)
Correlation between baseline & 6 month incontinence R^2 =0.088 (p= non sig)

Control group (n=30)
Baseline incontinence frequency = 0.47 (0.31); 6 month incontinence frequency = 0.49 (0.36)
Correlation between baseline & 6 month incontinence R^2 =0.58 (p=<0.05)

Number of participants showing decreased incontinence at 6 months
Intervention group = 28/44; control group 15/30

Discriminant function analysis – predicting improvement in incontinence in cognitive status, mobility and consistency in implementing IST program (n=44)
<table>
<tr><td colspan="3">Discriminant function: Wilks Lambada = 0.687 χ^2 (3) =14.836, p=0.002</td></tr>
<tr><td>Variable explained</td><td>Structure coefficient</td><td>Variance in variable by discriminant equation</td></tr>
<tr><td>Mental status questionnaire</td><td>0.753</td><td>56.7%</td></tr>
<tr><td>Composite mobility score</td><td>0.362</td><td>13.1%</td></tr>
<tr><td>IST implementation</td><td>0.235</td><td>5.5%</td></tr>
<tr><td colspan="3">Discriminant function: Wilks Lambada = 0.724 χ^2 (3) =12.764, p=0.005</td></tr>
<tr><td>Mental status questionnaire</td><td>0.823</td><td>67.7%</td></tr>
<tr><td>Speed</td><td>0.396</td><td>15.7$</td></tr>
</table>
</td></tr>
</table>

Bibliographic reference	Jirovec M M, Templin T (2001) Predicting success using individualised scheduled toileting for memory-impaired elders at home, Research in Nursing and Health, 24, pp1-8

IST implementation	0.152	2.3%

- **Clinical outcomes including cognitive, functional, behavioural ability**
  Mean (SD) of mental status- analysis based on 74 participants;
  Intervention group (n=44)
  Baseline mental status = 6.64 (2.20); 6 month mental status = 6.67 (2.09)

  Control group (n=30)
  Baseline mental status = 6.73 (2.44); 6 month mental status = 7.13 (2.26)

  Mean (SD) of mobility-
  Intervention group (n=44)
  Baseline mobility = 16.73 (3.91); 6 month mental status = 16.81 (4.10)

  Control group (n=30)
  Baseline mental status = 16.97 (3.50); 6 month mental status = 15.87 (3.87)

- **Change in prevalence of appropriate polypharmacy**
  Not reported
- **Intervention related problems such as potentially avoidable adverse effects**
  Not reported
- **Intervention related outcomes including concordance, compliance, satisfaction of person living with dementia and their carers**
  Not reported

Authors conclusion	Candidates for IST should be selected based on their cognitive ability. Prime candidates for IST are moderately cognitively impaired people and people able to cooperate
Source of funding	Not reported
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes, but unconcealed • Were patients, health workers and study personnel blinded? No • Were the groups similar at the start of the trial? Yes

Bibliographic reference	Jirovec M M, Templin T (2001) Predicting success using individualised scheduled toileting for memory-impaired elders at home, Research in Nursing and Health, 24, pp1-8
	• Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? How precise was the estimate of treatment effect? Both the results from 2 monthly and 6 monthly groups were combined at follow up due to attrition at 6 months • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

Bibliographic reference	Engberg S, Sereika SM, McDowell B, Weber E, Brodak I (2002) Effectiveness of prompted voiding in treating urinary incontinence in cognitively impaired homebound adults, Journal of wound ostomy & continence, 5, pp 252-265
Study type	Prospective controlled randomised cross over study
Aim	To examine the short term effectiveness of prompted voiding in cognitively impaired older adults.
Patient characteristics	N= 19 Intervention group n= 9, mean age 83.1 years; 67% female, 33% male
Inclusion/ exclusion criteria	A sub analysis of participants included in a wider trial involving both cognitively impaired and cognitively intact participants. This sample = Cognitively impaired all participants MMSE<24 Inclusion criteria: Aged 60 years or over; meet Center for Medicare and Medicaid services criteria for being homebound (needing assistance & requiring considerable and taxing effort to leave home or having a condition that contraindicates leaving home and leaving home only for short periods and primarily for medical reasons); understand and speak English; report at least 2 incontinent episodes per week; report incontinence for at least 3 months; have a full time carer Exclusion: terminal illness; post-void residual volume (PVR) > 100mL; caregiver unable or unwilling to provide toileting assistance; less than 2 incontinent episodes per week
Intervention	8 weekly sessions of behavioural therapy conducted in participants home by nurse practitioner (NP): NP educated caregiver in prompted voiding every 2 hours during waking hours; prompted time adjusted if participant self-initiated. Prompted voiding was not initiated during the night
Comparison	Control intervention - full details not reported
Length of follow up	8 week observation period
Outcomes measures and effect size	• **Clinical progression of comorbidity and associated symptoms** Treatment efficacy: Table shows change in continence characteristics at 8 week follow up

Bibliographic reference	Engberg S, Sereika SM, McDowell B, Weber E, Brodak I (2002) Effectiveness of prompted voiding in treating urinary incontinence in cognitively impaired homebound adults, Journal of wound ostomy & continence, 5, pp 252-265			
		Control group (n=10) Mean (SD) and range	Intervention group (n=6) Mean (SD) and range	P value
	ITT approach			
	%ge decrease in daytime incontinent episodes per day	37.3 (34.3) 32.0 - 94.0	50.1 (41.3) -4.0 – 100.0	P=0.27
	% reduction of all incontinent episodes per day	27.2 (26.1) -32.0-58.0	47.0 (39.2) -3.0 – 100.0	P=0.19
	% reduction in daytime wet	34.6 (33.5) -0.15- 92.0	43.1 (46.6)	P = 0.35
	% reduction in day and night wet	23.0 (22.7) -15.0 – 53.0	43.1 (46.6) -30.0 – 100.0	P= 0.20
	Change in self-initiated toilets per day	N= 9 1.9 (2.1) -1.8-5.8	N=9 3.1 (4.8) -2.1 – 12.6	P= 0.50
	Per protocol approach			
	%ge decrease in daytime incontinent episodes per day	37.3 (34.3) -0.32 – 94.0	59.8 (36.9) 2.0 – 100.0	P=0.10
	% reduction of all incontinent episodes per day	27.2 (26.1) -32.0 – 58.0	55.2 (33.5) 4.0 – 100.0	P=0.07
	% reduction in daytime wet	34.6 (33.5) -15.0 – 92.0	50.2 (48.0) -30.0 – 100.0	P=0.24
	% reduction in day and night wet	23.3 (22.7) -15.0 – 53.0	45.3 (43.3) 26.0 – 100.0	P=0.12
	Change in self-initiated toilets per day	1.9 (2.1) -1.8 – 5.8	2.7 (3.6) -2.1 – 7.4	P=0.80

Bibliographic reference	Engberg S, Sereika SM, McDowell B, Weber E, Brodak I (2002) Effectiveness of prompted voiding in treating urinary incontinence in cognitively impaired homebound adults, Journal of wound ostomy & continence, 5, pp 252-265
	Response to intervention for all participants: N= 15 Mean (SD) number of daytime incontinent episodes baseline = 2.2 (1.4) per day; post treatment =1.8 (1.6) 22% reduction t=1.8, p=0.04 Total (mean SD) number of incontinent episodes per day Baseline = 2.8 (1.5) post treatment 2.4 (1.7) (19% reduction, t= 1.7, p=0.06) Change in %ge wet during day (8%, p=0.34); during day and night (7%, p=0.33) Number of self initiated toilets baseline = 2.0 (2.3); post treatment = 3.3(3.4) t= 1.12, p=0.26) **Response to treatment** Improvement = 10/15 (67%); Decline = 5/15 (33%) • **Clinical outcomes including cognitive, functional, behavioural ability** Not reported • **Change in prevalence of appropriate polypharmacy** Not reported • **Intervention related problems such as potentially avoidable adverse effects** Not reported • **Intervention related outcomes including concordance, compliance, satisfaction of person living with dementia and their carers** Caregiver satisfaction with PV intervention Overall 14(93%) report satisfaction with recipients progress Caregiver believed fewer incontinent episodes (n=12; 80%) Caregiver believed number of episodes smaller (n=9; 60%) Caregiver believe recipient able to wear less protection (n=2; 13%) Caregiver believe recipient is better (n=12; 80%)/ unchanged (n=2 ; 13%)/ worse (n=1;) prior to treatment Caregiver report intervention had decreased their work (n= 7; 42%)/ unchanged (n=3; 20%)/ increased (n=5; 33%)
Authors conclusion	Clinically significant reductions in urinary incontinence were achieved for many of the participants and prompted voiding may be achievable for cognitively impaired homebound adults
Source of funding	Not reported

Bibliographic reference	Engberg S, Sereika SM, McDowell B, Weber E, Brodak I (2002) Effectiveness of prompted voiding in treating urinary incontinence in cognitively impaired homebound adults, Journal of wound ostomy & continence, 5, pp 252-265
Risk of bias	• Did the trial address a clearly focused issue? Yes • Was the assignment of patients to treatments randomised? Yes • Were patients, health workers and study personnel blinded? Controlled cross over • Were the groups similar at the start of the trial? Yes • Aside from the experimental intervention, were the groups treated equally? Yes • Were all of the patients who entered the trial properly accounted for at its conclusion? Yes • How large was the treatment effect? How precise was the estimate of treatment effect? Cross over element, small sample impacted on true effect estimates • Can the results be applied to the population of interest? Yes • Were all clinically important outcomes considered? Yes

E.14.3 Managing mental health conditions alongside dementia

- RQ20: What are the optimal management strategies (including treatments) for people with dementia and an enduring mental health condition?

No relevant evidence was identified for inclusion

E.15 Palliative care

E.15.1 Palliative care

- What models of palliative care are effective for people with dementia?

E.15.1.1 Qualitative evidence

Full citation	Crowther J, Wilson K C, Horton S, and Lloyd-Williams M. (2013). Compassion in healthcare - lessons from a qualitative study of the end of life care of people with dementia. Journal of the Royal Society of Medicine, 106(12), pp.492-7.
Study details	Country/ies where the study was carried out: Scotland, England and Wales, UK Study type: Unstructured interviews Aim of the study: This study explores the experiences of bereaved carers of people with dementia in their last year of life and time surrounding death and how the presence and lack of compassion, kindness and humanity influenced the experience of care. Study dates: February 2009 to August 2010 Source of funding: St Luke's Hospice, Winsford, Cheshire
Participants	• Sample size: Forty bereaved carers • Inclusion criteria: Bereaved carers • Exclusion criteria: None • Sample characteristics: 31 women and nine men – with an age range of 18–86 years and from wide socioeconomic backgrounds. Within the study, 22 people with dementia had died in a District General Hospital, 14 within care homes and four within a family home. The majority had experienced care in several different care settings prior to death. Average time since death was 1.75 years (range 3 months to 5 years).
Methods	This national study recruited bereaved carers from Scotland, England and Wales. Purposive sampling was used, and appeals for volunteers were made via the Alzheimer's Society, Age UK, the press and community networks. Interviews lasted between 30min and 80min. Participants were encouraged to tell 'their story' with minimal interruption from the researcher which ensured events and issues important and significant to the participant were reported. Data saturation, participants reporting the same or similar issues began to occur when recruitment reached 35 participants and a further five participants were recruited to ensure saturation had been fully been achieved.
Thematic analysis	• Theme 1: Bereaved carer – going beyond task-focused care. The words compassion, kindness and humane were frequently words used by participants to describe the care given and this included compassion, kindness and humanity in formal care and the compassion, kindness and the humanity of 'strangers'. ○ Finding 1: Compassion, kindness and humanity in formal care applied not only to direct care givers but also to ancillary staff: "Another act of kindness was when he was in hospital the secretary of the vicar in charge of the hospital, I went down enquiring about services, Muslim services, she said ''I believe your husband likes nice coffee, he can have a nice cup of coffee with me'' so she brought

Full citation	Crowther J, Wilson K C, Horton S, and Lloyd-Williams M. (2013). Compassion in healthcare - lessons from a qualitative study of the end of life care of people with dementia. Journal of the Royal Society of Medicine, 106(12), pp.492-7.
	special cups in, biscuits and special coffee for him." (Wife) As the quote below indicates, it is the small things and little acts of kindness that are most meaningful to people: "Another little act of kindness, I bought my husband new jogging bottoms and a top .....nurse didn't put it on until just before he was going to see the oncologist ...so he wouldn't make a mess of it...I just thought...they are so busy there...little acts of kindness like that are very important, aren't they?" (Wife) The ability of formal carers to put themselves in the informal carer's position was valued – this ability to provide compassionate care surpassed age and gender as the quote below reveals: "Care given by staff was truly excellent I can only praise them...certain older members of staff who were absolutely great with him...when I would thank them they would say ''well, we would do this for our own mum or our own dad you know''...also what I found was the young carers who were there they too were excellent, they were very patient." (Daughter) In the quote below, nine years since the death of her father, we can see evidence of the negative impact and lasting effects upon a carer when target driven care from professionals are perceived to have occurred: "The memory clinic showed no interest whatsoever in the carer, I think that's what struck me more than anything, they just wanted to know really whether dad could tick the right boxes to merit he could stay on Aricept." (Daughter) A participants' description of care within a specialist dementia care home reveals what can happen when compassion is not present. The behaviour of formal carers towards the father was interpreted by family as unkind and de-humanising: "He was really getting to be unhappy, we knew he was unhappy, a woman (member of staff) stood outside the door in the corridor outside his room, she couldn't see me, she didn't know I was there, she said ''I'm absolutely fed up with him'' at the top of her voice, so me dad would've heard it without a shadow of a doubt, ''if he doesn't wanna be here, we certainly don't want him here, I don't know why they don't just come and get him and take him'', Why the unkindness?...I never expected that, I never expected the disrespect, the unkindness." (Daughter) • Theme 2: Bereaved carer – Prioritising, planning, communication. ○ Finding 1: Dying on an open ward. As this participant's father approached death, there was no privacy and he died on an open ward. It was common place for people with dementia to die on an open busy ward with the promise of transfer to a side room not materializing: "Seemed to be no compassion on the ward it was...it was horrible the way me dad died, absolutely horrible...well I felt it was dreadful...I just felt there was no...there was no caring if he'd have been in a side room...had a little bit of dignity where he could have been quiet...where you'd got a lot of so poorly people...you go over what he must have gone through." (Daughter)
Author's comments	Target-driven care may be a necessity in healthcare but it must not be at the expense of compassion.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Uncertain. A structured element to the interview may have ensured comprehensive coverage of topics. • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Uncertain. Participants were self-selected. However, saturation of themes was reached. Average time since death was 1.75 years.

Full citation	**Crowther J, Wilson K C, Horton S, and Lloyd-Williams M. (2013). Compassion in healthcare - lessons from a qualitative study of the end of life care of people with dementia. Journal of the Royal Society of Medicine, 106(12), pp.492-7.**
	• Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Moderate

Full citation	**Davies N, Maio L, Vedavanam K, Manthorpe J, Vernooij-Dassen M, Iliffe S, and Team Impact Research. (2014). Barriers to the provision of high-quality palliative care for people with dementia in England: a qualitative study of professionals' experiences. Health & Social Care in the Community, 22(4), pp.386-94.**
Study details	Country/ies where the study was carried out: UK Study type: Semi-structured interviews Aim of the study: This study explored perceived barriers to the delivery of high-quality palliative care for people with dementia. Study dates: 2011, 2012 Source of funding: European Union's Seventh Framework Programme
Participants	• Sample size: 18 clinical practitioners, 2 researchers, 6 senior managers. • Inclusion criteria: Professionals involved in delivering palliative care • Exclusion criteria: None • Sample characteristics: They interviewed 18 clinical practitioners (5 GPs, 3 old age psychiatrists, 2 palliative medicine consultants, 1 dementia nurse, 4 palliative care nurses and 3 research nurses), 2 researchers and 6 senior managers (1 charity director, 2 policy advisors, 1 commissioning manager, 1 senior healthcare manager and 1 director of adult social services).
Methods	Participants were identified using purposive sampling supported by snow-balling methods through dementia care organisations and from palliative care providers known to the multidisciplinary research team, using a sampling framework.
Thematic analysis	• Theme 1: Professional - The growing number of guidelines and standards leaves no room for flexibility. ○ Finding 1: One hospital-based palliative care nurse said: "What I have seen over a 30-year period is a shift from that charismatic leadership to routinisation where it's just the same as every other service […]. It was a phenomenal change of approach when it first started [palliative care], it was about breaking the rules, breaking the boundaries, working at the edge all the time, […] there is nothing different, nothing is special about it anymore, so nobody is prepared to break the rules or bend the rules and everybody, because of the shift in clinical governance, the working guidelines, everybody is relatively obsessed with working within certain parameters […]."

Full citation	**Davies N, Maio L, Vedavanam K, Manthorpe J, Vernooij-Dassen M, Iliffe S, and Team Impact Research. (2014). Barriers to the provision of high-quality palliative care for people with dementia in England: a qualitative study of professionals' experiences. Health & Social Care in the Community, 22(4), pp.386-94.**
	A community palliative care nurse said: "Say, 'Okay we have to think outside the box', and I think that is a huge thing in end-of-life care. You can have your, 'This is how it should be', but when someone's dying, you, you have to be willing to give the extra or do something maybe slightly different […]." Another community palliative care nurse said: "[A patient] might have spent the last 20 years living on their sofa, but they're not allowed to die on their sofa. Or if they do, they're not allowed carers because they can't bend down to the sofa. And I don't know, it can be very frustrating sometimes." ○ Finding 2: NHS Primary Care Trusts have no duty of care for people who are self-funding their care home. One commissioning manager said: "We would have no jurisdiction over people who are self-funding and we [NHS Primary Care Trust] don't have a duty of care." • Theme 2: Professional – there is a need to incorporate elements of systemisation, such as the Gold Standards Framework into practice. Some tension was evident between expressed wishes for a set of rules, so professionals feel safe in what they are doing, and the view that the rules needed to be 'flexible'. One senior care home manager said: "[…] Liverpool Care Pathway and once somebody flashes that up, whether it be a family member or a nurse or a community worker, then it should be flashed up somewhere and then it all automatically brings a meeting." A research nurse said: "[…] the tools are so valuable, things like the GSF, like the LCP, when you teach somebody and they have it, and it's there." Another research nurse said: "Yes, and I think that actually having tools, you know, that they're very powerful. And, you know, things like the pain assessment, an embedded pain assessment tool that people are familiar with, that facilitates conversation with the GP." • Theme 3: Professional – Training to reduce the need to call for specialist help. A GP said: "I would like to be prepared for setting up a syringe driver really quickly and have a system in place for doing that, which is something I've asked our local palliative care team if they can provide direct training on that, so that it can happen really quickly if the need arises, because I don't know, I think most of the time the need isn't there, but I wouldn't like to feel uncomfortable about being a bit clumsy and slow about setting it up." An old age psychiatrist said: "[…] doctors and nurses didn't actually have the skill base and the response base and the structures to enable them to be good." A GP said: "[…] there's a lot, a huge amount of experience out there, they just need a little bit of confidence to get past the first hurdle and there will be a lot of good knowledge about, you know, just basic approaches around dementia care […] people will start, you know, thinking about what they're doing when they're prescribing, what checks, you know."

Full citation	**Davies N, Maio L, Vedavanam K, Manthorpe J, Vernooij-Dassen M, Iliffe S, and Team Impact Research. (2014). Barriers to the provision of high-quality palliative care for people with dementia in England: a qualitative study of professionals' experiences. Health & Social Care in the Community, 22(4), pp.386-94.**
	• Theme 4: Professional - In some cases, the lack of palliative care skills is not seen as a gap to be filled by the generalist, rather the responsibility of a specialist service. "Like you get a lot of district nurses which, and I know GPs that are very much sort of, 'If I wanted to do palliative care, I'd be a palliative care specialist'". (Community-based palliative care nurse) • Theme 5: Professional – Lack of trust, fear of litigation, fear of blame and threats to speciality. ○ Finding 1: Managing such risks can be difficult. One care home director said: "[…] where we struggle most at the moment is in communications between the nursing staff, the relatives and the medical staff. And we have a lot of difficulty sometimes in getting GP support that they will document that we've agreed that decision, they seem to be very reluctant to write anything down about the decision. And a lot of the decisions, our guidance is that they must be made by the medical officer, […] So the whole thing becomes a grey area where we talk to the relatives, but the GP doesn't support us in any way. So clear end of life decisions or ways forward are, are not, they're not clear any more, they're just grey areas, because there's not a consensus of opinion that the medical staff are signed up to." One GP said: "Yes and when I said, 'Look, you know, perhaps we should discuss this first', [prescribing] or something. [Specialist Palliative Care Nurse] Said, 'Well in that case I won't prescribe for them', and sort of took his ball away and well that isn't going to work. So that's why I'm slightly wary of having these very vertical special teams, because it disempowers everybody else and everybody else will say, 'Oh they'll do that then'." (GP) One hospital-based palliative care nurse said: "Yeah threats to specialism, threats to generalism, you know um professional rivalries and jealousies, um it's all there it's all out there. Yeah patients and relatives get exposed to all of it in all of those organisations." A senior care home manager said: "[…] sometimes some doctors are so frightened about litigation, they're very quick to send that person off to hospital, to get rid of the responsibility that they can decide on syringe drivers or whatever they can use in hospital, it's out of their hands, because they are just so frightened of making that decision." A GP said: "Well who's, who's decision is it whether this person goes to hospital? How do I make the decision? If I don't, if I think it's, there's a degree of medical futility, and it's in the patient's best interests to, where do I stand legally with that as a clinician? Where do I stand legally with that as a family member?" A clinical nurse specialist said: "And a lot of staff are very frightened about doing the wrong thing I think sometimes, they're quite frightened about families."
Author's comments	• The barriers highlighted in this study are underpinned by feelings of uncertainty of disease trajectory and aspects of systematisation. Fear also appears to underpin many barriers, which may be exacerbated by recent media and public criticism of the ethics of palliative care approaches.

Full citation	**Davies N, Maio L, Vedavanam K, Manthorpe J, Vernooij-Dassen M, Iliffe S, and Team Impact Research. (2014). Barriers to the provision of high-quality palliative care for people with dementia in England: a qualitative study of professionals' experiences. Health & Social Care in the Community, 22(4), pp.386-94.**
	• Practitioners' calls for greater structure and clearer rules to guide palliative care for people with dementia co-existed with feared loss of flexibility in clinical practice. • The views of participants in this study suggest that there should be some caution when systematising palliative care for people with dementia and that all care providers need to be fully engaged with this systematisation process so as to retain as much flexibility as possible. The recent controversy about the LCP illustrates this caution. • Palliative care should be based on a multidisciplinary approach, where a range of professionals work together (Pastrana et al. 2008). Participants suggested that this remains an aspiration as services remain fragmented, supporting the call from the National • Dementia Strategy for the construction of a clear, integrated dementia care pathway. Harrison-Dening et al. (2012) argue that a lack of coordination, such as that offered by a care pathway, has a profoundly negative effect on the co-ordination of care provided, particularly at times of crisis. • Previously, studies have argued that more education is needed for both professionals and the wider community to improve awareness of dementia, together with more training for professionals to improve the delivery of palliative care for dementia (Sachs et al. 2004). However, in the current study, the term 'training' had two meanings, the acquisition of skills and the development of confidence, which itself refers to the validation of experiential knowledge. There was also recognition that some professionals do not want to work with palliative care or around death, and may claim a lack of knowledge or skill and refer patients to other services, so relinquishing responsibility. Some believe that inadequate training may reinforce the tendency to give responsibility to others (Gott et al. 2012). It appears that 'training' for all professionals and in all sectors should address confidence and fear as well as skill development; this may be best achieved through workplace learning. Despite increasing attention to palliative care within undergraduate medical and nursing curriculum (Sullivan et al. 2003), currently, few educational interventions have been developed and evaluated (Raymond et al. 2014b). • There is little hospice care for people with dementia in England and the care home sector is large, but varies in capacity, engagement with health professionals and skill mix. The dementia care workforce in social care (including care homes and home care) is the least qualified part of the sector and experiences high levels of staff turnover. Policy aspirations about training need to recognise this.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Unclear. Participants were identified using purposive sampling supported by snow-balling methods. This could have led to sampling bias. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Unclear – see comment above. • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Unclear – the authors did not comment on whether saturation of themes had been reached. • Is there a clear statement of findings? Yes

Full citation	Davies N, Maio L, Vedavanam K, Manthorpe J, Vernooij-Dassen M, Iliffe S, and Team Impact Research. (2014). Barriers to the provision of high-quality palliative care for people with dementia in England: a qualitative study of professionals' experiences. Health & Social Care in the Community, 22(4), pp.386-94.
	• How valuable is the research? Very valuable Overall quality: Moderate

Full citation	Dening KH, Greenish W, Jones L, et al. Barriers to providing end-of-life care for people with dementia: a whole-system qualitative study. BMJ Supportive & Palliative Care (2012). doi:10.1136/bmjspcare-2011-000178
Study details	Country/ies where the study was carried out: UK Study type: Semi-structured interviews and focus groups Aim of the study: To identify perceived and real barriers that prevent people with dementia and their carers receiving end-of-life care of acceptable quality Study dates: 2010-11 Source of funding: Marie Curie Palliative Care Research Unit from Marie Curie Cancer Care (UK
Participants	• Sample size: 50 informal carers and staff • Inclusion criteria: Recently bereaved family carers of persons with dementia and health and social care professionals who were involved in care for people with dementia towards the end of life. • Exclusion criteria: None • Sample characteristics: 7 interviews with carers. Six focus groups were held. Participants were district nurses (five), the palliative care team (five), admiral nurses (four), care home managers (five), hospice staff (four) and adult social services care managers (three). Individual interviews were held with two local general practitioners (GP), two senior acute hospital nurses, one geriatrician, one ambulance manager, one doctor from the primary care out of hours service, one old age psychiatrist, one private care agency manager, two social services day care and care home managers, a community matron, advocates and two with staff from an Asian carers support group
Methods	Each focus group comprised of staff from one professional group, was led by a researcher with clinical experience in this field and lasted approximately 1 hour, using a structured topic guide. A topic guide similar to that for the focus groups was used to lead semi-structured interviews, allowing a natural flow of conversation while ensuring comprehensive data collection. Interviews were conducted in a place of the carer's choice, usually their own home, lasting approximately 1 hour.
Thematic analysis	• Theme 1: Pathways of care ○ Finding 1: People with advanced dementia had complex medical and social needs requiring input from a number of agencies, but the coordination was poor. ○ Finding 2: A significant factor for out of hours staff was that they could not contact a patient's GP and did not have access to primary care records. ○ Finding 3: Residential and social care staff often felt unsupported during out of hours periods and unclear as to what alternatives they had

Full citation	Dening KH, Greenish W, Jones L, et al. Barriers to providing end-of-life care for people with dementia: a whole-system qualitative study. BMJ Supportive & Palliative Care (2012). doi:10.1136/bmjspcare-2011-000178
	to acute hospital admission. ○ Finding 4: Both family carers and professionals were unsure when a person with dementia was entering the terminal phase of the illness. They found it difficult to manage uncertainty; this would lead to inappropriate or reactive care. "...difficulty in enabling staff carers and GP to acknowledge that the person with dementia is in the terminal phase and when it is not clear, there is a tension about what to do or not to do in the event of a sudden change in the persons condition". (Community Matron) • Theme 2: Impact of hospitalisation ○ Finding 1: Both family carers and staff discussed the negative impact of hospital admissions for the person with dementia towards the end of their lives. "Send an elderly patient with dementia to hospital and they will probably die. A&E is not the place for palliative dying patients". (GP) ○ Finding 2: In particular, people with dementia were often discharged from hospital in a worse state than when they had been admitted; hospital acquired infections, bedsores and worsening of behavioural problems were described. ○ Finding 3: In addition to staff feeling that they needed more training and support, the acute hospital and its systems were recognised as providing barriers to good quality care. "...hospital environment is not conducive to supporting patients with advanced dementia....we do not treat or provide care differently to patients with dementia. The hospital layout does not lend itself to wandering or agitated patients". (First Response Nurse) ○ Finding 4: Carers described how acute hospital staff struggled to provide basic care. Carers perceived a lack of understanding, little compassion and low staffing levels. "He was agitated and frustrated in hospital...he didn't know where he was, why he was there and was aggressive a couple of times...he wandered and when (they) tried to get him back he hit out. They got security in, sedated him and he slept for 24 hours with no food or drink...that was in the last three months of his life". (Carer) ○ Finding 5: For some family carers, the demands placed upon them were more burdensome than if the person with dementia was still at home "They had no skills or awareness of dementia...staff called me day and night when they had problems. I was called at 2 am one morning...he could not understand why they were doing these things to him. He had no dignity...no one helped him to eat or drink". (Carer) • Theme 3: Advance care planning ○ Finding 1: There was variable awareness of advance care planning among family and professional carers. Social care staff feared censure from regulatory authorities if they did not call emergency services during a crisis. "If we had prior knowledge...then a resuscitation attempt would not have been attempted. Where there is a properly constituted AD [advanced directive] then it will be honoured...people still call the ambulance, emotions go to pot in a crisis". (Ambulance Manager) ○ Finding 2: There was little evidence that people at any stage of dementia were asked about their wishes. Carers therefore often have to make complex decisions for their relative, with little support or information. "We had to make important decisions... we found this hard and needed help...they thought he might need a tube to feed or another treatment that I cannot remember. Three different doctors said three different things...they said 'you have to decide'". (Carer) ○ Finding 3: If advance care plans were in place then more appropriate care could be given

Full citation	Dening KH, Greenish W, Jones L, et al. Barriers to providing end-of-life care for people with dementia: a whole-system qualitative study. BMJ Supportive & Palliative Care (2012). doi:10.1136/bmjspcare-2011-000178
	• Theme 4: Impact on carers ○ Finding 1: Family carers described how little happened routinely; they had to initiate and then "push" for services to be provided, these were unpredictable and fragmented. "I had to request her annual review...no automatic follow up...no routine visits ... I had to ring up the surgery to request a visit to the home for the flu vaccine. She was on (medication) for years and received a continuous prescription without reviews". (Carer) ○ Finding 2: Carers described the physical and emotional demands of caring over long periods of time, incontinence, lack of sleep and behavioural problems were particularly difficult to manage ○ Finding 3: Care home staff felt that their feelings of loss when a resident died were not acknowledged • Theme 5: Skills and training of staff ○ Finding 1: During their day-to-day practice, a wide range of health and social care staff came into contact with people dying with dementia. Many, particularly hospice, ambulance staff and district nurses acknowledged they had received little or no training in dementia, in particular concerning communication and managing behavioural problems "Dealing with people with dementia is not part of the crew's training package. It is touched on but it is not sufficient". (Ambulance Manager) "Staff at the hospital need to have more knowledge and skills to care for people with dementia....I found three nurses trying to restrain him in a corridor, one was hit by him. It was not his fault; he couldn't understand why they were doing these things to him. When I cared for him they said 'oh he is like a baby with you'". (Carer) ○ Finding 2: High staff turnover made effective care difficult. "The staff turnover is high in residential care homes and therefore investment in training is difficult and needs to be constantly ongoing". (Community Matron) • Theme 6: Good practice points ○ Finding 1: The Admiral Nursing service supported people with dementia and their carers throughout the illness trajectory and beyond to bereavement "The Admiral Nurse was very supportive; I do not know what I would have done without her". (Carer) ○ Finding 2: 'In reach' services which worked to improve staff confidence were particularly valued; particularly the Community Matron supporting care homes in dementia care and end-of-life care and the Gold Standards Framework. "...it is the greatest improvement in residential care in the last few years". (Care Home Manager)
Author's comments	• Qualitative methods of service evaluation facilitated a broader and deeper understanding of a range of perspectives, which, with other components of rapid participatory appraisal, generated potential solutions to improve care • All staff were keen to provide better quality end–of-life care to people with dementia and were acutely aware of the limitations, both in their own knowledge and skills and in the health and social care system within which they were working. Many of the barriers were associated with lack of inter-agency communication, not having a clear dementia care pathway and a sense of helplessness. However, none of these are likely to require specialist palliative care interventions.
Quality	• Was there a clear statement of the aims of the research? Yes

Full citation	Dening KH, Greenish W, Jones L, et al. Barriers to providing end-of-life care for people with dementia: a whole-system qualitative study. BMJ Supportive & Palliative Care (2012). doi:10.1136/bmjspcare-2011-000178
assessment	• Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Unclear – no clear justification for sample sizes used. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Unclear – no details reported • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Moderate

Full citation	Grisaffi K, Robinson L. (2010). Timing of end-of-life care in dementia: difficulties and dilemmas for GPs. Journal of Dementia Care, 18(3), pp.36-39.
Study details	Country/ies where the study was carried out: Northumberland, UK Study type: Semi-structured interviews Aim of the study: To research GP's views and experiences of end-of-life care for their patients who have dementia. Study dates: 2010 Source of funding: Scientific Foundation Board of the Royal College of General Practitioners
Participants	• Sample size: 10 GPs • Inclusion criteria: GPs with experience of end-of-life care for people with dementia • Exclusion criteria: None • Sample characteristics: 10 GPs including: 7 principals (of whom 4 had been in practice for over 25 years), 1 locum GP, 1 GP registrar and 1 salaried GP.
Methods	The invitation to participate was sent to all GPs in 12 practices. The interview guide, developed following a literature review, was initially piloted and refined. The interview enquired about participants': understanding of end-of-life care, especially in dementia; views and experiences of providing end-of-life care for people with dementia; unmet needs in this area.
Thematic analysis	• Theme 1: Professional - Difficulty in deciding when to start end-of-life care. The typically slow erratic decline and the indicators for starting the pathway could lead to either a person being on it for a long time or 'yo-yoing' on and off as their state fluctuated. One GP said: "If you think of the sort of criteria for people on to the pathway you know I think a few of my demented patients who would have met the criteria for at least eighteen months or more before they've actually died… we put them on the pathway one day because they're not eating… three

Full citation	Grisaffi K, Robinson L. (2010). Timing of end-of-life care in dementia: difficulties and dilemmas for GPs. Journal of Dementia Care, 18(3), pp.36-39.
	days later you take them off again because they've suddenly got a bit better." • Theme 2: Professional - GP's prior knowledge of the person with dementia is important in informing decisions. To help the person overcome the communication and capacity issues, relatives and carers are seen as an expert source of information regarding the person's wishes. One GP said: "It's much easier to look after somebody with dementia if you've known them for years and years… you've seen them gradually decline and you sort of know yourself that they're slowly dying… there are no rules." Another GP said: "I think what you try and do is to get a flavour from the people who have responsibility for their care as to what it is that they would have wanted… if you can't get it from the person themselves." • Theme 3: Professional - Indicators for end-of-life care include: social withdrawal, concurrent illness, diminished oral intake, becoming bed bound, weight loss and bed sores. ○ Finding 1: One GP said: "The few cases of end-of-life dementia that I've seen have generally just disappeared into themselves." ○ Finding 2: Concurrent illness was frequently cited as another indicator for the end of life in dementia. One GP suggested that concurrent illness was welcomed, providing an opportunity to discuss difficult end-of-life decisions. ○ Finding 3: Other clinical features suggesting proximity of the end of life included diminished oral intake, becoming bed bound, weight loss, and bed sores. One GP said: "Inability to tolerate any sort of oral intake – particularly fluids, unconsciousness, respiratory problems – particularly when infection supervenes, severe skin problems. Those are the obvious ones, I think." • Theme 4: Professional – Planning. Advance planning for end-of-life care needed to be held far in advance of the event. ○ Finding 1: Advance planning for end-of-life care needed to be held far in advance of the event. One GP said: "I suspect it might be more difficult… if you're going to talk to people who have dementing illness when they're still well enough to be able to engage and to comprehend… you may actually be having to have that conversation with them a long time before they actually die." Another GP said: "If I was going to look at one particular aspect of what I do, it would be the avoiding of crisis… planning crisis management, so that people didn't end up where they don't want to be." ○ Finding 2: Discontinuity of care. One GP said: "In a nursing home, you're often seeing somebody you've never met before. You've got a list of their medication and their diagnosis and you might have a carer who has only looked after them for a couple of days or something… and it makes it really, really difficult to make a proper decision." • Theme 5: Professional - There is a need to incorporate elements of systemisation. One GP said: "I think it is very difficult, and I think it's because we don't have clear guidelines, protocols and so on… that we're saying there is no point in

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	pursuing this treatment any further or this disease or that disease and we… I don't believe we have for dementia."
Author's comments	• GPs experience difficulty in knowing when to initiate end-of-life care. • GPs felt a need for education on end-of-life care for dementia, improved planning and protocols and pathways to aid this were seen as key to improving such care.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. The GPs in this study came from only 4 out of the 12 practices invited to participate. Data saturation was not achieved. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Moderate

Full citation	Lamahewa K, Mathew R, Iliffe S, Wilcock J, Manthorpe J, Sampson E L, and Davies N (2017) A qualitative study exploring the difficulties influencing decision making at the end of life for people with dementia. Health Expectations 22, 22
Study details	Country/ies where the study was carried out: UK Study type: focus groups and semi-structured interviews Aim of the study: To explore difficulties in decision making for practitioners and family carers at the end of life for people with dementia Study dates: not provided Source of funding: the Clinical Research Networks of the National Institute for Health Research (NIHR)
Participants	• Sample size: 10 carers of people living with dementia • Inclusion criteria: former and current family carers of a person with dementia • Exclusion criteria: none • Sample characteristics: not provided
Methods	Focus groups (n=6) with current carers and individual semi-structured interviews (n=4) with former carers
Thematic	• Theme 1: Knowing the person well and having a sense of their personal and social identity was said to enable carers and health-care

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analysis	professionals to make better informed best interests decisions on behalf of a person with dementia. This was thought to be particularly pertinent at the end of life, when the person with dementia may not always able to verbally express themselves. ○ Finding 1: A former carer said: "Really to look at that [best interests], you've got to know what their quality of life was to start with, to be able to judge their loss of quality of life." ○ Finding 2: A former carer said: "It is a sustained observation, actually from the family carers that they know little nuances... [which] at times, the ward doctors, the nurses do not." • Theme 2: A sense of preparedness, understanding and insight into the impact of dementia on the end of life seemed likely to have resulted in a greater level of acceptance amongst some carers, which was said to have a powerful influence on decision making between families and practitioners. This was highlighted through the account of one carer who explained that she had not wanted to put her husband through any unnecessary effort to extend his life: ○ Finding 1: A former carer said: "Well […] the stage that he was at, there was no point in trying to extend life. He, we were at the end. We'd done everything that we could. It was not that we were trying to get rid of him… We had no other, we were only after his best interests." • Theme 3: As people moved through the care pathway, the lack of familiarity of the person with dementia by health-care providers inadvertently leads to disease labelling, whereby the individuality and identity of the person is lost and they are defined by their disease. This was considered to be particularly relevant when a person with dementia is admitted to hospital where staff have no information about them. ○ Finding 1: A current carer said: "…they're treating him, you know, like this old person with dementia, not another one, you know, coming in with a UTI or a collapse…sort of getting rid of you as soon as they can and not that sort of personalised care." • Theme 4: When healthcare professionals do not communicate with carers because of poor communication or lack of time to involve the family, this can complicate decision making. As one family carer described: ○ Finding 1: A current carer said: "…in the past I've been with him to the hospital where they didn't really want… weren't interested in what I was saying. I was saying, this is not normal, but they were just getting on doing their checks and didn't appear to be taking much notice of what I said, really, which I thought was a bit off but, okay, we go along with whatever we get, you know, I thought, okay, that's their way of working." • Theme 5: There was a sense of frustration due to the lack of continuity in some settings, where family carers reported often having to retell the same narrative to different health-care professionals, sometimes, even within the same care setting. One family carer explained: ○ Finding 1: A current carer said: "…I don't get to speak to the same person, it's another person and you think, oh, you know, they don't know what I said last time." • Theme 6: Often decisions were based on the family member's insight about/or knowledge of the values or preferences of the person with dementia. However, they expressed feelings of uncertainty in how to best meet the needs of their relative. Further complications resulted if formal discussion had not taken place or if legal arrangements were not in place. ○ Finding 1: A current carer said: "It is difficult for me, or anybody else, probably, to understand what's going on in her brain. The only measure I've got is that she is calm, contented and, as far as I'm aware, well looked after… my view would be that she is where she does not want to be… we both were of the view that we didn't want to go that route… My perception is that she is… existing, which is not the situation, when we sort of had our faculties that we wanted to be in, either of us. In fact, my… I think probably one of the things to bring

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	out is you've got a living will, but it needs to be updated on a regular basis… Now, effectively, that's what I would have put in M's, if we'd done it, because, I mean, she's living on a knife-edge…" ○ Finding 2: A current carer said: "I mean, she's had breast cancer twice – if something, another cancer developed, my view would be, let it be; keep her comfortable…you think you know what the individual would want. We've been married, what, 50-odd years, 52 years, but that's my perception. I don't know hers other than what might have been expressed in a living will."
Author's comments	This study suggests that the physical impacts of dementia, beyond cognitive decline, may need to be better recognised by practitioners and that there should be more efforts to engage families in such discussions if they wish. In terms of changes in care settings, decision makers need to consider the impact of moving as weighed against the potential gains. It is likely that some conversations with relatives need to be revisited multiple-times, as appropriate. Although increased importance is being given to advance care planning, it is evident that the uncertainty around decision making continues; therefore, important conversations between the triad of decision makers need to take place at an early stage. Movement through care settings is likely to complicate decision making and make it unclear as to whether end of life conversations have taken place. The role of GPs may extend to forestalling unnecessary movement through different care settings, facilitating a more seamless journey of care when necessary, and ensuring better transfer of information about the person with dementia. Additionally, there appears to be a pressing need for improvements in informational sharing practices and policy. Practitioners should reflect on their own values and whether the expectations they place on themselves are in line with good decision making for their patients. Training is not always enough and guidelines can only guide to some extent. The authors suggest what is needed is more practical assistance, a tool such as a decision aid that encourages more engagement between professionals and carers, to have difficult conversations and carefully consider difficult decisions which need to be made. A tool such as this may enhance the engagement with advance care planning, and encourage both more professionals and people with dementia and their families to forward plan. Similarly, such a tool may be useful when planning has not taken place and decisions need to be made later on in the course of dementia when the person no longer has capacity. Finally, such a tool could be used as a means of engaging those practitioners and or family in difficult conversation which many so often actively avoid.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Unclear. There relatively few participants. The authors did not say that saturation of themes had been reached. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Yes • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable

Full citation	Lamahewa K, Mathew R, Iliffe S, Wilcock J, Manthorpe J, Sampson E L, and Davies N (2017) A qualitative study exploring the difficulties influencing decision making at the end of life for people with dementia. Health Expectations 22, 22
	Overall quality: Moderate

Full citation	Lawrence V, Samsi K, Murray J, Harari D, Banerjee S. (2011). Dying well with dementia: qualitative examination of end-of-life care. British Journal of Psychiatry, 199(5), 417-22.
Study details	Country/ies where the study was carried out: South London, UK Study type: Structured interviews Aim of the study: To identify how effective good-quality end-of-life care might be delivered for people with dementia across care settings Study dates: 2011 Source of funding: The Maudsley Charity
Participants	• Sample size: 23 care professionals, 27 bereaved family carers. • Inclusion criteria: Four community mental health teams, five care homes, five NHS continuing care units and two general hospitals participated in the research. Researchers introduced the aims and objectives of the study at staff meetings, and care professionals were invited to participate in an interview and to identify and introduce the research to eligible bereaved carers. The researchers emphasised that they were interested in speaking with carers with both positive and negative end-of-life care experiences. Carers were defined as eligible if the person with dementia for whom they had cared had died in the previous 2–6 months. Carers who expressed an interest in hearing more about the study were sent an information sheet, which was followed by a telephone call from the researcher. They also interviewed care professionals in palliative care teams, liaison psychiatry teams, Alzheimer's Society and carer organisations. Purposive sampling was conducted across four south London boroughs. • Exclusion criteria: None • Sample characteristics: Within the sample of 27 bereaved carers, 11 people with dementia had died in an NHS continuing care ward, 5 in a care home, 5 in their own home and 6 in a general hospital. However, most had experience of care in several different settings. Within the sample of 23 professionals, 1 was an assistant psychologist, 3 were care assistants, 2 were clinical nurse specialists, 1 was a clinical psychologist, 1 was a consultant physician, 3 were deputy managers, 4 were managers, 3 were nurses, 2 were psychiatric nurses and 3 were psychiatrists.
Methods	Initial interview guides incorporating topics of interest were generated from the literature. The interviews with carers began by exploring the quality of life of their relative (the person with dementia) in the final 6 months of their lives. Carers identified positive and negative aspects of care relating to: staff, the care environment, the management of pain and distress, treatment decisions, and their relative's death. Carers were also asked to reflect on their relative's care preferences, attitudes towards care planning and what, if anything, they wished they had done differently. Interviews with care professionals examined attitudes towards good end-of-life care, the challenges to its provision and issues surrounding planning, treatment decisions and interaction with the family. The interview guides were amended iteratively and followed the participants' concerns. Obtaining the perspectives of family and paid carers provided insights into the provision of care. Interviews lasted for up to an hour.
Thematic	• Theme 1: Bereaved carer – meeting physical care needs:

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analysis	○ Finding 1: Ensuring adequate food and fluid intake was considered paramount, but care homes were occasionally evaluated negatively in this respect. Some were criticised for providing insufficient support with eating, whereas others were criticised for feeding the person with dementia unnecessarily. Hospitals were condemned for failing to meet this basic need. Numerous examples were given of people with dementia being offered food that they were unable to chew, swallow or cut up. For many, this typified hospital staff's lack of understanding of the needs of people with dementia and what to do to meet them: 'There was no people feeding them and I went, I used to go in and feed her and they said, ''Oh no, she's here to be rehabilitated, you shouldn't feed her, it's spoiling her, she can do it herself,'' well . . . she couldn't do it at all and as I say her eating was getting worse and worse at that stage.' (Daughter, general hospital) The provision or absence of good nursing care frequently dominated family carers' accounts. Family carers were highly appreciative when their relative's personal care and hygiene were attended to efficiently: equally, instances (often in general hospitals) in which individuals were not routinely washed, toileted or dressed provoked enormous distress. • Theme 2: Bereaved carer – going beyond task-focused care End-of-life care was evaluated positively if it was felt that the professionals cared about their dying relative. Families prioritised a 'warm atmosphere' where people with dementia were made to feel relaxed and safe: 'We was just glad that my mum had found this lovely home for him and I would recommend it to anybody because they do care. When he was in his bed they used to tell him what they was going to do, like if he was going to be washed, they would tell him that they was going to wash him . . . they talked him all the way through so that he wouldn't get frightened or anything and they were just brilliant with him.' (Cousin, continuing care unit) • Theme 3: Bereaved carer – Planning ○ Finding 1: Although family members speculated about the respective advantages and disadvantages of advance directives and advance statements, few were aware of their existence. One family member commented that advance care planning might alleviate the burden associated with this role: 'I think it makes it easier for the carer if they know because then you haven't got that moral dilemma. Because like I was placed in . . . was I stopping her having her last chance of life by not letting her go to [hospital] for the dehydration? . . . Would she have wanted it? You know you tear yourself in pieces.' (Daughter, general hospital) ○ Finding 2: A distinguishing feature of NHS continuing care wards and certain care homes was the attention given to discussing treatment with families and the wider care team. Meetings were often scheduled to provide family members with information and to reach a unified position. Some relatives complained that hospital staff neither informed nor consulted them about the use of feeding tubes, catheters, antibiotics, investigative procedures and interventions. ○ Finding 3: Achieving a good death also involved enabling family members to be present at the time of death. There was consensus that this was of enormous importance for both the person with dementia and the family: 'We knew she wanted to be at home so we put in place arrangements . . . we were talking about palliative care and that sort of thing with local authorities . . . and things like the carers, for example, we took them into the hospital, the administrators from the care company, to be with the nurse who showed how to actually feed her, to put some water in her mouth and how to actually handle her. And we had got the hospital bed in, we turned the dining room into the bedroom, we got a big hospital bed, we got a hoist, we got all the equipment in and the carer

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administrator came on the first day to do the risk assessment.' (Son)

- Theme 4: Professional – meeting physical care needs:
  - Finding 1: Palliative care specialists emphasised that identifying and responding to the physical care needs of the person with dementia must form the cornerstone of any approach:

"Well people with dementia in the advanced stages actually don't have that many complex needs, it's actually quite basic care needs that are not being met." (Specialist nurse, palliative care)

  - Finding 2: Staff in almost all settings identified pain control as underlying good-quality end-of-life care for people with dementia; however, it was implied that this was challenging because individuals might be unable to verbalise their discomfort. Continuing care staff and palliative care nurses stressed the importance of assessing facial expressions, movements, reactions and changes in the individual when assessing pain – skills developed by working with people with dementia and getting to know individuals. Care professionals working in general hospitals acknowledged that these needs risked being overlooked in the hectic and demanding ward environment:

'You have other distractions and that's as much a challenge, isn't it, that you've got to make sure that person who can't communicate, can't move, can't respond at all, is comfortable and got good mouth care and so on, and yet the acutely unwell person is, you know, we have lifesaving maybe.' (Matron, general hospital)

  - Finding 3: Palliative care nurses were considered skilled in identifying and managing pain in patients with complex needs and were also sensitive to nausea and hallucinations in people with dementia at the end of life. Second to pain control was the perceived support and reassurance that palliative nurses offered nursing staff in these settings. Managers and care assistants stated that they found it helpful to know what to expect in the patient's last few days and to be reassured that they were doing the right thing. Continuing care staff often felt equipped to provide end-of-life care, yet also valued the option of making a referral to palliative care if necessary. Expertise, and confidence in one's expertise, were considered vital in making difficult treatment decisions, such as withdrawing active treatment. Palliative care guidelines helped care professionals and family members accept the legitimacy of such action.

'I think it has changed people's attitudes and I think it makes sure that somebody, because we think she's dying we shouldn't be bleeding her every day or sticking any tubes in her or that sort of thing. Before there was no structure on how you would look after somebody who's dying on the ward.' (Liaison psychiatrist, general hospital)

Pain management in care homes was criticised:

'My experience of going into nursing homes is that I will often think that non-verbally someone is indicating to me that they have got pain, but because the person can't tell the nurse looking after them that they have got pain the nurse doesn't recognise it.' (Palliative care nurse, general hospital)

Palliative care nurses commented that the Gold Standards Framework (www.goldstandardsframework.org.uk) was helping their involvement in the care of individuals in the community and care homes. However, there was also recognition that this framework required a substantial financial commitment from care homes and a willingness to release staff for training. Other care homes were not working with these protocols and did not appreciate why they might be of benefit.

- Theme 5: Professional – going beyond task-focused care
  - Finding 1: One psychologist and two palliative care specialists highlighted the risk of becoming entirely task-focused, noting how important but difficult it is for staff to empathise with the person with dementia in the final stages of the illness. It was felt this was a particular problem

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in dementia because of cognitive and communication issues, which may even make a person with dementia a less favoured patient owing to a lack of reciprocity.

Care professionals across settings acknowledged that they sometimes struggled to see that the person was 'still there':

'We don't know whether someone is still hearing what we are saying. You know, you think only their heartbeat is left.' (Deputy manager, care home).

It was suggested that concentrating on practicalities rather than on individuals' emotional needs might allow staff to distance themselves from difficult situations. This was epitomised in attitudes towards a good death. Whereas some care professionals focused on providing emotional comfort, others listed the practical tasks that had to be completed at that time:

'We were just preparing, tidying up, making her clean, her face and then sitting her up. All we can do for someone is make sure the room is clean, tidy.' (Deputy manager, care home)

- Finding 2: Staff described getting to know individual's interests, sensitivities and preferences. A number of NHS continuing care staff stated that assessments were conducted with the patient and their family at admission, which helped to build a portrait of the person. Getting to know the individual's family also provided insight into the patient and helped to make decisions regarding their everyday care. This was identified as a difficulty within general hospitals, as staff did not have the advantage of spending time with the individual and their families over a long period. Getting to know the individual also proved expedient in meeting physical needs, as care professionals were better placed to identify changes in the patient and thus detect suffering or discomfort. Providing individualised care could also avoid distress:

'She would never ever wear skirts, she would wear trousers and jumpers and the staff not knowing that would put her skirt on her and she would get all upset and irate and wasn't able to express that to the staff.' (Community psychiatric nurse, community)

- Theme 6: Professional – Planning
  - Finding 1: Despite a consensus among care professionals that people with dementia should be given the opportunity to plan for the future, it was apparent that this opportunity might not always arise. Advance statements and advance planning were seen as 'someone else's problem'. Only one of the 23 care professionals, manager of a local Alzheimer's Society branch, considered it her responsibility to assume this role.
  - Finding 2: The question of whether individuals should be transferred to hospital during the final stages of their life emerged as one of the most common and problematic decisions. It was evident that hospitalisation was a frequent occurrence despite agreement among care professionals that this was often inappropriate:

'If you take a nursing home patient you know, somebody who isn't eating or drinking, I mean they're dehydrated, they will send them to hospital when actually invariably somebody may die but actually those are the people that we shouldn't see. Those are the people who should remain in nursing homes and they should have an end-of-life care plan.' (Nurse, general hospital)

  - Finding 3: Palliative care staff noted that professionals across care settings could be reluctant to withdraw active treatment in the absence of explicit planning or a clear consensus among the care team:

'He was imminently dying, yet the [general practitioner] phoned the family and I think the way it was put to the family, well, the family then said let's send him to hospital, I don't know if the family actually realised that he was imminently dying or what they thought hospital would achieve. So it was quite distressing for me and the staff to see this man who was imminently dying being shipped off to hospital.' (Nurse specialist, palliative care)

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Author's comments	• If end-of-life care does not take into account the unique circumstances and needs of people with dementia, it is likely to fail them. This requires service providers and care professionals to ensure that the environments in which people live and die – be they at home, in a care home, in NHS continuing care or in a general hospital – do three things: use knowledge of dementia to identify and respond to physical care needs; go beyond task focused care; and prioritise planning and communication with the family. • The data support the suggestion that NHS continuing care units might act as a model for meeting the complex needs of people with advanced dementia.17 The units in this study provided valuable examples of good end-of-life care, whereby care plans were carefully formulated with the family and services worked to ensure that they were followed, including the avoidance of transfer to acute hospitals. • For people with dementia we found that death in general hospital was almost invariably associated with poor quality, with staff appearing to provide inadequate assistance with eating and drinking, and failing to manage pain, to seek information from carers about the individual or to discuss treatment options with families at the end of life. • Staff interviews tended to focus on the specialist nursing skills that are required at end-of-life care, and although controlling pain and other symptoms is integral to a palliative care approach, this must not overshadow the imperative of meeting basic nursing needs. Where available, specialist palliative input from staff knowledgeable in dementia provided valuable instruction and support, helping to instil staff with the confidence to manage end-of-life care themselves.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? Yes – recruitment continued until there was saturation of themes. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Unclear. The professionals were asked to recruit the carers. Therefore, there is the possibility of confirmation bias even though negative experiences were sought as well as positive ones. • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? It is valuable Overall quality: Moderate

Full citation	**Moore K J, Davis S, Gola A, Harrington J, Kupeli N, Vickerstaff V, King M, Leavey G, Nazareth I, Jones L, and Sampson E L (2017) Experiences of end of life amongst family carers of people with advanced dementia: longitudinal cohort study with mixed methods. BMC Geriatrics 17, 135**
Study details	Country/ies where the study was carried out: UK Study type: Interviews

Full citation	**Moore K J, Davis S, Gola A, Harrington J, Kupeli N, Vickerstaff V, King M, Leavey G, Nazareth I, Jones L, and Sampson E L (2017) Experiences of end of life amongst family carers of people with advanced dementia: longitudinal cohort study with mixed methods. BMC Geriatrics 17, 135**
	Aim of the study: The aim was to understand the experiences of carers during advanced dementia, examining links with both mental health and experiences of EOL care. Study dates: May 2012 to December 2014 Source of funding: This work was supported by a grant from Marie Curie through a process administered in partnership with Cancer Research UK.
Participants	• Sample size: 35 family carers of people living with dementia • Inclusion criteria: family carers of people living with advanced dementia who were aged 65 years and over. Functional Assessment Staging Scale grade 6e and above (e.g. doubly incontinent, loss of ability to speak more than six words, ambulatory ability lost or can't hold up head independently). Carers approached for participation included family members or friends in regular contact with the person with dementia, usually the next of kin or a key decision maker. • Exclusion criteria: none • Sample characteristics: not provided
Methods	Qualitative interviews after death enabled an in-depth exploration of carers' experiences of end of life care. They invited bereaved carers to take part in in-depth qualitative interviews at a place of their choice 2-months after the death.
Thematic analysis	• Theme 1: Carers often held strong views regarding the perceived quality of care. ○ Finding 1: A daughter of a person living with dementia said: "So I got back to her care manager and said 'this isn't on… give me lists of all other homes. I'm going to find her a better home and I'm going to complain formally about this particular care home because they should not be EMI [Elderly Mentally Impaired] registered'… I went around and found her another care home and in June 2010 she moved… and they were absolutely brilliant." ○ Finding 2: Five carers moved their relative from one service to another (3 from a care home and 2 from home-based care provision) when they were dissatisfied with the quality of care. • Theme 2: Carers valued continuity and receiving regular feedback about their relative's health condition and the progression of dementia. ○ Finding 1: A daughter of a person living with dementia said: "[Care home staff] were very good that they sort of found out different ways to help her… and they always kept us informed of what they'd found better for mum. Because they obviously saw her all the time, so that was very good we felt." • Theme 3: Going beyond task-focused care: Carers were comforted when they felt that care staff genuinely cared for their relative and were trustworthy. ○ Finding 1: A daughter of a person living with dementia said: "It wasn't until she went into the final care home in June 2010 that I could relax about her care, because, as I said, they had the best provision for it, and I felt she was treated as an individual." • Theme 4: Being able to monitor services was important and reflected poor levels of trust in service providers. One carer received input from the warden in the block of flats who would take note of when social services staff would visit for only a few minutes. Some carers monitored services through regular visits to the care home.

Full citation	Moore K J, Davis S, Gola A, Harrington J, Kupeli N, Vickerstaff V, King M, Leavey G, Nazareth I, Jones L, and Sampson E L (2017) Experiences of end of life amongst family carers of people with advanced dementia: longitudinal cohort study with mixed methods. BMC Geriatrics 17, 135

- Finding 1: A son of a person living with dementia said: "I knew if you'd stopped going up then like the standards would drop. When they knew I was coming up, I knew my Mum was always like kept spotless, if they knew I was there, everything would be near enough right."

- Theme 5: Carers' capacity to understand the progression of dementia and be involved and informed during advanced dementia relied on information provision throughout the different stages of dementia. At diagnosis, carers were rarely informed about the likely progression of dementia.
  - Finding 1: A daughter of a person living with dementia said: "Nobody said anything about the Alzheimer's ever. Maybe they don't know what... how it's going to proceed. It was never really an issue any more. It was a label that had been given her and if she went into hospital it was mentioned."
- Theme 6: The unpredictable course of dementia made it very challenging for carers to prepare for the end of life (EOL) and some were unsure about the value of early information about advanced stages of disease given the potentially unnecessary anxiety this might create.
  - Finding 1: A husband of a person living with dementia said: "I don't know whether it [information about symptoms of advanced dementia] would've helped or not actually. I mean it's nothing I could have done anything about… …I think it might have helped yes. Might have made me more fearful of the future of course."
- Theme 7: Findings also supported timely and sensitive information provided by a knowledgeable professional and that was reinforced in writing. Some felt that the lack of basic information left them struggling to adapt to changes and feeling ill-prepared for symptoms that they later discovered were common in advanced dementia:
  - Finding 1: A daughter of a person living with dementia said: "Nobody really explained to me then when she was admitted into [Hospital] A&E. I said what is the cause of this foaming at the mouth? … I found out later it's quite a common symptom of end stage dementia.
  - Finding 2: A daughter of a person living with dementia said: "If I'd have had a session with me and someone at the beginning, face to face, to say "right your mum has been diagnosed; this is what you need to expect". But in a very gentle kind of... Like the leaflet you showed me that time. That would've been brilliant… being ignorant isn't going to save you in the long term… need to know that this is a terminal illness, it's not going to just "oh yeah they're old they'll go on till they're a hundred but they'll just have Alzheimer's". …maybe my sister wouldn't have emigrated had she realised "look I've got mum in a home now…right I'm off."
- Theme 8: EOL plans were not started early enough. EOL plans were rarely initiated during the early stages of dementia preventing the person with dementia being involved in decision making. Sometimes the person with dementia was never informed of their diagnosis. EOL planning often occurred after admission to a care home or after a critical health event usually involving hospitalisation in the advanced stages of dementia. Carers often appreciated these conversations as they could be involved in care and feel that they had contributed to a plan to promote comfort care at EOL. However, even when carers were well informed and prepared, a crisis could test these goals for comfort care as the carer was conflicted with wanting to keep their relative alive.
  - Finding 1: A daughter of a person living with dementia said: "…the four paramedics stormed in, took over completely, and sent me and my sister out into the hallway… My sister couldn't watch she was getting so upset and crying her eyes out because they literally pushed everything out of the way, threw her onto the floor, and she's so frail... I don't know whether they cracked her ribs and I was just standing there calmly watching them and saying to my sister "there's still a chance." But it never occurred to me to ask them to stop because we did agree on DNR but in the heat of that moment when you call 999 and when they ask you to do CPR you just do it. You know, it's your

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mum; you try to revive her."

- Theme 9: Some carers were satisfied with EOL care if they felt adequately informed and involved, even when EOL care was not in accordance with advance care plans. One carer indicated that her father was not for resuscitation or hospitalisation but at the end of his life he was taken to hospital and experienced numerous investigations for suspected pneumothorax. She described the hospital staff as "brilliant" as they kept her informed. Other examples of potentially burdensome interventions were seen as necessary by carers, particularly when the intervention had been successful in the past and the person with dementia had recovered:
  - Finding 1: A husband of a person living with dementia said: "They said on one occasion she could be treated here [care home] with oral antibiotics or she could go to hospital and have intravenous antibiotics. And I quickly plumped for the hospital and they sorted her out in a day or two. She may not have recovered if she'd stayed here. That was maybe a year or two before she died."
- Theme 10: Enabling family members to be present at the time of death. For most, but not all, being present at EOL was important and some described vigils from hours to weeks, being with the person before they died.
  - Finding 1: A daughter of a person living with dementia said: "[*So who fed your mum?*] I used to go over and, the last few weeks I used to go over four times a day… Because her lips were cracked and she, she liked tasty bits… I'd sit and feed those to her. And she would eat them."
- Theme 11: Carers often grieve for their relative before the person dies. While carers often described how well they coped with their relative's dementia and dying, there were also many accounts that supported the quantitative findings of high levels of grief and distress. Carers described grief as a staged process pre and post death with losses associated with dementia before death:
  - Finding 1: A daughter of a person living with dementia said: "It's sort of two bereavements really isn't it… first time when he moved out and went into a home... that was more traumatic to be honest… I was crying for about two weeks on and off when that happened and also I suppose it's because you felt inadequate as well that you couldn't cope with it. So this time, although you've lost them, before you'd lost the person he was."
- Theme 12: There was evidence of links between satisfaction with EOL care, the carer's capacity to influence the care being provided, and emotional consequences. Two carers who had not moved their relative from what they perceived as a poor quality care home, reported the lowest satisfaction. This was influenced by their guilt at not having done more to improve EOL care:
  - Finding 1: A daughter of a person living with dementia said: "I'm not making excuses, you know, I could have been more proactive… I just feel I wish I'd done more for him really. I just think he deserved better and I hope that guilt feeling… that I'll learn to live with that really.
  - Finding 2: A daughter of a person living with dementia said: "It's left us burdened with the care system like this… I'd have turned our dining room into a bedsit for her regardless of what the doctors said. God yes, my husband cries about it. He gets so distressed. For months since she died I find it very hard to sleep. I feel I let her down…"
- Theme 13: Participants discussed the failure of services to acknowledge their grief or to provide information about obtaining support. This was both prior to and after their relative's death.
  - Finding 1: A daughter of a person living with dementia said: "As soon as mum died... we had no meetings with social services or no communication even… We did find that strange that there wasn't even a letter saying "sorry what's happened", you know, there was nothing… that would have been nice really to have a bit of continuing help for you or just to say "we're here, this is where you could go for

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	help, counselling or whatever or you might need it in the future". • Theme 14: Despite high levels of grief, many carers felt they did not need formal support or counselling and did not seek it. Instead they described the benefits of their social network including friends, family or faith community. Some carers could not face their grief or the fact that their relative had dementia. For one this led to episodes of binge drinking. Another explained: ○ Finding 1: A daughter of a person living with dementia said: "I suppose we had been told a bit [about dementia] and we knew from what we see on the news and maybe you don't want to accept it… for me personally maybe I pushed it to the back…didn't want to believe it was happening. It was so awful I just didn't want to believe that it was happening." • Theme 15: Carers who felt well informed about how dementia progressed, were regularly updated on their relative's health condition and felt involved appeared more satisfied with EOL care. Those who failed to influence care that they perceived as poor reported high levels of grief after death and experienced guilt and regret. Admission to a care home was often associated with a loss of control and a need for heightened vigilance. One carer whose mother remained at home until her death stated: ○ Finding 1: A daughter of a person living with dementia said: "I have had experience with care homes I suppose with my mother-in-law, I suppose they weren't great. But I'm sure there are good ones if you can afford them, but you don't have the chance to see what they're really like, you can't spend time there. And also, the big issue was that you lost control. If you go into a home you don't know whose looking after them, what's happening at night when the main staff are away." ○ Finding 2: A son of a person living with dementia said: "I was pretty lucky because where I've always probably had people work for me for like 20 odd years, I was used to being in control. So I could go 'well I want that done, that done, this done, that done.' And I sort of worked the same way with me mum."
Author's comments	For some, the difficulty in determining the exact time of death prevented being present at the time of death. Specialist palliative care was requested for some people in hospital; however, this was often described as occurring too late or after demands from the family. Once commenced, specialist palliative care was viewed as enabling a comfortable death and minimising distressing symptoms. During interviews, the poor experiences of care reported were alarming. A number of carers described the need to pay considerably higher financial amounts for better quality services, raising concerns about the quality of services available to more deprived members of society. Any need to change service provider is disruptive and impacts on the continuity of care for the person with dementia and creates additional, unnecessary stress for carers. Carers report high levels of psychological distress during advanced dementia and in the immediate months into bereavement. However, the experience of EOL care in dementia may be amenable to change with the provision of sensitive and timely information about the natural progression of dementia to family carers. Also, providing regular updates about changes in the health status of the person with dementia and discussing EOL preferences can help families understand the progression of disease and prepare for end of life. The extent to which our findings reflect practice across the UK or internationally warrants further investigation.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No. There is not much information as to how these specific groups of people were selected.

Full citation	**Moore K J, Davis S, Gola A, Harrington J, Kupeli N, Vickerstaff V, King M, Leavey G, Nazareth I, Jones L, and Sampson E L (2017) Experiences of end of life amongst family carers of people with advanced dementia: longitudinal cohort study with mixed methods. BMC Geriatrics 17, 135**
	• Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? Unclear. There is not much information as to how these specific groups of people were selected. • Have ethical issues been taken into consideration? Yes • Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Valuable Overall quality: Moderate

Full citation	**Treloar A, Crugel M, and Adamis D. (2009). Palliative and end of life care of dementia at home is feasible and rewarding: results from the 'Hope for Home' study. Dementia (14713012), 8(3), pp.335-347.**
Study details	Country/ies where the study was carried out: Oxleas, UK Study type: Mixed methodology was used with a qualitative semi-structured questionnaire, which allowed the opportunity for interviewees to free interview. Aim of the study: To study a novel service that supports people with advanced dementia at home until death. Study dates: 2003 to 2006 Source of funding: Not stated. The authors work for Oxleas NHS Trust and the Institute of Psychiatry, UK, and Memorial Hospital, UK.
Participants	• Sample size: Carers of 14 people with dementia who had died. • Inclusion criteria: Carers who had looked after people with dementia at home until death. • Exclusion criteria: None • Sample characteristics: The average age at death of the patients was 80.64 [range 55 to 95, median 83],6 were men. The oldest key carer was 91 (average 68.1 [range 36–91]) and half (7) were women. Ten were spouses, and four were children of the index patient. The length of time cared for at home after which the patients would normally have been expected to be in dementia nursing care was between 4 months and 8 years. Two, who turned out to have a very slow progression of illness, were cared for at home for more than 5 years, and three for less than 1 year. Eleven were rated by their carers as having had challenging behaviour problems in the last 2 months of life. Three of the subjects were discharged back to their home from fully funded Dementia Nursing Care Homes, the rest (11) had never been into a care home. Family care of dementia occurred in a variety of settings. Property sizes ranged from 25m2 (a one-bed first-floor maisonette) to 200m2 with between 1 and 11 people resident alongside the index patient. The home of 11 residents constituted a large extended family many of whom contributed to the care of the patient. Eight of the subjects died at home and six in hospital, following brief admissions (maximum three weeks) that resulted from very sudden deterioration or acute respiratory distress, which was difficult to manage at home. The most frequently certified cause of death was pneumonia

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	(9 out of 14). It was thought that with better support services at least some of those six could have been managed at home without a hospital admission. Carers were determined and often quite able. Some said they had been told by statutory agencies they could not do what they intended as they had no experience of such care and thought it would be risky or impossible. They reported the need to be determined to just go ahead anyway.
Methods	This was an exploratory retrospective study of patients who had been supported at home until death. The study did include those who spent the last few days of their lives in hospital. Key carers were identified and interviewed more than three months after the death of the patient.
Thematic analysis	• Theme 1: Bereaved carer – going beyond task-focused care ○ Finding 1: People with dementia can have preferences for food. They may not like hospital food. One carer said: 'When he came out of the hospital he was starving, he would eat anything you would put in front of him. He did not want to eat the hospital food.' Another carer said: 'They kept him in too long. They wanted him to walk with a frame. But he did not like it in there,he did not like the food,he was crying all the time,he was very depressed.' ○ Finding 2: Not liking the hospital environment. One carer said: 'A person with dementia in a normal hospital ward: they just don't go together. One time he was in the hospital they kept calling me again and again to go up there, as they could not cope with him. The first time he went in he was so disruptive he had a nurse 1 to 1 for three days but the next time he went in they had no funding, they could not do it. The first time he was so disruptive they called security, poor bloke was terrified. He was only frightened and trying to get out.' Another carer said: 'We watched somebody dying in the hospital and they put him in a side room, it was very sad. With dad at home we put the video with their marriage and we were singing Christmas carols and have a laugh, you cannot have this in a hospital.'
Author's comments	Anecdotally, as part of their work in this field, they formed the impression that mentally fragile carers are not able to undertake this work.
Quality assessment	• Was there a clear statement of the aims of the research? Yes • Is a qualitative methodology appropriate? Yes • Was the research design appropriate to address the aims of the research? Yes • Was the recruitment strategy appropriate to the aims of the research? No – there are no details of recruitment method. Selection bias is possible. The authors did not comment on whether saturation of themes had been reached. • Was the data collected in a way that addressed the research issue? Yes • Has the relationship between researcher and participants been adequately considered? No – see above comment about the recruitment strategy. • Have ethical issues been taken into consideration? Yes

Full citation	Treloar A, Crugel M, and Adamis D. (2009). Palliative and end of life care of dementia at home is feasible and rewarding: results from the 'Hope for Home' study. Dementia (14713012), 8(3), pp.335-347.
	• Was the data analysis sufficiently rigorous? Yes • Is there a clear statement of findings? Yes • How valuable is the research? Fairly valuable Overall quality: Low

E.15.1.2 Quantitative evidence

Bibliographic reference	Ahronheim JC, Morrison RS, Morris J, Baskin S, Meier DE. Palliative care in advanced dementia: a randomized controlled trial and descriptive analysis. Journal of Palliative Medicine 2000;3(3):265-73
Methods	Randomised controlled trial, randomisation at the level of the individual, conducted over a 3-year period in 1 acute hospital in New York, US.
Participants	99 participants with advanced dementia, staged as FAST 6d or greater, hospitalised for an acute illness. 48 in intervention group, 51 in control group.
Interventions	Intervention: a palliative care team was established in the hospital, consisting of an experienced clinical nurse specialist and ≥ 1 attending geriatrician(s), who also held academic appointments. The palliative care team conducted a palliative consultation for each participant, visited the participant and discussed participant management with the primary healthcare team in the hospital on a daily basis. The palliative care team also met with family carers or other surrogates when they were available and attempted to arrange meetings after hours or by telephone. The goal of the intervention was to enhance participant comfort. During consultation, options discussed included: • avoidance of non-palliative procedures • avoidance of mechanical constraints • administration of pain medication for painful manoeuvres, e.g. ulcer debridement • rehabilitation methods e.g. repositioning, massage • counselling of surrogates and care providers about participant's rights and surrogates responsibilities as decision makers • alternate planning, e.g. forgoing life-sustaining treatments, discharge to hospice, discharge with palliative care plans and avoidance of re-hospitalisation. Control: treatment by primary care team without the input of the palliative care team.
Outcomes	• Number of admissions, length of stay and number of deaths in hospital • Number of non-palliative procedures and interventions • Decisions to forgo life-sustaining treatments • Decision to adopt a palliative care plan, during hospitalisation and on discharge
Notes	1 additional participant was randomised but lost to the study (discharged from the hospital within 24 hours of randomisation) and not

Bibliographic reference	Ahronheim JC, Morrison RS, Morris J, Baskin S, Meier DE. Palliative care in advanced dementia: a randomized controlled trial and descriptive analysis. Journal of Palliative Medicine 2000;3(3):265-73
	included in the analysis. This study was supported by grants from The Greenwall Foundation and The Kornfeld Foundation.
Risk of bias	• Random sequence generation (selection bias): Unclear risk - No details given on method of randomisation used. • Allocation concealment (selection bias): Unclear risk - No details given on method of allocation concealment. • Blinding of participants and personnel (performance bias): High risk - Given the nature of the intervention, there was no blinding of participants or personnel. We judged the risk of bias due to this lack of blinding to be high for all subjective outcomes, as the primary care team may have made different decisions knowing whether a participant was in the intervention or control group. • Blinding of outcome assessment (detection bias): Low risk • Incomplete outcome data (attrition bias): Low risk • Selective reporting (reporting bias): Low risk • Recruitment bias (cluster trials only): Low risk • Other bias: High risk - Potential contamination of control participants, who were being treated by the same primary care team that were receiving input from the palliative care team for the intervention participants.

Bibliographic reference	Hanson LC, Carey TS, Caprio AJ, Lee TJ, Ersek M, Garrett J, et al. Improving decision making for feeding options in advanced dementia: a randomized, controlled trial. Journal of the American Geriatric Society 2011;59(11):2009-16
Methods	Cluster randomised controlled trial, in 24 nursing homes in the US, randomisation at the nursing home level, with enrolment over a 2-year period.
Participants	In total, 256 dyads of a resident with advanced dementia and feeding problems and their surrogate were enrolled in the study, 127 in the intervention group and 129 in the control group. Of these, 90 dyads included a resident with advanced dementia staged as GDS 7 and their surrogate, 46 in intervention group, 44 in control group.
Interventions	Intervention: surrogates received a structured decision aid (printed or audio version) providing information about dementia and feeding options, including feeding for comfort near the end of life, and the outcomes, advantages and disadvantages of feeding tubes or assisted oral feeding. The decision aid also discussed the surrogate's role in decision making. Surrogates reviewed the decision aid during their enrolment interview and received the printed decision aid to take home. Research assistants prompted the surrogates to discuss the decision aid with healthcare providers. Control: surrogates received usual care, including any information typically provided by healthcare providers.
Outcomes	**For all study participants:** Primary outcome: decisional conflict at 3 months, measured by the Decisional Conflict Scale (O'Connor 1995) Secondary outcomes (at 3 months): surrogate knowledge about dementia and feeding options, surrogate-reported frequency of feeding discussions between surrogate and care provider, and feeding treatment use Secondary outcomes (at 9 months): use of new feeding tubes, number of 'do not tube feed' orders, weight loss and mortality

Bibliographic reference	Hanson LC, Carey TS, Caprio AJ, Lee TJ, Ersek M, Garrett J, et al. Improving decision making for feeding options in advanced dementia: a randomized, controlled trial. Journal of the American Geriatric Society 2011;59(11):2009-16
	Outcomes included in re-analysis of subset of participants meeting the inclusion criteria of this review (as requested by review team): Primary outcome: decisional conflict at 3 months, measured by the Decisional Conflict Scale (O'Connor 1995) Secondary outcomes: frequency of feeding discussions between surrogate and care providers and the use of assisted feeding treatments
Notes	90/256 (35%) participants had advanced dementia as defined for this systematic review (staged at GDS 7). The study team reran the analysis to produce data for this subset of the study population for this review. Funding source: NIH-National Institute for Nursing Research RO1 NR009826
Risk of bias	• Random sequence generation (selection bias): Low risk • Allocation concealment (selection bias): Low risk • Blinding of participants and personnel (performance bias): High risk - It was not possible to blind surrogates to the intervention. • Blinding of outcome assessment (detection bias): High risk – Lack of data assessor blinding judged to be a high risk of bias for all outcomes. • Incomplete outcome data (attrition bias): Low risk - Numbers lost to 3-month follow-up in both groups was low (5% and 13%). • Selective reporting (reporting bias): Low risk - All outcomes listed in the Methods section were reported and there was no evidence of selective outcome reporting. • Recruitment bias (cluster trials only): High risk - Because of the nature of the intervention, nursing homes were randomised before recruitment of all participants and surrogate dyads. • Other bias: Low risk - Baseline imbalance between clusters and cluster effects both accounted for in analysis.

Bibliographic reference	Hanson LC, Zimmerman S, Song, MH, et al. Effect of the Goals of Care intervention for advanced dementia: a randomized clinical trial. JAMA Internal Medicine 2017;177(1):24-31
Methods	Cluster randomised controlled trial, in 22 nursing homes in the US, randomisation at the nursing home level
Participants	In total, 302 dyads of a resident with advanced dementia and their family decision makers were enrolled in the study, 151 in the intervention group and 151 in the control group. All the people living with dementia had a global deterioration scale (GDS) score of 5-7, with 25% having a score of 5, 59% a score of 6 and 25% a score of 7.
Interventions	Intervention: 2-part intervention. An 18-minute Goals of Care video decision aid, and a structured discussion with the nursing home care team. Decision aid developed using the International Patient Decision Aid Standards. Includes information on dementia, goals of prolonging life, supporting function, or improving comfort, treatments consistent with each goal, and how to prioritise goals. 1-hour training session with nurses, social workers, therapists and nutritionists who create care plans; physicians and nurse practitioners were invited but rarely attended. Control: usual care with no specific interventions.

Bibliographic reference	Hanson LC, Zimmerman S, Song, MH, et al. Effect of the Goals of Care intervention for advanced dementia: a randomized clinical trial. JAMA Internal Medicine 2017;177(1):24-31
Outcomes	**For all study participants:** Primary outcomes: quality of communication, concordance with clinicians on goals of care, Advance Care Planning problem score Secondary outcomes: quality of symptom management and overall care, satisfaction with care
Notes	Funding source: NIH-National Institute for Nursing Research RO1 AG037483
Risk of bias	• Random sequence generation (selection bias): Low risk • Allocation concealment (selection bias): Low risk • Blinding of participants and personnel (performance bias): High risk - It was not possible to blind surrogates to the intervention. • Blinding of outcome assessment (detection bias): Low risk • Incomplete outcome data (attrition bias): Low risk - Numbers lost to follow-up in both groups were low. • Selective reporting (reporting bias): Low risk - All outcomes listed in the Methods section were reported and there was no evidence of selective outcome reporting. • Recruitment bias (cluster trials only): High risk - Because of the nature of the intervention, nursing homes were randomised before recruitment of all participants and surrogate dyads. • Other bias: Low risk - Baseline imbalance between clusters and cluster effects both accounted for in analysis.

Bibliographic reference	Sampson EL, Candy B, Jones L. Enteral tube feeding for older people with advanced dementia. Cochrane Database of Systematic Reviews 2009, Issue 2. Art. No.: CD007209
Study type and aim	To evaluate the outcome of enteral tube nutrition for older people with advanced dementia who develop problems with eating and swallowing and/or have poor nutritional intake
Included study criteria	Randomized controlled trials (RCTs), controlled clinical trials, controlled before and after studies and interrupted time series studies that evaluated the effectiveness of enteral feeding via a nasogastric tube or via a tube passed by percutaneous endoscopic gastrostomy
Included participant criteria	Adults aged 50 and over, with a diagnosis of primary degenerative dementia made according to validated diagnostic criteria such as DSM-IV or ICD-10 and with advanced cognitive impairment defined by a recognised and validated tool or by clinical assessment and had poor nutrition intake and/or develop problems with eating and swallowing
Interventions	• Studies were included if they evaluated the effectiveness of enteral tube feeding via a nasogastric tube or via a tube passed by percutaneous endoscopic gastrostomy (PEG) to deliver artificial nutrition. • Interventions of oral supplementation of vitamins and or minerals were not included. • Comparative interventions included usual treatment or wait list groups.
Outcome measures	• Mortality

Bibliographic reference	Sampson EL, Candy B, Jones L. Enteral tube feeding for older people with advanced dementia. Cochrane Database of Systematic Reviews 2009, Issue 2. Art. No.: CD007209
	• Quality of life • Nutritional status • Pressure ulcers • Behavioural and psychiatric symptoms of dementia
Included studies	No randomized controlled trials were identified. Seven observational controlled cohort studies were identified, six of which included the primary outcome of mortality
Study dates	Databases searched up to April 2008
Author's conclusions	Despite the very large number of patients receiving this intervention, there is insufficient evidence to suggest that enteral tube feeding is beneficial in patients with advanced dementia. Data are lacking on the adverse effects of this intervention.
Risk of bias (systematic review)	• Was an 'a priori' design provided? Yes • Was there duplicate study selection and data extraction? Yes • Was a comprehensive literature search performed? Yes • Was the status of publication (i.e. grey literature) used as an inclusion criterion? Yes • Were the characteristics of the included studies provided? Yes • Was the scientific quality of the included studies assessed and documented? Yes • Was the scientific quality of the included studies used appropriately in formulating conclusions? Yes • Were the methods used to combine the findings of studies appropriate? Yes • Was the likelihood of publication bias assessed? Yes • Was the conflict of interest included? No Overall quality: High

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