# Appendix L: Research recommendations

## L.1 Dementia diagnosis (amyloid PET imaging)

| Research recommendation 1 | Does amyloid PET imaging provide additional diagnostic value, and is it cost effective, for the diagnosis of Alzheimer's disease and other dementias when compared with standard diagnostic procedures and other imaging or biomarker tests? |
|---|---|
| Population | People (aged 40 years and over) with a suspected diagnosis of dementia, who have already undergone initial assessment in a specialist dementia diagnostic service |
| Index Test | Amyloid PET imaging<br><br>Studies could also included other imaging or biomarker tests (such as SPECT, FDG PET or CSF examination) to evaluate the accuracy of amyloid PET imaging compared with other techniques |
| Reference Test(s) | • Diagnosis of dementia according to established clinical criteria<br>• Diagnosis of dementia based on neuropathology |
| Outcomes | • Sensitivity and specificity<br>• Positive and negative likelihood ratios<br>• Resource use and costs |
| Study design | Diagnostic cross-sectional studies (case-control studies should be avoided) |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Amyloid imaging could prove useful in the diagnosis of individuals with dementia who lack a formal dementia subtype diagnosis after initial assessment in specialist care. The diagnosis of a correct dementia subtype can improve people's future care by allowing the support provided to be tailored to their specific needs. It is hypothesised that amyloid imaging could provide additional diagnostic value, over and above that of other imaging and diagnostic tests, and therefore improve the accuracy of dementia diagnostic pathways. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make a recommendation on this issue due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | There was only limited evidence available around the accuracy and cost-effectiveness of amyloid imaging despite licensed products now being available. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the difficulty of diagnosing dementia in people with learning disabilities). |
| Feasibility | There is a large enough population of people presenting with suspected dementia that diagnostic accuracy studies in this area should be feasible. |

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## L.2 Assessing for dementia after delirium

| Research recommendation 2 | In people with treated delirium who no longer meet the DSM-5 criteria for delirium, but who have persistent cognitive deficits, when is the most appropriate time to carry out an assessment for dementia? |
|---|---|
| Population | People (aged 40 years and over) with cognitive impairment and resolved delirium |
| Intervention | Repeated assessments for dementia following the resolution of delirium |
| Outcomes | • Incidence of dementia detected at each time point<br>• Time at which cognitive scores stabilise |
| Study design | Repeated measures prospective cohort study (whilst this question could be addressed by RCTs of different assessment times, as no intervention would be offered to people in whom dementia is not identified, a repeated measures cohort study should provide the same data in an easier to undertake study) |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Delirium may mask other cognitive deficits and it is therefore important that people who have been diagnosed with delirium are assessed for dementia once the acute delirium has been resolved. Assessing too early may mean the residual effects of the delirium lead to false positives, whilst assessing too late may either lead to delays in identification, or that contact may be lost with them after their acute delirium symptoms have resolved, and the assessment therefore not undertaken. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make a recommendation on this issue due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | There is uncertainty surrounding the best time to administer tests to detect dementia in people whose acute delirium has resolved. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the difficulty of diagnosing dementia in people with learning disabilities). |
| Feasibility | There is a large enough population of people presenting with delirium that a prospective cohort study in this area should be feasible. |

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# L.3 Case finding

| Research recommendation 3 | What is the effectiveness of structured case finding (including a subsequent intervention for people identified as having dementia) in people at high risk of dementia, following up both people identified as having or not having dementia? |
|---|---|
| Population | People (aged 40 years and over) at high risk of dementia in :<br>• Primary care<br>• Acute hospitals<br>• Care homes<br>Populations of particular interest include:<br>• People over 60 at high vascular risk (e.g. prior stroke)<br>• People with learning disabilities<br>• People with other neurological disorders (e.g. multiple sclerosis) |
| Intervention | An identification and treatment pathway consisting of:<br>• Standard cognitive tests for case finding, with referral to specialist dementia diagnostic services for those found to be positive<br>• Subsequent optimal treatment for people diagnosed with dementia |
| Comparator | Usual care (including diagnosis of dementia and treatment in people presenting with suspected dementia) |
| Outcomes | • Sensitivity and specificity of case finding<br>• Positive and negative likelihood ratios for case finding<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Structured case finding for dementia is only worth carrying out if it is associated with a change in clinical practice that improves outcomes for the person diagnosed with dementia or their carers. Therefore, it was agreed the most important research to undertake was not in the usefulness of case finding for identifying people with dementia, but instead whether that earlier identification lead to improved outcomes. |
| Relevance to NICE guidance | Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue. |
| Current evidence base | Only a single RCT was identified that that looked at case finding in people at high risk of dementia, as opposed to screening of older people. In addition, there was a lack of evidence on the effects of case finding on the people who were diagnosed with dementia, or their carers, as a result of this intervention. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the difficulty of diagnosing dementia in people with learning disabilities). |
| Feasibility | There is a large enough population of people at higher risk of dementia that randomised controlled trials in this area should be feasible. |

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## L.4 Case management

| Research recommendation 4 | What is the effectiveness and cost effectiveness of high-intensity case management compared with usual care on quality of life (for the person living with dementia and for their carer) and the timing of entry to long-term care? |
|---|---|
| Population | People (aged 40 years and over) living with dementia and their carers |
| Intervention | High-intensity case management |
| Comparator | Usual care, which may consist of either:<br>• Lower-intensity case management<br>• No case management |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Entry to long stay care<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | There is evidence that case management is an effective intervention for people living with dementia. However, the effectiveness and cost effectiveness of high-intensity case management has not been tested in the UK. It has a high upfront cost, but there is some evidence from settings outside the UK that it may reduce the use of other services, leading to cost savings across the whole system. Because of the cost, robust evidence of and cost effectiveness from a UK setting is needed. |
| Relevance to NICE guidance | High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area. |
| Current evidence base | Although there is evidence on case management that enabled a positive recommendation to be made for its use, the evidence did not allow a recommendation to be made on the intensity of case management, or how it should be organised |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of case management in people who do not have an informal carer). |
| Feasibility | There is a large enough population of people living with dementia in the community that randomised controlled trials in this area should be feasible. |

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## L.5 Care planning in residential care

| Research recommendation 5 | What are the most effective methods of care planning for people in residential care settings? |
|---|---|
| Population | People (aged 40 years and over) living with dementia in a residential care setting |
| Intervention | Structured care planning interventions |
| Comparator | • Other types of care planning<br>• Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | A large proportion of people diagnosed with dementia will spend at least some of their life in a residential care setting. Therefore, evidence on how test people's care should be planned and coordinated in that setting would be of value to improving people's quality of life. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Only very limited evidence was identified in people living with dementia in residential care settings, and therefore the current recommendations had to be extrapolated from the evidence in people in community settings. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of care planning in people with communication difficulties). |
| Feasibility | There is a large enough population of people living with dementia in residential care settings that randomised controlled trials in this area should be feasible. |

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## L.6 Care planning for people without informal carers

| Research recommendation 6 | What are the most effective methods of care planning for people who do not have regular contact with an informal carer? |
|---|---|
| Population | People (aged 40 years and over) living with dementia who do not have regular contact with an informal carer |
| Intervention | Care planning interventions that do not rely on regular contact with an informal carer |
| Comparator | • Other types of care planning<br>• Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Entry to long stay care<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Many randomised controlled trials of care planning or case management specifically exclude people without an informal carer. Conducting similar studies on case management and care planning for people without an informal carer would fill this gap in the evidence base, and help to identify whether these people have different needs. |
| Relevance to NICE guidance | High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area. |
| Current evidence base | Few of the studies identified in this guideline provided relevant evidence to address this issue, as they routinely excluded people without an informal carer from being in the study, often as the carer was needed for data collection purposes within the trial design. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of care planning in people with communication difficulties). |
| Feasibility | Initial identification of people with dementia living alone and without an informal carer may be difficult. However, it was agreed this was an important enough issue to identity that this was not a sufficient reason for studies not to be undertaken. |

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# L.7 Transitions between care settings

| Research recommendation 7 | What is the effectiveness of structured transfer plans to ease the transition between different environments for people living with dementia and their carers? |
|---|---|
| Population | People (aged 40 years and over) living with dementia and their carers |
| Intervention | Structured transfer plans aimed at easing the transition between different environments |
| Comparator | Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | There are established harms caused by transitions between care settings for people living with dementia, often as a result of the transition not being coordinated appropriately (e.g. relevant information not being shared). One possible solution to this problem is structured transfer plans, but there are currently no trials looking at the effectiveness of their use. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | No evidence was identified in the guideline that enabled recommendations (either positive or negative) to be made on the use of structured transfer plans. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of care planning in people with communication difficulties). |
| Feasibility | Initial identification of people with dementia living alone and without an informal carer may be difficult. However, it was agreed this was an important enough issue to identity that this was not a sufficient reason for studies not to be undertaken. |

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# L.8 Pharmacological treatment of DLB

| Research recommendation 8 | What is the effectiveness of combination treatment with a cholinesterase inhibitor and memantine for people with dementia with Lewy bodies if treatment with a cholinesterase inhibitor alone is not effective or no longer effective? |
|---|---|
| Population | People (aged 40 years and over) living with dementia with Lewy bodies in whom treatment with a cholinesterase inhibitor alone is not effective or no longer effective. |
| Intervention | Treatment with a cholinesterase inhibitor and memantine |
| Comparator | • Treatment with a cholinesterase inhibitor alone<br>• Treatment with memantine alone |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Adverse events<br>• Entry to long stay care<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Although no studies were identified where participants were randomised to combination treatment with a cholinesterase inhibitor and memantine, the committee recognised that this option was being used in practice. From their clinical experience, some people do respond to combination treatment, and therefore evidence on its effectiveness would be of value, particularly as the guideline already recommends combination treatment in people with Alzheimer's disease. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | No evidence was identified in the guideline on the co-prescription of cholinesterase inhibitors and memantine in people living with dementia with Lewy bodies. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia with Lewy bodies that randomised controlled trials in this area should be feasible. |

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## L.9 Anticholinergic burden

| Research recommendation 9 | Does actively reducing anticholinergic burden in people living with dementia improve cognitive outcomes compared with usual care? |
|---|---|
| Population | People (aged 40 years and over) living with dementia |
| Intervention | Active reduction in anticholinergic burden by:<br>• A structured assessment of the medicines they are taking that have an anticholinergic effect<br>• Switching where possible to alternative medicines with a lower anticholinergic effect |
| Comparator | Usual care |
| Outcomes | • Management of the comorbidity for which the medicine is identified<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Adverse events<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Many people living with dementia are still prescribed medicines with a high anticholinergic burden (which can be caused by individual medicines or by combinations of medicines). It is often unclear if this prescribing is appropriate, or whether actively reducing the number of these medicines would improve cognition. Randomised controlled trials could be conducted, using structured tools to assess anticholinergic burden and actively switching medicines if possible. This would help to identify whether cognition can be improved without adversely affecting the management of the conditions these medicines are prescribed for. |
| Relevance to NICE guidance | High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area. |
| Current evidence base | Evidence was identified in the guideline to show there are tools that are able to detect anticholinergic burden in people living with dementia, but no evidence was identified on the effectiveness of using those tools prospectively. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.10 Psychosocial interventions

| Research recommendation 10 | What are the most effective psychosocial interventions for improving cognition, independence, activities of daily living and wellbeing in people living with dementia? |
|---|---|
| Population | People (aged 40 years and over) living with dementia |
| Intervention | Psychosocial interventions |
| Comparator | Alternative psychosocial interventions |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Independence<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | The guideline found evidence on a small number of psychosocial interventions, a positive recommendations for cognitive stimulation therapy and reminiscence therapy were made based on this. However, the committee agreed there was value in testing a wider range of possible psychosocial interventions, in order to optimise the interventions available to support people living with dementia. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Evidence was identified for only a limited number of psychosocial interventions, and information on a wider range of potential interventions would allow more detailed recommendations to be made. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.11 Community activities

| Research recommendation 10 | What is the effectiveness of unstructured community activities on wellbeing for people living with dementia? |
|---|---|
| Population | People (aged 40 years and over) living with dementia |
| Intervention | Unstructured community group activities |
| Comparator | Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Similar effect sizes were found for a range of group, activity based interventions for people living with dementia (e.g. cognitive stimulation, reminiscence therapy, music, exercise, etc.). One possible interpretation is that the benefits of many of these interventions were driven less by the specific content of the interventions, and more by the benefits from support groups more generally. If this is true, these groups could potentially be delivered more cheaply than structured interventions, therefore a larger number of people could have access to them. |
| Relevance to NICE guidance | Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue. |
| Current evidence base | Evidence was identified for a range of structured interventions, but only limited evidence was available on the effectiveness of unstructured group activities. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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## L.12 Self-management

| Research recommendation 11 | What is the effectiveness and cost-effectiveness of self-management training for people living with dementia and their carers? |
|---|---|
| Population | People (aged 40 years and over) living with dementia and their carers |
| Intervention | Self-management training for both the person living with dementia and their carer |
| Comparator | Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Entry to long stay care<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | The committee considered the evidence on self-management groups was insufficient to make either a positive or a negative recommendation. In particular, self-management interventions were agreed to comprise such a wide range of possible interventions that the literature currently available did not cover the full range of possible interventions adequately to be able to make recommendations. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Only a very limited number of small studies were identified looking at self-management interventions for people living with dementia |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.13 Managing depression and anxiety

| Research recommendation 12 | What are the most effective psychological treatments for managing depression or anxiety in people living with dementia at each stage of the condition? |
|---|---|
| Population | People (aged 40 years and over) living with dementia and diagnosed with depression or anxiety |
| Intervention | Psychological treatments for managing depression or anxiety |
| Comparator | • Other psychological treatments for managing depression or anxiety<br>• Usual care |
| Outcomes | • Anxiety<br>• Depression<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Depression and anxiety are common problems for people living with dementia, and some of the main treatments used in people without dementia (including antidepressants such as sertraline and mirtazapine) were shown to work less well in people without dementia. This increases the important of optimising non-pharmacological treatment, due to there being less pharmacological treatments available as an alternative. |
| Relevance to NICE guidance | Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue. |
| Current evidence base | Although evidence was identified for the effectiveness of psychological treatments for depression and anxiety in people living with dementia, these studies covered a wide range of different psychological interventions, and therefore it was not possible to make recommendations on what the most appropriate psychological treatment to use is. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.14 Managing agitation

| Research recommendation 13 | What is the effectiveness and cost-effectiveness of dextromethorphan-quinidine for managing agitation in people living with dementia? |
|---|---|
| Population | People (aged 40 years and over) living with dementia who are diagnosed with agitation |
| Intervention | Dextromethorphan-quinidine |
| Comparator | Placebo |
| Outcomes | • Agitation<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Adverse events<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Agitation is a common problem in people living with dementia, and although evidence was identified on effective non-pharmacological management strategies, there is a still a need for effective pharmacological treatments if first line non-pharmacological management is not effective. |
| Relevance to NICE guidance | Low priority: it was possible to make recommendations on managing agitation, but these could be improved by the existence of more evidence on this specific issue. |
| Current evidence base | One small study on dextromethorphan-quinidine for managing agitation was identified, but further evidence would be necessary in order to be able to make recommendations on its use. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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## L.15 Managing apathy

| Research recommendation 14 | What is the effectiveness and cost-effectiveness of choline alphoscerate for managing apathy in people living with dementia? |
|---|---|
| Population | People (aged 40 years and over) living with dementia and diagnosed with apathy |
| Intervention | Choline alphoscerate |
| Comparator | Placebo |
| Outcomes | • Apathy<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Adverse events<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Apathy is a common problem in people living with dementia, and no evidence is currently available on effective non-pharmacological treatments, increasing the importance of potentially effective pharmacological treatments. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | One small study on choline alphoscerate for managing apathy was identified, but further evidence would be necessary in order to be able to make recommendations on its use. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.16 Managing sleep problems

| Research recommendation 15 | What is the effectiveness of pharmacological treatments for sleep problems in people who have not responded to non-pharmacological management? |
|---|---|
| Population | People (aged 40 years and over) living with dementia and sleep problems who have not responded to non-pharmacological management |
| Intervention | Pharmacological treatments for sleep problems |
| Comparator | Usual care |
| Outcomes | • Sleep quality<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Adverse events<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Sleep problems are common in people living with dementia, and although evidence was identified on effective non-pharmacological management strategies, there is a still a need for effective pharmacological treatments if first line non-pharmacological management is not effective. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | No evidence on effective pharmacological treatments for sleep problems in people living with dementia was identified in the guideline. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.17 Managing depression in carers

| Research recommendation 16 | What is the effectiveness and cost-effectiveness of group-based cognitive behavioural therapy for carers of people living with dementia who are at high risk of developing depression? |
|---|---|
| Population | Carers of people (aged 40 years and over) living with dementia who are at high risk of developing depression |
| Intervention | Group-based cognitive behavioural therapy |
| Comparator | Usual care |
| Outcomes | • Incidence of carer depression<br>• Severity of carer depression<br>• Carer quality of life<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Carers of people living with dementia are at a higher risk of developing depression than the general population. Therefore, prophylactic strategies designed to reduce the incidence of depression diagnosis in the group of people at high risk could not only improve outcomes, but also potentially save money on depression treatment. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Good quality evidence was identified that group CBT reduces depressive symptoms in carers of people living with dementia. However, these trials were primarily conducted in a broad population of carers without defined symptoms at baseline, and it was agreed to be unrealistic to provide CBT for all carers, regardless of their baseline risk of depression. Therefore, trials conducted specifically in a population at high risk of depression would allow for more targeted recommendations to be made. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of carers of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.18 Training community staff

| Research recommendation 17 | What is the cost effectiveness of using a dementia-specific addition to the Care Certificate for community staff, including dementia-specific elements on managing anxiety, communication, nutritional status and personal care? |
|---|---|
| Population | Community staff caring for people (aged 40 years and over) living with dementia |
| Intervention | A dementia-specific addition to the Care Certificate, including dementia-specific elements on managing anxiety, communication, nutritional status and personal care. |
| Comparator | The existing Care Certificate |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Entry to long stay care<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Robust evidence demonstrates the effectiveness of intensive training for staff heavily involved in providing care and support for people living with dementia. However, it is not clear if it is effective to provide basic training to all staff who come into contact with people living with dementia, or how this training should be provided. One possibility is an expanded version of the Care Certificate that includes additional dementia-specific elements. Because this training would need to be given to a large number of staff, there needs to be good evidence of benefits, specifically in improving quality of life for people living with dementia and their carers, to justify the upfront costs. |
| Relevance to NICE guidance | High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area. |
| Current evidence base | Although the evidence currently available did allow for recommendations to be made on the general principles of staff training, it did not allow specific recommendations to be made on how that training should be conducted. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of community staff working with people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.19 Training hospital staff

| Research recommendation 18 | What is the effectiveness of training acute hospital staff in managing behaviours that challenge in people living with dementia on improving outcomes for people and their carers? |
|---|---|
| Population | Acute hospital staff caring for people (aged 40 years and over) living with dementia who exhibit challenging behaviours |
| Intervention | Training in managing challenging behaviours |
| Comparator | Usual training |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | People living with dementia are known to have poor outcomes in hospital, and one potentially reason for this is a lack of dementia-specific training for hospital staff. Appropriate training could both improve outcomes for people living with dementia, and allow for people to be more easily and appropriately discharged back in to the community. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Only very limited evidence was identified on the training of hospital staff – the majority of evidence on staff training came from community or care home setting. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of hospital staff working with people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.20 Managing delirium superimposed on dementia

| Research recommendation 19 | What are the most clinically and cost-effective non-pharmacological interventions for helping the long-term recovery of people with delirium superimposed on dementia? |
|---|---|
| Population | People (aged 40 years and over) diagnosed with delirium superimposed on dementia |
| Intervention | Non-pharmacological interventions aimed at helping the long-term recovery of people with delirium superimposed on dementia |
| Comparator | • Other non-pharmacological interventions<br>• Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | The acute management of delirium superimposed on dementia is likely to be similar to the management of delirium in people without dementia. However, there may be differences in the interventions needed to aid long-term recovery, particularly because people with different severities of dementia will have different baseline cognitive status. Research on the most effective non-pharmacological methods of promoting long-term recovery would help to identify whether alternative approaches are needed for people living with dementia. |
| Relevance to NICE guidance | High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area. |
| Current evidence base | No evidence is currently available on how the long-term recovery from delirium superimposed on dementia should be managed. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people diagnosed with delirium superimposed on dementia that randomised controlled trials in this area should be feasible. |

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# L.21 Managing incontinence

| Research recommendation 20 | What is the effectiveness of interventions to improve faecal and urinary continence in people living with dementia? |
|---|---|
| Population | People (aged 40 years and over) living with dementia who have faecal and urinary continence issues |
| Intervention | Interventions to improve faecal and urinary continence |
| Comparator | Usual care |
| Outcomes | • Faecal and urinary continence<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Incontinence is a common problem in people living with dementia, and one that is known to be associated with increased carer burden and rates of entry to long stay care. Effective interventions to manage incontinence would be expected to improve outcomes for both people living with dementia and their carers. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Only very limited evidence is currently available on the management of incontinence in people living with dementia, and none that is sufficient to allow recommendations to be made. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible. |

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# L.22 Managing cardiovascular disease

| Research recommendation 21 | What is the impact on cognition, quality of life and mortality of withdrawing treatments for the primary and secondary prevention of vascular outcomes in people with severe dementia? |
|---|---|
| Population | People (aged 40 years and over) living with severe dementia who are also at high cardiovascular risk |
| Intervention | Withdrawal of treatment for the primary and secondary prevention of cardiovascular outcomes |
| Comparator | Continuation of treatment for the primary and secondary prevention of cardiovascular outcomes |
| Outcomes | • Mortality<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | There are a considerable number of people living with both dementia and a high risk of cardiovascular events. Interventions can reduce the risk of those events, but are often quite intensive and may cause distress or other harms to the person. Therefore, there is a need for evidence on where there is an appropriate time for these interventions to be withdrawn in people living with severe dementia. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Only very limited evidence is currently available on the management of cardiovascular disease in people living with severe dementia, and none that is sufficient to allow recommendations to be made. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with severe dementia that randomised controlled trials in this area should be feasible. |

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# L.23 Managing diabetes

| Research recommendation 22 | What is the impact on cognition, quality of life and mortality of withdrawing intensive treatments for diabetic control in people with severe dementia? |
|---|---|
| Population | People (aged 40 years and over) living with severe dementia who are also diagnosed with diabetes |
| Intervention | Withdrawal of intensive treatments for diabetic control |
| Comparator | Continuation of intensive treatments for diabetic control |
| | • Mortality<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | There are a considerable number of people living with both dementia and diabetes. Interventions can reduce the risk of diabetes associated harms, but are often quite intensive and may cause distress or other harms to the person. Therefore, there is a need for evidence on where there is an appropriate time for these interventions to be withdrawn in people living with severe dementia. |
| Relevance to NICE guidance | Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue. |
| Current evidence base | Only very limited evidence is currently available on the management of cardiovascular disease in people living with diabetes, and none that is sufficient to allow strong recommendations to be made, other than by cross-referencing to the existing NICE guideline on diabetes. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with severe dementia that randomised controlled trials in this area should be feasible. |

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# L.24 Managing mental health problems

| Research recommendation 23 | What are the optimal management strategies for people with enduring mental health problems (including schizophrenia) who subsequently develop dementia? |
|---|---|
| Population | People (aged 40 years and over) who have mental health problems and go on to develop dementia |
| Intervention | Management strategies for people with enduring mental health problems |
| Comparator | • Other management strategies for people with enduring mental health problems<br>• Usual care |
| Outcomes | • Management of mental health condition<br>• Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | A substantial number of people living with dementia also have a comorbid mental health problem that predates their dementia. The management of that mental health problem may need to be modified as the person's dementia becomes more severe, but there is little evidence currently on how best this should be one. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | No evidence was identified in the guideline on the optimal management strategies for people with enduring mental health who subsequently develop dementia |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with dementia who also have a comorbid mental health problem that randomised controlled trials in this area should be feasible. |

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## L.25 Palliative care

| Research recommendation 24 | What are the most effective models of general and specialist palliative care support to meet the needs of people with advanced dementia? |
|---|---|
| Population | People (aged 40 years and over) living with advanced dementia |
| Intervention | Models of general and specialist palliative care support aimed at people with advanced dementia |
| Comparator | • Other palliative care models<br>• Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Palliative care is a key part of the support offered to people with advance dementia, and therefore it is important to maximise the effectiveness of the support provided, including how both general and specialist palliative care services can be coordinated to provide optimal care. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Only a small number of trials were identified on specific palliative care interventions for people living with dementia. As a result, whilst it was possible to make recommendations on general principles of palliative care, it was not possible to make specific recommendations on how it should be delivered. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with advanced dementia that randomised controlled trials in this area should be feasible. |

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# L.26 Recognising end of life

| Research recommendation 25 | What are the most effective interventions to support staff to recognise advanced dementia and develop appropriate escalation/end of life plans to facilitate care to remain at home? |
|---|---|
| Population | People (aged 40 years and over) living with advanced dementia |
| Intervention | Interventions that aim to facilitate care to remain at home by developing escalation/end of life plans |
| Comparator | • Other interventions with the same goals<br>• Usual care |
| Outcomes | • Cognition<br>• Activities of daily living<br>• Behavioural and psychological symptoms of dementia<br>• Quality of life<br>• Entry to long stay care<br>• Carer outcomes<br>• Resource use and costs |
| Study design | Randomised controlled trials |

| Potential criterion | Explanation |
|---|---|
| Importance to patients, service users or the population | Recognising when a person living with dementia is approaching end of life can be complex, and as a result it is often not clear wither when end of life plans should be implemented, and what plans are most effective. Effective support programmes for staff could help them to deliver more appropriate and timely care, and improve outcomes for people living with dementia. |
| Relevance to NICE guidance | Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations. |
| Current evidence base | Only a small number of trials were identified on specific palliative care interventions for people living with dementia. As a result, whilst it was possible to make recommendations on general principles of palliative care, it was not possible to make specific recommendations on how it should be delivered. |
| Equality | No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia. |
| Feasibility | There is a large enough population of people living with advanced dementia that randomised controlled trials in this area should be feasible. |

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