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SURE
Support Unit for Research Evidence

Approaches for adult nursing and residential care homes on promoting oral health, preventing dental health problems and ensuring access to dental treatment.

Protocol

Produced by Support Unit for Research Evidence (SURE), Cardiff University
http://www.cardiff.ac.uk/insrv/libraries/sure/index.html

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Section	Content	Page
	List of contents	2
	Executive Summary	
	Evidence statements	
	Abbreviations	
1	**Introduction**	4
1.1	Aims of the review	4
1.2	Research questions	4
1.3	Background – setting the context	4
2	**Methods**	8
2.1	Logic model	8
2.2	Literature search	8
2.3	Inclusion and exclusion criteria	10
2.4	Study selection	12
2.5	Quality assessment	12
2.6	Data extraction – study characteristics and methodology	13
2.7	Data synthesis – theme extraction and synthesis	13
2.7.1	Review 1	13
2,7.2	Review 2	14
2.7.3	Review 3	14
2.8	Communications of findings tools (Review 3)	14
3	**Results**	
3.1	Search results	
3.2	Quality and applicability of studies	
3.3	Outcomes	
Table 1	**Brief Summary of included studies**	
4	**Findings**	
4.1	Question 1	
4.2	Question 2	
4.3	Question 3	
5.1	Logic model and identified key themes	
5.2	PARiHS Framework	
6	**Discussion**	

7	References	
8	Acknowledgements	
Appendices		
Appendix 1	Search strategy (Medline/Medline in Process)	16
Appendix 2	Data Extraction Form – Review 1	18
Appendix 3	Data Extraction Form – Review 3	20
Appendix 4	Modified Checklist for Correlation or Cross-sectional studies	22
Appendix 5	Time line	24

1 Introduction

1.1 Aim

To review the evidence about approaches, activities and interventions that promote oral health, prevent dental problems and ensure access to treatment for adults in care home settings.

1.2 Review questions

Question 1: What approaches, activities or interventions are effective in promoting oral health, preventing dental problems and ensuring access to dental care (including regular check-ups) for adults in care homes?

Question 2: What methods and sources of information will help care home managers and their staff identify and meet the range of oral health needs and problems experienced by their people living in care homes?

Question 3: What helps and hinders oral health promotion, prevents dental problems and ensures access to dental check-ups and treatment in care homes?

1.3 Background and understanding

Adults living in residential care generally fit one or more of three categories: those aged 65 years and older, those who have learning disabilities or physical disabilities. According to Age UK (2014) calculations, in April 2012 there were 431,500 elderly and disabled adults in residential care of whom approximately 414,000 (95%) were aged 65 or over.

The numbers of disabled adults may be higher than estimated by Age UK. Excluding adult placement schemes, Emerson (2013) states that the number of people with learning disabilities in residential care in England at 31 March 2012 was over 36,000 of whom just under 6000 were aged 65 or over. A previous report (Emerson 2012) noted that that the proportion of residential care use by learning disabled adults aged 65 or over was increasing (from 11.3% in 2005/06 to 15.8% in 2011/12).

The most recent figures from the Office for National Statistics (ONS 2014) indicate that the numbers of people aged 65 or over in the UK continues to rise and is currently 11.1 million or 17.4% of the UK population. The biggest percentage rise is in the population aged 85 or older and the 2011 census (ONS 2013) found 1.25 million people aged 85 or older; almost a 25% increase from the 2001 census. Of these "oldest old", 103,000 were living in a care home without nursing and 69,000 were in a care home with nursing.

Policies designed to encourage more independent living for people with learning disabilities in group and halfway houses, and to support older people to live in their own homes mean that numbers in residential care have decreased slightly. However, the evidence also suggests higher levels of care are being required by those in residential homes (ONS 2013; ONS 2014).

People with learning disabilities have poorer oral health when compared to the general population (Faculty of Dental Surgery, 2012) and care needs are also changing amongst the growing population of frail elderly, increasing numbers of whom retain their own teeth. This may have been brought about by complex and expensive dental work including crowns, prostheses, implants and bridges; bringing a new range of challenges (British Dental Association, 2012).

When older adults become physically dependent or cognitively impaired, oral hygiene frequently declines, and the incidence of oral diseases tends to increase (Naorungroj 2013). This may happen prior to individuals entering residential care and may be exacerbated by medications that cause dry mouths (South Australia Dental Service 2009). Therefore as the UK National Minimum Standards for Care Homes for Older People (DH 2003) states, a review of oral health status should be part of any initial health evaluation.

Dental caries and periodontal disease are preventable oral diseases. However, failure to maintain good oral hygiene allows them to develop. These diseases can have a significant impact on the management of medical conditions, general health status, ability to eat and quality of life (Weening-Verbree 2013). In addition, Azarpazhooh (2006) undertook a systematic review of associations between oral health and respiratory disease. The presence of oral pathogens, dental decay and poor oral hygiene were all identified as potential risk factors for pneumonia.

A Cochrane review (Brady et al 2006) looked at the oral health of stroke patients in residential care and identified a lack of rigorous evidence on the topic, but stated that oral healthcare interventions "can improve staff knowledge and attitudes, the cleanliness of patients' dentures and reduce the incidence of pneumonia."

A decline in oral health may be avoided as long as caregivers help in the maintenance of routine care (South Australia Dental Service, 2009). However, researchers note a range of problems associated with caregiver delivery of oral hygiene care.

In a systematic review Miegel (2009) identified a number of barriers to good oral health in care homes. These included lack of oral health education of care providers (including staff training); care provider attitudes to the oral health of residents; oral health policy and documentation; lack of oral health resources in terms of equipment and staff time and a failure to undertake oral health assessments. Wardh (2012) identified dislike or fear of providing oral care particularly when combined with lack of adequate training or time to

complete the task to be an issue for caregivers. These problems are exacerbated where the older person has dementia, communication or behaviour difficulties, or resists care (Jablonski 2011).

The National Institute for Health and Care Excellence (NICE) has been asked by the Department of Health to develop guidance on approaches for adult nursing and residential care homes on promoting oral health, preventing dental health problems and ensuring access to dental treatment.

The team will conduct three evidence reviews (effectiveness, best practice and barriers/facilitators) to inform this guidance.

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Wardh, I., Jonsson, M., & Wikstrom, M. 2012. Attitudes to and knowledge about oral health care among nursing home personnel--an area in need of improvement. *Gerodontology*, 29, (2) e787-e792

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2 Methods

In keeping with the NICE Manual: Methods for the development of NICE public health guidance[1] a best evidence approach will be adopted for each question (Section 1.5.1).

The team proposes to undertake three reviews; each review answering a different question. Results from the effectiveness review (Review 1) will inform the subsequent best practice (Review 2) and barriers/facilitators (Review 3) work.

2.1 Logic Model

Central to the review methods will be the development of a logic/conceptual model to serve as a map. This will guide the organisation of results and the communication of review findings.

2.2 Literature search

Systematic reviews of the evidence to address the review questions will be undertaken.

A wide range of databases and websites will be searched systematically; supplemented by grey literature[2] searches. Searches will be carried out to identify relevant evidence in the English language published between January 1995 and September 2014 that is:

- of the highest quality available;
- publicly available, including trials in press ("academic in confidence")

The following types of evidence will be sought for inclusion:

Review 1 – Effectiveness: systematic reviews and meta-analyses[3]; randomised controlled trials; controlled trials; controlled before and after studies, interrupted time series, uncontrolled before and after studies.

Review 2 – Best Practice: guidelines developed by governmental bodies and specialist societies; toolkits; care pathways; quality improvement projects; UK Health Department directives.

Review 3 – Barriers and Facilitators: quantitative and qualitative research and process evaluations that report the views and perspectives of service users and providers.

[1] http://publications.nice.org.uk/methods-for-the-development-of-nice-public-health-guidance-third-edition-pmg4

[2] Technical or research reports, doctoral dissertations, conference papers and official publications.

[3] Unless directly relevant to answering one or more question, systematic reviews and meta-analyses will be unpicked to identify studies meeting the inclusion criteria.

A single search will be conducted to identify evidence for all three reviews. A search strategy has been developed in Ovid Medline (see Appendix 1) and will be adapted to all other databases listed below.

Databases

AMED (Allied and Complementary Medicine) - Ovid
ASSIA (Applied Social Science Index and Abstracts) - Proquest
CINAHL (Cumulative Index of Nursing and Allied Health Literature) - EBSCO
Embase - Ovid
Health Management Information Consortium (HMIC) - Ovid
MEDLINE and MEDLINE in Process - Ovid
OpenGrey http://www.opengrey.eu/
Social Care Online http://www.scie-socialcareonline.org.uk/

Websites

Australian Research Centre for Population Oral Health
http://www.adelaide.edu.au/arcpoh/
British Society of Gerodontology
British Society for Disability and Oral Health
Clinical trial registers:

- WHO ITCRP http://www.who.int/ictrp/en/
- Clinicaltrials.gov http://www.clinicaltrials.gov/

Electronic Theses Online Service (EThOS) http://ethos.bl.uk
European Association of Dental Public Health http://www.eadph.org/
Health Evidence Canada http://www.healthevidence.org/
International Association of Dental Research (IADR)
National Oral Health Conference
http://www.nationaloralhealthconference.com/
NICE Evidence Search https://www.evidence.nhs.uk/
Public Health England https://www.gov.uk/government/organisations/public-health-england
Public Health Wales http://www.wales.nhs.uk/sitesplus/888/home
Scottish Public Health network http://www.scotphn.net/
Social Care Institute for Excellence (SCIE) http://www.scie.org.uk/
US National Guideline Clearing House http://www.guideline.gov/
Australian Clinical Practice Guidelines Portal http://www.clinicalguidelines.gov.au/
New Zealand Guidelines Group http://www.health.govt.nz/about-ministry/ministry-health-websites/new-zealand-guidelines-group

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Public Health Agency of Canada http://www.phac-aspc.gc.ca/dpg-eng.php

In addition a variety of supplementary methods will be employed to identify additional research:

- Checking reference lists and undertake citation tracking of included papers in Web of Knowledge and Scopus databases.
- Searching the electronic table of contents of key journals: *Special Care in Dentistry*, *The Journal of Disability and Oral Health* and *Gerodontology*.
- Contacting experts in the field via networks and authors of included papers to identify additional research and 'sibling' studies.
- Considering papers identified via a call for evidence.

A log of all searches will be kept with details of search terms used for each database or website. Results of all searches would be combined in a Reference Manager 12 database. A de-duplicated copy of the database will be provided to NICE.

2.2 Inclusion and exclusion criteria

Inclusion	**Population** All adults in residential or nursing care homes, including people staying for rehabilitation or respite care. **Activities, approaches or interventions:** • Conducting assessments of individual oral health, for example on entry to a care home and in response to changing oral health needs. • Maintaining access to dental services, including those offered by local salaried dental services, general dental practice and coordinating other health care services. For example joining up dental health services with other health initiatives provided in care home settings (such as services offered by GPs, vision testing, social services, podiatry). • Staff training about oral health (including understanding the effect of oral health on general health and wellbeing). • Increasing access to fluoride for people living in care homes. For example, by providing free fluoride toothpaste or gels, providing fluoride supplements, or by dental health care professionals offering fluoride varnish applications in care homes.

	• Providing oral health education and information about promoting and maintaining oral health (for example the role of diet, techniques for brushing teeth and maintaining healthy dentures).
	• Providing resources to improve oral hygiene for people living in care homes (as appropriate), for example providing a range of toothbrushes including electric toothbrushes.
	• Managing transitions if oral function deteriorates and a person's usual diet has to change.
	• Considering the effect of diet, alcohol and tobacco on the oral health of people living in care homes.
	• Restrict to UK, Western Europe, North America and Australia/New Zealand to ensure full applicability
	
	Comparator:
	All comparators
	
	Potential Outcomes:
	• Changes in:
	    . The oral health of people living in care homes. For example, earlier identification of incidence and prevalence of oral cancers, tooth decay, periodontal disease, oral discomfort including pain; also nutritional status among people living in care homes.
	    . Modifiable risk factors, including the use of high concentration fluoride toothpaste, fluoride supplements, fluoride varnishes, frequency and quality of oral hygiene practices, and access to or visits from dental services.
	    . Policies or procedures in care homes.
	    . Knowledge and attitudes of care home managers and staff, and other health and social care professionals.
	    . Quality of life, including social and emotional wellbeing.
	    . People's knowledge and ability to improve and protect their oral health.
	    . People's oral health behaviours.
	• Adverse events or unintended consequences

Exclusion	• Adults living independently in the community.

	• Adults in hospitals providing secondary or tertiary care for example acute hospitals or specialised units. • Adults in prison. • Children and young people. • Water fluoridation. • Dental clinical interventions, treatments or medicines. • Content of fluoride toothpastes, fluoride supplements, or type and range of particular pieces of oral hygiene equipment. • Specific techniques for carers to help people with their oral hygiene (for example techniques to remove dentures, clean the mouth, brush teeth, or perform a range of oral hygiene tasks). • Interventions to manage behaviours associated with resisting care or treatment.

Other than to fill evidence gaps, studies will be restricted to those conducted in the UK, Western Europe, North America and Australia/New Zealand. This will ensure high levels of applicability.

2.3 Study selection

Study selection will be carried out as detailed in Section 5 of the NICE Methods Manual. After de-duplication and removal of clearly irrelevant citations:

- Titles and abstracts will be screened independently by two reviewers using the inclusion/exclusion parameters. Where there is disagreement this will be resolved by discussion with a third reviewer and, if in doubt, included.
- Full paper screening will also be conducted independently by two people with recourse to a third to resolve any disagreements. Excluded papers will be retained with reasons for exclusion. Reasons will be reported in a Table of Excluded Studies.

2.4 Quality assessment

Quality assessment will be conducted using the relevant quality appraisal checklist (NICE 2012). Each paper will be assessed by one reviewer and checked for accuracy by another. Ten percent of the studies will be double assessed. Each study will be rated ('++', '+' or '−') to indicate its quality.

For information considered in Review 2: Best Practice, the AGREE II Instrument (AGREE Trust 2013) will be used as appropriate. Where information providers are accredited under the NICE Accreditation Scheme (NICE 2013) this will be considered a sufficient guarantor of quality. A clear distinction will be made between evidence based and expert (consensus) based guidelines.

For Review 3: Barriers and Facilitators, quantitative cross-sectional studies will be assessed using a modified version of the Correlation Studies checklist from Appendix G (NICE 2012). The modified checklist contains an additional question relating to piloting of survey items and highlights which questions are only applicable either to correlation studies or to cross-sectional surveys. An example of this modified checklist is presented in Appendix 4. No checklists are available for process evaluation studies which will not be assessed for validity.

2.5 Data extraction – study characteristics and methodology

Evidence will be extracted directly into a form agreed with NICE. Data will be selected and characterised using PROGRESS-Plus.

Outline forms were developed for previous reviews based on the Evidence Table format outlined in Appendix K of the manual (NICE 2012) and adapted to ensure all appropriate data were collected. Use of this form ensured that the process was as streamlined as possible. Proposed forms for this review are provided as Appendix 3 and 4

Each data extraction form will be completed by one reviewer and checked for accuracy by another. Ten percent of the studies will be extracted independently by two reviewers.

2.7 Data Synthesis

The key findings of evidence will be summarised in concise narrative summaries and evidence statements, and will be supported by evidence tables. The statements will indicate:

- the message given by the evidence;
- the applicability of the results to the UK

2.7.1 Review 1

Statistical meta-analyses with Forest plots will be conducted where feasible. Homogeneity between study design, interventions and populations will be explored using sub-group analyses. Treatment estimate and precision will be used to determine if studies, interventions and populations are suitable for pooling.

All meta-analyses will be conducted using random effects models and all summarised data will be provided with associated 95% CI.

Intervention papers will also be added to an NVivo database and relevant outcomes and demographic data coded. This will aid rapid identification for data 'slicing', including data specific to populations of interest.

2.7.2 Review 2: Summary of best practice

Format of evidence presentation to be discussed and agreed with NICE

2.7.3 Review 3: Theme extraction and synthesis

Key themes will be extracted and coded by one reviewer and checked by another. Studies will be coded using the software NVivo.

The synthesis of the study participant views will be performed by the SURE team, guided by the methods manual (Section 5.4) and Dixon Woods (2004)[4], with advice and support where required from the team's qualitative expert.

A broad synthesis of the included evidence will be performed across all eligible evidence. Where applicable, views and opinion-based data gathered from quantitative studies will be analysed thematically and integrated with the key findings from qualitative studies.

Data synthesis will be dependent on the nature of the evidence available. If the body of evidence is sparse and does not share common interventions or themes, a narrative description of the themes in each paper will be presented.

Where the evidence is sufficiently rich and shares common themes, a thematic synthesis will be performed. An index ladder of codes will be developed a priori, in accordance with Richie and Spencer (1994)[5] so that key findings can be extracted and organised at the same time. The index ladder of codes will be developed after reading a sample of eligible papers and discussion with the team.

The coded findings will be read and re-read by at least two members of the team and categories may be further refined and organised. The coding framework may also be modified during coding as new themes emerge.

[4] Dixon-Woods M, Agarwal S, Young B, Jones D, Sutton A. (2004) Integrative approaches to qualitative and quantitative evidence. London: Health Development Agency

[5] Richie, J and Spencer, L (1994), 'Qualitative data analysis for applied policy research', in Bryman and Burgess, eds., Analysing Qualitative Data, London:Routledge, p173-194.

2.8 Communication of findings tools (Review 3)

In addition to a narrative summary/thematic synthesis of results; results will be summarised using two communication tools, as described below.

Logic model

The logic model will be developed and refined based on the results of the review. Key themes will be mapped onto the model and considered for inclusion. This will be used to present the findings to the PHAC committee.

PARIHS Framework

The review team will also map the identified barriers and facilitators against a conceptual model of implementation (Promoting Action on Research Implementation in Health Services (PARIHS) framework[6] to better understand the critical factors that enhance or inhibit appropriate oral care.

[6] Kitson AL, Rycroft-Malone J, Harvey G, McCormack B, Seers K and Titchen A. (2008) Evaluating the successful implementation of the PARiHS framework: theoretical and practical challenges. Implementation Science 3:1 DOI 10.1186/1748-5908-3-1

Appendix 1 - Search Strategy - Medline

The search comprises two groups of terms with a mix of indexed terms and keywords. The first group of terms is designed to identify care home residents. This includes a failsafe component (lines 17 to 22) to ensure that studies in adults with disabilities are identified. The second group of terms relates to oral health. The strategy was designed to enhance specificity, but testing against a core set of 50 potentially relevant papers indicates that the strategy is well balanced for sensitivity (all papers included in Medline were identified by the search).

	Searches	Results
1	exp nursing homes/	32415
2	Residential Facilities/	4748
3	Homes for the Aged/	11296
4	Assisted Living Facilities/	943
5	Long-Term Care/	22022
6	nursing home*1.tw.	21267
7	care home*1.tw.	1771
8	((elderly or old age) adj2 home*1).tw.	1614
9	assisted living facilit*.tw.	452
10	((nursing or residential) adj (home*1 or facilit*)).tw.	24158
11	(home*1 for the aged or home*1 for the elderly or home*1 for older adult*).tw.	2247
12	residential aged care.tw.	362
13	("frail elderly" adj2 (facilit* or home or homes)).tw.	52
14	(residential adj (care or facilit* or setting*)).tw.	3107
15	or/1-14	69174
16	Disabled Persons/	32526
17	Vulnerable Populations/	6120
18	Intellectual Disability/	47834
19	Learning Disorders/	12832
20	Mentally Disabled Persons/	2344
21	((physical* or learning or mental* or intellectual*) adj (disorder* or disab* or impair*)).tw.	45798
22	or/16-21	130980
23	(residential or home*1 or facilit*).tw.	543808
24	22 and 23	8763
25	15 or 24	75868
26	Preventive dentistry/	3096
27	Oral Hygiene/	10553

28	Dental Care/	15591
29	Toothbrushing/	6206
30	Mouthwashes/	4447
31	Health Education, Dental/	5816
32	Oral health/	10546
33	Dental Care for Chronically Ill/	2708
34	Dental Care for Aged/	1734
35	Geriatric Dentistry/	982
36	Dental Care for Disabled/	3986
37	((access* or availab*) adj2 dentist*).tw.	185
38	((dental health or oral health) adj3 (care or promotion or training)).tw.	3590
39	((oral or dental or mouth or teeth or tooth or gum or periodontal) adj (care or hygiene or health)).tw.	35651
40	(mouthwash* or mouth-wash* or mouth-rins* or mouthrins* or oral rins* or oralrins* or toothpaste* or tooth paste* or dentifrice* or toothbrush* or tooth brush* or fissure sealant* or floss*).tw.	13228
41	exp Dentifrices/	5699
42	(fluorid* adj2 (varnish* or topical or milk)).tw.	1441
43	Fluorides, Topical/	3947
44	Mouth Diseases/pc	899
45	Periodontal diseases/pc	2561
46	Mouth neoplasms/pc	1145
47	Xerostomia/pc	358
48	(dental adj (crown* or implant* or bridge* or denture* or inlay*)).tw.	8345
49	or/26-48	87974
50	(oral disease* or oral neoplasm* or oral cancer* or dental disease* or mouth disease* or dental decay or mouth neoplasm* or mouth cancer* or gum disease* or DMF or caries or gingivitis or periodontal disease* or periodontitis or dental plaque or oral plaque or dry mouth or xerostomia).tw.	84386
51	((tooth or teeth) adj2 (decay* or loss)).tw.	4675
52	(prevent* or control* or reduc*).tw.	4582217
53	50 or 51	86866
54	52 and 53	32141
55	49 or 54	108782
56	25 and 55	1264
57	limit 56 to (english language and humans and yr="1995 - 2014")	742

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Appendix 2 – Data Extraction Form (Effectiveness)

Study details	Population and Setting	Intervention/control	Outcomes and methods of analysis	Results	Notes
Programme theory (as described by author)	*Country; Number of participants; Setting [Community, Primary Care, Secondary Care, In patients etc.]; Location Urban/rural]; PROGRESS-Plus data in this order 1.Age, 2. Gender, 3. Socio-economic status 4. Race/ethnicity, 5. Disability [or medical diagnosis], Religion, Education, Social capital Specify inclusion and exclusion criteria*	*Describe allocation method including whether blocked, stratified, concealed, etc. How was confounding minimised?* *Describe Intervention in detail What delivered; Where; By whom?* *Method/intensity of delivery (how often, how long for)* ***Sample sizes:*** *Include number screened/approached (and % take up) as well as final sample sizes.* ***Baseline:*** *State 'no statistically significant differences' or describe differences.*	*Indicate if measure is non-validated or self-report* *Underline primary outcome*	***Narrative text ie 'Statistically significant results were found for…'*** *Effect sizes with 95% CI; p values; Any unintended consequences; Include adjusted and unadjusted results* *Outcomes to be listed for each follow-up period* *Details on attrition at each time point.*	*Include confounders and limitations;* *Funding sources should also note potential conflicts of interest.*
First author and year: **Aim of study:** **Study Design :**	**Setting:** **Participants:** **Inclusion:**	**Method of allocation:** **Intervention(s):** **Control:**	**Outomes:** **Follow-up periods:**	**Results:** **Attrition:**	**Limitations (author):** **Limitations (review team):** **Evidence gaps:**

Quality score: **External validity score:**	**Exclusion:**	**Sample sizes:** **Baseline comparisons:** **Study power:** **Intervention delivery:**	**Method of analysis:**		**Funding sources:** **Applicable to UK?**

Appendix 2 – Data Extraction Form (Barriers and Facilitators)

Study details	Research parameters	Population and sample selection	Outcomes and methods of analysis Results	Notes
		Description of participants: State sample size; whether parents / children / or providers and following details of participants: *Country; Number of participants; Setting [Community, Primary Care, Secondary Care, In patients etc.]; Location Urban/rural]; PROGRESS-Plus data in this order* ***1.Age, 2. Gender, 3. Socio-economic status 4. Race/ethnicity, 5. Disability [or medical diagnosis],*** *Religion, Education, Social capital*		*Include confounders and limitations; Applicability to UK populations and settings. Expert Advice: Other settings with similar weight management programmes include Spain, Norway, Denmark, Australia and New Zealand.*

Author and year: **Study design:** **Quality score: (inc external validity for surveys)**	**What was/were the research questions:** **What theoretical approach (e.g. grounded theory, IPA) does the study take (if specified):** **How were the data collected:** • **What method(s):** • **By whom:** • **What setting(s):** • **When:**	**Description of study participants:** **What population were the sample recruited from:** **How were they recruited:** **How many participants were recruited:** **Were there specific exclusion criteria:** **Were there specific inclusion criteria:** **Motivation / referral of participants:**	**Brief description of method and process of analysis:** **Key themes (with illustrative quotes if available) relevant to this review:**	**Limitations (author):** **Limitations (review team):** **Evidence gaps and/or recommendations for future research:** **Funding sources:** **Applicable to UK?** (if appropriate):

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APPENDIX 4: Modified Checklist for Correlation or Cross-sectional studies

Quality Appraisal of Correlation Studies or Cross-sectional Surveys			
	++ = good, + = mixed, - = poor, nr = not reported, na = not applicable		
	Cells are colour-coded to demonstrate the relationship with the summary questions below.		
	Study identification *(include full citation details)*		
	Study design:	**Cross-sectional**	
	Evaluation criteria	**Quality ++ + - nr na**	**Guidance topic:** **Assessed by:**
Population	**Section 1: Population**		
	1.1 Is the source population or source area well described?		
	1.2 Is the eligible population or area representative of the source population or area?		
	1.3 Do the selected participants or areas represent the eligible population or area?		
Exposure (& Comparison)	**Section 2: Method of selection of exposure (or comparison) group**		
	2.1 [XSS] Selection of exposure (and comparison) group. How was selection bias minimised?		
	2.2 [CS] Was the selection of explanatory variables based on sound theoretical basis?	**na**	
	2.3 [CS] Was the contamination acceptably low?	**na**	
	2.4 How well were likely confounding factors identified and controlled?	**na**	
	2.5 [XSS] Were rigorous processes used to develop the questions (e.g. were the questions piloted / validated?)		
	2.6 Is the setting applicable to the UK?		
Outcomes	**Section 3: Outcomes**		
	3.1 Were the outcome measures and procedures reliable?		
	3.2 Were the outcome measurement complete?		

	3.3 Were all important outcomes assessed?		
Time	**3.4 CS:** Was there a similar follow-up time in exposure & comparison groups?	**na**	
	3.5 CS: Was follow-up time meaningful?	**na**	
Results	**Section 4: Analyses**		
	4.1 CS: Was the study sufficiently powered to detect an effect if one exists?	**na**	
	4.2 CS: Were multiple explanatory variables considered in the analyses?	**na**	
	4.3 Were the analytical methods appropriate?		
	4.4 Was the precision of association given or calculable? Is association meaningful?		
Summary	**Section 5: Summary**		
	5.1 Are the study results internally valid (i.e unbiased)?		
	5.2 Are the results generalisable to the source population (i.e externally valid)?		

Appendix 5 –Time Line

	2014				2015												
	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J
Scoping and Protocol																	
Contract Start – 5 September 2014																	
Agree protocol for all reviews with NICE																	
Identification of Evidence																	
Finalise search strategy																	
Run database and website searches for all reviews and document																	
Select via title/abstract for each review																	
Select via full text for each review																	
Supplementary searching:																	
Review 1																	
Agree included studies																	
Appraisal/data extraction																	
Synthesise quantitative data																	
Complete evidence tables and write up																	
Submit draft to NICE: 6 Jan																	
Submit revised draft: 28 Jan																	
Present review to PHAC meeting: 11 Feb																	
Submit amendments post-PHAC meeting by 27 Feb																	
Review 2																	
Agree included studies																	
Appraisal/data extraction																	
Complete evidence tables and write up																	
Submit draft to NICE: 11 Feb																	
Submit revised draft: 6 Mar																	
Present review to PHAC meeting: 26 March																	
Submit amendments post-PHAC meeting by 10 April																	
Review 3																	
Agree included studies																	
Appraisal/data extraction																	
Develop outline coding framework																	
Synthesise qualitative/observational findings																	
Complete evidence tables and write-up																	
Submit draft to NICE: 8 April																	
Submit revised draft: 1 May																	
Present review to PHAC meeting: 20 May																	

	2014				2015												
	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J
Amendments following PHAC meeting by 5 June																	
Meetings and quality process																	
Fortnightly meetings with NICE (teleconference)																	
Possible additional PHAC meetings 24 June, 9/10 Sept, 21 Jan																	
Assist NICE with responses to stakeholders and submit final revised reports																	