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Strategies to prevent oral disease in dependent older people (Protocol)

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[Intervention Protocol]

Strategies to prevent oral disease in dependent older people

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects and costs of primary, secondary and tertiary strategies to prevent oral disease in dependent older people.

BACKGROUND

Description of the condition

The number of older people, defined as those above sixty-five years of age, is projected to increase exponentially from an estimated 524 million in 2010, to nearly 1.5 billion in 2050 worldwide (WHO 2011). Demographic and family changes mean that as people age further and lose their independence (defined as a reduction in their ability to perform activities of daily living) (Kingston 2012), fewer will have families to care for them and an increasing number will either be cared for at home or will enter formal care (WHO 2008; Branca 2009; Belsi 2013).

The cost of treating oral disease is expected to rise and a significant proportion of this cost in the future will relate to the provision of treatment for dependent older people (FDI 2016). For example, in the European Union, this cost is projected to rise from EURO54 billion in 2000 to EURO93 billion in 2020, greater than the costs of treating stroke and dementia combined (Widstrom 2004). Compared to two decades ago, many older people will keep their teeth for their lifetime (Samson 2008; Steele 2009; Hopcraft 2012; Thomson 2014). Since many in this population were not exposed to fluoride at an early age, dental decay in this population is now a major public health issue (Thomson 2014; Karki 2015; Morgan 2015). Moreover, restorations ('fillings') have a limited lifespan. Gum disease disproportionately affects older adults and is

becoming an increasing problem around dental implants, leading to implant failure (Derks 2015).

Self-care deteriorates with increasing age, dry mouth increases due to poly-pharmacy and diets also become rich in sugars, further increasing the risk of future disease. Overall, poor oral health impacts on older people's quality of life, their self-esteem, general health and diet (Nowjack-Raymer 2003; Walls 2004; Moynihan 2007; Gerritsen 2010; Thomson 2014; Porter 2015). In dentate older people, a number of oral diseases have risk factors such as smoking, age, and poor glycaemic control, that are in common with systemic diseases. There is also a growing interest in the possibility of a bi-directional relationship between oral health and cardiovascular disease, across a shared inflammatory-mediating pathway (Ford 2010). Diet plays a key role in disease prevention in older age, as poor diet has been linked to illnesses such as osteoporosis, atherosclerosis and bowel disease (Touger-Decker 2007). Equally, there is evidence that good oral health has very positive effects on the nutritional intake of older adults (Moynihan 2007). Evidence suggests that poor oral health can impact significantly on older patients' quality of life and their ability to go about their daily routines (Nitschke 2004; Steele 2004). Large sets of longitudinal epidemiological data on ageing have shown that a deterioration in oral health and oral health-related quality of life increases the risk of depressive symptoms among older adults, highlighting the importance of oral health as a determinant of subjective well-being in later life (Rouxel 2016).

Service provision for older people is often poor for those who reside at home and in residential care (De Visschere 2006; Gluhak 2010; Hopcraft 2012), given the challenge of the setting (Bots-VantSpijker 2014; van der Putten 2014; Walls 2014). Access to domiciliary services is difficult and admission to hospital for dental problems is distressing and costly (Kandelman 2008; Pretty 2014a). The standard of knowledge about oral health amongst formal and informal carers is poor (Paulsson 2002; Nitschke 2005; De Visschere 2015a; Brocklehurst 2015; Everaars 2015), and income-related inequality in dental service utilisation, and oral health inequalities amongst older people are common (Listl 2010; Tsakos 2011; Thomson 2012). As older people's independence deteriorates, all these factors are compounded further (WHO 2012; Thomson 2014). This makes prevention paramount.

Description of the intervention

Primary prevention includes the provision of information to help individuals make informed choices about their health-related behaviour and strategies to reduce the risk factors associated with disease expression. Examples of primary prevention include care-home initiated health promotion programmes by professional staff, or targeted health promotion programmes for individuals who are cared for at home by family or other informal carers. Further examples include the application of topical high strength fluoride, chlorhexidine and other health technologies, or toothbrushing programmes and toothpaste schemes.

Secondary prevention strategies include those that detect disease early and intervene to prevent its progression. Examples of secondary prevention include the use of population-based or care-home screening and early detection programmes undertaken by members of the dental team or care-home staff.

Tertiary prevention strategies include those that reduce morbidity by restoring function and reducing disease-related complications. Examples of tertiary prevention include the use of domiciliary care or mobile services to restore diseased teeth.

How the intervention might work

Primary prevention strategies like health education aim to improve the knowledge and skill levels of people providing care for older people (Heath 1999; Albrecht 2013; Pretty 2014b; Janssens 2016). Often designed as complex interventions, these types of programmes commonly target carers (for those being cared for at home) and care-home staff (Frenkel 2002; MacEntee 2007; Janssens 2016). Fluoride is central to the primary prevention of dental caries in older people (Murray 1991; Pretty 2014b). Fluoride can be delivered either locally or systemically, and reduces the susceptibility of tooth enamel to demineralisation (Tan 2010; Gibson 2011). In addition, it prevents disease progression by promoting remineralisation of early caries lesions (Featherstone 1988). Systemic methods of delivery include water fluoridation, whilst local methods of delivery, like fluoride varnish, are commonly provided by dental professionals (Maurinho 2013). Fluoride varnish is recommended for vulnerable groups (Maurinho 2013) and the use of high strength topical fluorides (greater than 5000 parts per million (ppm)) has recently been advocated for dependent older people (Walls 2012; Pretty 2014b). Toothpaste has both a systemic and topical effect. Alongside fluoride (Wong 2011), other active ingredients in toothpaste, such as triclosan, have demonstrated an ability to inhibit bacterial growth and reduce inflammation (Riley 2013). The mechanical removal of dental plaque by toothbrushing can also help prevent dental caries and reduce gingival inflammation.

Screening is a secondary preventive strategy to detect early disease (Wilson 1968) and so prevent its progression. Identifying older adults before they begin to manifest dental problems is considered to be an important strategy (De Visschere 2015b). The use of fluoride is also an effective secondary preventive strategy to prevent the progression of existing carious lesions, and has been recommended for this population group (MacEntee 2000; Pretty 2014b).

The provision of domiciliary and mobile care is a tertiary preventive strategy and can help reduce the impact of the disease burden once it has been expressed (Jablonski 2009; Pretty 2014a). An example of one such project is the Gerodent project being conducted in Belgium.

Why it is important to do this review

Most high-income countries that provide state-funded or subsidised dental care allocate the vast majority of these public funds to primary dental care, where dentists see patients in high-street practices. Dental diseases are almost entirely preventable, but little or no provision is being made for the prevention of oral disease in older people as they become increasingly dependent. As Walls argues "the physical and clinical changes that occur with ageing require an altered pattern of care for older people which is adjusted to their disease risk" (Walls 2014).

The standard of knowledge amongst formal and informal carers is poor (Paulsson 2002; Nitschke 2005; Vanobbergen 2005; Wardh 2013; De Visschere 2015a) and there is considerable variation in oral hygiene practices in long-term care institutions (Vanobbergen 2005). Service provision is also poor due to the barriers of delivering oral health care in remote settings (De Visschere 2006; Bots-VantSpijker 2014; Pretty 2014a; Walls 2014) and there is a need to develop a multi-disciplinary approach across dental and non-dental professionals, given the impact that oral health has on general health in this population (Coleman 2002; Andersson 2007; Bethel 2014). If these issues are not addressed, inequalities in dental service utilisation and oral health are likely to deteriorate (Listl 2010; Tsakos 2011; Thomson 2012).

The World Health Organisation has called for a paradigm shift towards the concept of ageing and has developed a set of priorities based on four strategic areas (WHO 2012):

- healthy ageing over the life-course to tackle non-communicable diseases;
- the design of health and long-term care systems that is fit for ageing populations;
- provision of supportive age-friendly environments;
- strengthening the research and the evidence base.

Recommendations regarding the oral care of dependent older people have been advocated (FDI 2016; Platform for Better Oral Health in Europe 2015) and preventive care pathways have been suggested (Pretty 2014b; Walls 2014), but little is known about the effectiveness, cost-effectiveness or acceptability of primary, secondary and tertiary prevention for interventions delivered at a population level.

OBJECTIVES

To assess the effects and costs of primary, secondary and tertiary strategies to prevent oral disease in dependent older people.

METHODS

Criteria for considering studies for this review

Types of studies

We will include studies of an experimental (randomised and non-randomised) and observational design:

- randomised controlled trials (RCTs);
- cluster RCTs;
- non-randomised controlled trials (NRCTs);
- controlled before-after studies (CBAs) with at least two intervention and two control sites;
- interrupted time series studies (ITSs) with a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention.

Randomised trials are often not available to address questions about the effects of health system interventions and implementation strategies and as such, it is appropriate to include NRCTs, CBAs and ITSs.

Types of participants

Individuals over sixty-five years of age who depend on others to provide some or all of their own self-care. This includes people with no current disease and those with existing disease, residing in care homes (residential and nursing) or those who reside at home. It is anticipated that the types of participants included in this review will be heterogenous. However, a number of subgroups may be identified, such as those living with dementia. Where possible, these will be subject to subgroup analysis.

We will exclude:

- studies of participants who are independent enough to attend primary dental care services;
- studies of participants who are hospitalised.

Types of interventions

The focus of this review is on primary, secondary and tertiary prevention interventions to improve the oral health of dependent older people. The comparator will be no treatment or different treatment ('head-to-head').

Primary prevention includes the provision of information at a population level to help individuals make informed choices about their health-related behaviour and strategies to reduce the risk factors associated with disease expression. Examples of population-based primary prevention include:

- population-based health promotion programmes for dependent older people;
- targeted health promotion programmes for individuals who are cared for at home or in residential care;
- the use of professional staff to administer topical preventive regimes, e.g. fluoride varnish;

- the use of postal schemes to distribute high-dose fluoride toothpaste to dependent older people (e.g. 5000 ppm or 2800 ppm).

Secondary prevention strategies include those population-based programmes that detect early disease and intervene to prevent its progression. Examples of population-based secondary prevention programmes include:

- dentists screening for oral disease in dependent older people;
- the use of non-dentist members of the dental team (e.g. hygienists or hygiene therapists) to screen for oral disease in dependent older people;
- non-dentally-trained care staff screening for oral disease in dependent older people.

Tertiary prevention strategies include those that reduce morbidity by restoring function and reducing disease-related complications. Examples of population-based tertiary prevention programmes include:

- initiatives to improve the sign-posting of services for dependent older people and their carers;
- access to services for dependent older people or people in care homes (e.g. the use of mobile units to provide domiciliary care in care homes) (e.g. http://www.gerodent.be).

We will exclude studies of interventions that are based on 'downstream' individual clinical interventions rather than a population-level approach to prevention.

Types of outcome measures

Primary outcomes

The primary outcome measure for the review is oral disease status. This will include:

- pain;
- decayed, missing and filled teeth (e.g. DMFT, DMFS or International Caries Detection and Assessment System);
- proportion of individuals with active coronal caries;
- proportion of individuals with active root caries;
- proportion of sites that bleed on probing.

Secondary outcomes

Where possible, we will collect other relevant outcome measures including the following.

1. Other patient outcome measures, including:

- health status:
  - physical health, e.g. reduced function (eating, speaking);
  - psychosocial outcomes, e.g. oral health related quality of life (e.g. Oral Health Impact Profile);
- health behaviour:
  - uptake and adherence to preventive interventions (e.g. recruitment and retention rates);
  - healthcare seeking behaviour as a result of the intervention (e.g. improvements in access to care).

2. Quality of care, including:

- adherence to preventive strategies (primary, secondary and tertiary) by dental professionals and formal and informal caregivers.

3. Utilisation, coverage or access, including:

- utilisation of preventive strategies, e.g. uptake amongst care homes, uptake amongst residents;
- coverage, e.g. number and type of dependent settings utilising preventive strategies;
- access to services, e.g. availability of dental services, waiting times to see dental professional.

4. Resource use, including:

- healthcare resources and costs, e.g. dental professional resources and time, consumables and supplies of health technologies;
- non-healthcare resources, e.g. transportation to healthcare facilities;
- formal and informal caregiver time.

5. Healthcare provider outcomes, including:

- workload of dental professionals and formal and informal caregivers;
- work morale of dental professionals and formal and informal caregivers;
- stress, burnout, sick leave of both dental professionals and formal and informal caregivers.

6. Social outcomes, including:

- empowerment, participation and networking of care homes;
- reduced isolation of informal caregivers at home;
- education of formal and informal caregivers.

7. Equity; in particular, inequalities in:

- oral and general health;
- utilisation, coverage or access;
- quality of care;
- resource use.

8. Adverse effects or harms (in particular):

- oral and general health (e.g. fluoride toxicity);
- utilisation, coverage or access;
- quality of care;
- resource use;
- healthcare providers;
- social outcomes.

Search methods for identification of studies

Electronic searches

The Effective Practice and Organisaton of Care (EPOC) Information Specialist will develop the final search strategy in consultation with the authors. A preliminary draft of the MEDLINE strategy is available in Appendix 1. We will adapt the MEDLINE strategy for subscription databases and translate MeSH terms to the controlled vocabularies of those databases as appropriate. We will apply shorter, less complex strategies to open access databases and search websites for grey literature because these search interfaces do not usually support complex Boolean or other operators. We will publish all search strategies used in the review. All databases will be searched from inception to the date of search.

We will search the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effects (DARE) for related systematic reviews.

We will search the following databases (from inception) for primary studies:

- Cochrane Central Register of Controlled Trials (CENTRAL), including the EPOC Group Specialised Register;
- MEDLINE, 1946 to present, In-Process and other non-indexed citations, OvidSP;
- Embase, 1974 to present, OvidSP;
- CINAHL (Cumulative Index to Nursing and Allied Health Literature), 1980 to present, EbscoHost;
- Science Citation Index and Social Sciences Citation Index, 1975 to present, ISI Web of Knowledge.

We will search the following trial registries:

- International Clinical Trials Registry Platform (ICTRP), Word Health Organization (WHO) (www.who.int/ictrp/en/);
- ClinicalTrials.gov, US National Institutes of Health (NIH) (clinicaltrials.gov/).

We will also conduct a grey literature search of the following resources to identify studies not indexed in the databases listed above:

- OpenGrey (www.opengrey.eu/);
- Joanna Briggs Institute (www.joannabriggs.edu.au/Search.aspx);
- National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk/).

Searching other resources

We will review reference lists of all included studies and relevant systematic reviews for additional potentially-eligible primary studies. We will also contact the authors of eligible studies and researchers with expertise relevant to the review topic. We will also conduct cited reference searches in ISI Citation indexes via Web of Knowledge. All strategies used, including a list of sources screened and relevant reviews/primary studies reviewed, will be provided in appendices.

Data collection and analysis

Selection of studies

We will download all the titles and abstracts identified by the electronic searches to a reference management database. We will then remove duplicate entries and three of the review authors (Paul Brocklehurst (PRB), Lynne Williams (LW) and Katarina Jerković -Ć osić (KJ)) will independently examine the remaining references. We will exclude studies that do not meet the inclusion criteria and obtain full-text copies of the identified references that appear to meet the inclusion criteria. When there are insufficient data in the study title or abstract to determine whether a study fulfils the inclusion criteria, the same review authors will obtain and assess the full report independently. Disagreement will be resolved by discussion and, if needed, by an arbitrator. We will record studies rejected at this and subsequent stages in the table 'Characteristics of excluded studies'.

We will include studies in the review irrespective of whether measured outcome data are reported in a 'usable' way. Studies that meet the inclusion criteria will be included and described in the 'Characteristics of included studies' table, even if they do not report usable results.

We will document the selection process in sufficient detail to complete a PRISMA flow chart (PRISMA 2016) and a table of 'Characteristics of excluded studies'.

Data extraction and management

We will extract data from included studies and assess their risk of bias. Two review authors will extract data from each included study independently and in duplicate using a tool developed for the review. We will resolve differences by discussion and, if needed, arbitration by a third person. If a single publication reports two or more separate studies, then we will extract data from each study separately. If the findings of a single study are spread across two or more publications, then we will extract data from the publications as one. For each study with more than one control or comparison group for the intervention, we will extract the results for each intervention arm. We will not double count data within a meta-analysis and we will combine groups to create single pairwise comparisons as appropriate. For each trial we will record the following data:

- year of publication, country of origin and source of study funding;
- details of the participants, including demographic characteristics and criteria for inclusion;

- details of the study design;
- details of the outcomes reported, including method of assessment and adverse outcomes.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and the guidance from the EPOC group (EPOC 2015). Any disagreement will be resolved by discussion or by involving a third review author. We will assess the risk of bias according to the following domains:

1. Random sequence generation;
2. Allocation concealment;
3. Blinding of participants and personnel;
4. Blinding of outcome assessment;
5. Incomplete outcome data;
6. Selective outcome reporting;
7. Baseline outcomes measurement;
8. Baseline characteristics;
9. Other bias.

For non-randomised studies we will use the criteria detailed in Appendix 2.

We will judge each potential source of bias as high, low or unclear risk, and provide a quote from the study report together with a justification for our judgment in the 'Risk of bias' table. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed.

For each study, we will provide a summary assessment of overall risk of bias:

- low risk when there is a low risk of bias across all key domains;
- unclear risk of bias when there is an unclear risk of bias in one or more of the key domains;
- high risk of bias when there is a high risk of bias in one or more of the key domains.

We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient-reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

Measures of treatment effect

We will report outcomes for each study in natural units.

For dichotomous outcomes, if possible, the risk ratio (RR) from statistical analyses adjusting for baseline differences (such as poisson regressions or logistic regressions) or the ratio of risk ratios (i.e. the risk ratio post-intervention/risk ratio pre-intervention) will be reported. We will not pool in one meta-analysis RRs that have been adjusted for baseline differences and those that have not. For continuous variables, if possible, the absolute change from a statistical analysis adjusting for baseline differences (such as regression models, mixed models or hierarchical models) or the relative change adjusted for baseline differences in the outcome measures (i.e. the absolute post-intervention difference between the intervention and control groups - the absolute pre-intervention difference between the intervention and control groups)/the post-intervention level in the control group) will be reported.

For ITS studies, we will use either a regression analysis with time trends before and after the intervention (adjusted for auto-correlation and any periodic changes) or ARIMA analysis. The results for the outcomes will be presented as changes along two dimensions: change in level and change in slope. Change in level is the immediate effect of the intervention and is measured as the difference between the fitted value for the first post-intervention data point (one month after the intervention) minus the predicted outcome one month after the intervention based on the pre-intervention slope only. Change in slope is the change in the trend from pre- to post-intervention, reflecting the long-term effect of the intervention. As interpretation of the change in slope can be difficult, we will present the long-term effects in a similar manner to the way that immediate effects are presented.

If papers with ITS design do not provide an appropriate analysis or reporting of results, but present the data points in a scannable graph or in a table, the slope will be analysed using the methods described in Ramsey 2003.

We will use summary tables to present the findings for the main comparisons in the review, to interpret the results and draw conclusions about the effects of different interventions including the size of effects and certainty of the evidence.

Unit of analysis issues

Should cluster randomised trials be included, we will undertake analysis, whenever feasible, at the same level as the randomisation or at the individual level, accounting for the clustering. The intracluster correlation coefficient (ICC) of any included cluster RCTs will be utilised to incorporate the design effect into the analysis. If ICC is not apparent in the reports, estimation methods will not be used. In this circumstance, we will not report the P values or confidence intervals, as analyses not accounting for the design effect have the potential to inflate the type 1 error rate and result in artificially narrow confidence intervals.

Dealing with missing data

Where possible, we will contact the authors of included papers if important data are not available. If we are not able to obtain missing data, we will explicitly state this and report the results that are available, provided they are not likely to be misleading (e.g. if there is a unit of analysis error).

Assessment of heterogeneity

We will assess the significance of any discrepancies in the estimates of the treatment effects from the different studies by means of Cochrane's test for heterogeneity, where $P < 0.1$ will be considered significant (Higgins 2011). We will use the I^2 statistic, which describes the percentage total variation across studies that is due to heterogeneity rather than chance, to quantify heterogeneity, with an I^2 statistic over 50% representing substantial heterogeneity (Higgins 2011).

Assessment of reporting biases

If there is a sufficient number of studies (more than 10) included in any meta-analysis, we will assess publication bias according to the recommendations on testing for funnel plot asymmetry as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Data synthesis

We will only undertake meta-analysis for clinically homogeneous RCTs. We will undertake meta-analysis using a random-effects model. We will combine risk ratios for dichotomous data and mean differences for continuous data using a random-effects model, if the data allow. Due to the expected diversity of the interventions and outcomes, it may not be possible to pool the results. If combining outcome data is not possible due to differences in the types and reporting of outcomes then we will present a narrative summary, alongside a table of the standardised median effect size for each outcome and the median effect sizes across studies for each comparison. We will draw conclusions on the basis of methodological quality, transferability and results of the studies.

We will describe ongoing studies, where available, detailing the primary author, research question(s), methods and outcome measures together with an estimate of the reporting date.

Subgroup analysis and investigation of heterogeneity

The review team accepts that subgroup comparisons are by their nature observational and so subject to bias. If a small number of studies is found, we will not undertake subgroup analyses or random-effects modelling. Should sufficient studies warrant subgroup analysis, this will be undertaken on the following basis:

- intervention type;
- setting (residential versus nursing care versus care at home) - given the potential difference between staffing levels and formal and informal caregivers;
- level of functional dependence - given the impact on uptake and fidelity.

We will only undertake meta-analyses if there are studies of similar comparisons reporting the same outcome measures. Should meta-analysis be considered appropriate, these will be undertaken on the basis of the subgroups identified above.

Sensitivity analysis

We will consider performing sensitivity analyses for missing data by imputing a plausible range of data, and the potential implications of missing information will be discussed. In order to determine how robust and consistent the results are, we will compare RCTs deemed to be at low risk or bias to other studies. Any methodological decisions taken in the course of preparing the review will be checked for stability of results in a sensitivity analysis.

Summary of findings

We will summarise the findings of the main intervention comparison for the most important outcomes by undertaking the following procedure to create a 'Summary of Findings' (SoF) table:

- listing the outcomes that we identify as the primary outcome (health status and health behaviour);
- adding other important outcomes for which data are reported, as appropriate (uptake amongst care homes, uptake amongst residents, access to services and resource use and equity);
- adding other outcomes for which data are not reported, but which would be important for policy-makers and stakeholders;
- assessing the certainty of the evidence for each outcome using the GRADE approach (Appendix 3);
- summarising the findings for each outcome (quantitatively, where possible);
- completing the SoF table;
- preparing bullet points that summarise the information in the SoF table in plain language.

Two review authors will independently assess the certainty of the evidence (high, moderate, low, and very low) using the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias). We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook* (Higgins 2011) and the EPOC worksheets (EPOC 2013), and using GRADEpro software (GRADEpro GDT 2015). We will resolve disagreements on certainty ratings by discussion, provide justification for decisions to down- or up-grade the ratings using footnotes in the table, and make comments to aid readers' understanding of the review where necessary. We will use plain language statements to report these findings.

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REFERENCES

Additional references

Albrecht 2013

Albrecht (nee Bunge) M, Kupfer R, Reissmann D, Haastert B, Mühlhauser I, Köpke S. Oral health educational interventions for nursing home staff and residents. *Cochrane Database of Systematic Reviews* 2013, Issue 5. [DOI: 10.1002/14651858.CD010535]

Andersson 2007

Andersson K, Furhoff AK, Nordenram G, Wardh I. "Oral health is not my department" - perceptions of older patients' oral health by general medical practitioners in primary health care centres: a qualitative interview study. *Scandinavian Journal of Caring Sciences* 2007;**21(1)**:126–33.

Belsi 2013

Belsi A, Gonzalez-Maffe J, Jones K, Wright D, Gallagher JE. Care home managers' views of dental services for older people living in nursing and residential homes in inner city London. *Community Dental Health* 2013;**30**:77–82.

Bethel 2014

Bethel LA, Kim EE, Seitz CM, Swann BJ. Innovations in dental care delivery for the older adult. *Dental Clinics of North America* 2014;**58**:845-55.

Bots-VantSpijker 2014

Bots-VantSpijker PC, Vanobbergen JN, Schols JM, Schaub RM, Bots CP, de Baat C. Barriers of delivering oral health care to older people experienced by dentists: a systematic literature review. *Community Dentistry and Oral Epidemiology* 2014;**42(2)**:113–21.

Branca 2009

Branca S, Bennati E, Ferlito L, Spallina G, Cardillo E, Malaguarnera M, et al. The health-care in the extreme longevity. *Archives of Gerontology and Geriatrics* 2009;**49**(1): 32-4.

Brocklehurst 2015

Brocklehurst PR, Mackay L, Goldthorpe J, Pretty IA. Older people and oral health: setting a patient-centred research agenda. Gerodontology 2015 May 23 [Epub ahead of print]. [DOI: 10.1111/ger.12199]

Coleman 2002

Coleman P. Improving oral health care for the frail elderly: a review of widespread problems and best practices. *Geriatric Nursing* 2002;**23**:189–99.

De Visschere 2006

De Visschere LM, Grooten L, Theuniers G, Vanobbergen JN. Oral hygiene of elderly people in long-term care institutions - a cross-sectional study. *Gerodontology* 2006;**23** (4):195-204.

De Visschere 2015a

De Visschere L, de Baat C, De Meyer L, van der Putten GJ, Peeters B, Söderfelt B, et al. The integration of oral health care into day-to-day care in nursing homes: a qualitative study. *Gerodontology* 2015;**32**(2):115–22.

De Visschere 2015b

De Visschere L, Janssens B, De Reu G, Duyck J, Vanobbergen J. An oral health survey of vulnerable older people in Belgium. Clinical Oral Investigations 2015 Nov 14 [Epub ahead of print]. [DOI: 10.1007/s00784-015-1652-8]

Derks 2015

Derks J, Tomasi C. Peri-implant health and disease. *Journal of Clinical Periodontology* 2015;**42(Suppl)**(16):S158- S171.

EPOC 2013

Cochrane Effective Practice and Organisation of Care Group. EPOC Worksheets for preparing a Summary of Findings (SoF) table using GRADE. EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services, epoc.cochrane.org/epoc-specific-resources-review-authors 2013 (accessed prior to 16 September 2016).

EPOC 2015

Cochrane Effective Practice and Organisation of Care Group. Suggested risk of bias criteria for EPOC reviews. EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services. epoc.cochrane.org/epoc-specific-resources-review-authors 2015 (accessed prior to 16 September 2016).

Everaars 2015

Everaars B, Jerković -Ć osić K, van der Putten G-J, van der Heijden GJMG. Probing problems and priorities in oral health (care) among community dwelling elderly in the Netherlands - a mixed method study. *International Journal of Health Sciences Research* 2015;**5**(9):415–29.

FDI 2016

FDI/World Dental Federation. Shaping the future of oral health. www.fdiworldental.org/oral-health/vision-2020/shaping-the-future-of-oral-health.aspx (accessed prior to 16 September 2016).

Featherstone 1988

Featherstone JDB, Ten Cate JM. Physicochemical aspects of fluoride-enamel interactions. In: Ekstrand J, Fejerskov O, Silverstone LM editor(s). *Fluoride in Dentistry*. Copenhagen: Munksgaard, 1988:125–49.

Ford 2010
Ford PJ, Raphael SL, Cullinan MP, Jenkins AJ, West MJ, Seymour GJ. Why should a doctor be interested in oral disease?. *Expert Review of Cardiovascular Therapy* 2010;**8**: 1483–93.

Frenkel 2002
Frenkel H, Harvey I, Needs K. Oral health care education and its effect on caregivers' knowledge and attitudes: a randomised controlled trial. *Community Dentistry and Oral Epidemiology* 2002;**30**(2):91-100.

Gerritsen 2010
Gerritsen AE, Allen PF, Witter DJ, Bronkhorst EM, Creugers NH. Tooth loss and oral health-related quality of life: a systematic review and meta-analysis. *Health and Quality of Life Outcomes* 2010;**8**(126):1–13.

Gibson 2011
Gibson G, Jurasic MM, Wehler CJ, Jones JA. Supplemental fluoride use for moderate and high caries risk adults: a systematic review. *Journal of Public Health Dentistry* 2011; **71**(3):171-84.

Gluhak 2010
Gluhak C, Arnetzl GV, Kirmeier R, Jakse N, Arnetzl G. Oral status among seniors in nine nursing homes in Styria, Austria. *Gerodontology* 2010;**27**(1):47-52.

GRADEpro GDT 2015 [Computer program]
GRADE Working Group, McMaster University. GRADEpro Guidance Development Tool. gradepro.org. Version (accessed prior to 16 September 2016). Hamilton (ON): GRADE Working Group, McMaster University, 2015.

Heath 1999
Heath MR, Müller F, Lewis D, McKerlie R. Clinical progress: standards of dental care in residential homes: a web way forward. *Gerodontology* 1999;**16**:123–5.

Higgins 2011
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Hopcraft 2012
Hopcraft MS, Morgan MV, Satur JG, Wright FA. Edentulism and dental caries in Victorian nursing homes. *Gerodontology* 2012;**29**(2):512-9.

Jablonski 2009
Jablonski RA, Swecker T, Munro C, Grap MJ, Ligon M. Measuring the oral health of nursing home elders. *Clinical Nursing Research* 2009;**18**(3):200–5.

Janssens 2016
Janssens B, De Visschere L, van der Putten GJ, de Lugt-Lustig K, Schols JM, Vanobbergen J. Effect of an oral healthcare protocol in nursing homes on care staffs' knowledge and attitude towards oral health care: a cluster-randomised controlled trial. Gerodontology 2016 Nov 26 [Epub ahead of print]. [DOI: 10.1111/ger.12164]

Kandelman 2008
Kandelman D, Petersen PE, Ueda H. Oral health, general health, and quality of life in older people. *Special Care Dentistry* 2008;**28**:224–36.

Karki 2015
Karki AJ, Monaghan N, Morgan M. Oral health status of older people living in care homes in Wales. *British Dental Journal* 2015;**219**(7):331–4.

Kingston 2012
Kingston A, Collerton J, Davies K, Bond J, Robinson L, Jagger C. Losing the ability in activities of daily living in the oldest old: a hierarchic disability scale from the Newcastle 85+ study. *PLoS ONE* 2012;**7**(2):e31665. [DOI: http://dx.doi.org/10.1371/journal.pone.0031665]

Listl 2010
Listl S. Income-related inequalities in dental service utilization by Europeans aged 50+. *Journal of Dental Research* 20101;**90**(6):717–23. [DOI: 10.1177/0022034511399907]

MacEntee 2000
MacEntee MI. Oral care for successful aging in long-term care. *Journal of Public Health Dentistry* 2000;**60**(4):326–9.

MacEntee 2007
MacEntee MI, Wyatt CC, Beattie BL, Paterson B, Levy-Milne R, McCandless L, et al. Provision of mouth-care in long-term care facilities: an educational trial. *Community Dentistry and Oral Epidemiology* 2007;**35**(1):25-34.

Maurinho 2013
Marinho VCC, Worthington HV, Walsh T, Clarkson JE. Fluoride varnishes for preventing dental caries in children and adolescents. *Cochrane Database of Systematic Reviews* 2013, Issue 7. [DOI: 10.1002/14651858.CD002279.pub2]

Morgan 2015
Morgan MZ, Johnson IG, Hitchings E, Monaghan NP, Karki AJ. Dentist skill and setting to address dental treatment needs of care home residents in Wales. Gerodontology 2015 Feb 3 [Epub ahead of print].

Moynihan 2007
Moynihan PJ. The relationship between nutrition and systemic and oral well-being in older people. *Journal of the American Dental Association* 2007;**138**:493–7.

Murray 1991
Murray JJ, Rugg-Gunn AJ, Jenkins GN. *Fluorides in Caries Prevention*. Oxford: Wright, 1991.

Nitschke 2004
Nitschke I, Muller F. The impact of oral health on the quality of life in the elderly. *Oral Health & Preventive Dentistry* 2004;**2**:271–5.

Nitschke 2005
Nitschke I, Ilgner A, Müller F. Barriers to provision of dental care in long-term care facilities: the confrontation with ageing and death. *Gerodontology* 2005;**22**:123–9.

Nowjack-Raymer 2003
Nowjack-Raymer RE, Sheiham A. Association of edentulism and diet and nutrition in US adults. *Journal of Dental Research* 2003;**82**:123–6.

Paulsson 2002
Paulsson G, Söderfeldt B, Nederfors T, Fridlund B. Nursing personnels' views on oral health from a health promotion perspective: a grounded theory analysis. *Acta Odontologica Scandinavica* 2002;**60**:42–9.

Platform for Better Oral Health in Europe 2015
Platform for Better Oral Health in Europe. Targets for 2020. www.oralhealthplatform.eu/our-work/targets-for-2020/ (accessed prior to 17 September 2016).

Porter 2015
Porter J, Ntouva A, Read A, Murdoch M, Ola D, Tsakos G. Impact of oral health on the quality of life of nursing home residents. *Health and Quality of Life Outcomes* 2015;**13**:102.

Pretty 2014a
Pretty IA. The life course, care pathways and elements of vulnerability. A picture of health needs in a vulnerable population. *Gerodontology* 2014;**31 (Suppl. 1)**:1-8.

Pretty 2014b
Pretty IA, Ellwood RP, Lo ECM, MacEntee MI, Muller F, Rooney E, et al. The Seattle Care Pathway for securing oral health in older patients. *Gerodontology* 2014;**31 (Suppl. 1)**: 77-87.

PRISMA 2016
Preferred Reporting Items for Systematic Reviews and Meta-Analyses. prisma-statement.org (accessed prior to 17 September 2016).

Ramsey 2003
Ramsay CR, Matowe L, Grilli R, Grimshaw JM, Thomas RE. Interrupted time series design in health technology assessment: lessons from two systematic reviews of behavior change strategies. *International Journal of Technology Assessment in Health Care* 2003;**19(4)**:612–23.

Riley 2013
Riley P, Lamont T. Triclosan/copolymer containing toothpastes for oral health. *Cochrane Database of Systematic Reviews* 2013, Issue 12. [DOI: 10.1002/14651858.CD010514.pub2]

Rouxel 2016
Rouxel P, Tsakos G, Chandola T, Watt RG. Oral health: a neglected aspect of subjective well-being in later life. Journals of Gerontology Series B Psychological Sciences and Social Science 2016 Mar 12 [Epub ahead of print]. [DOI: 10.1093/geronb/gbw024]

Samson 2008
Samson H, Strand GV, Haugejorden O. Change in oral health status among institutionalized Norwegian elderly over a period of 16 years. *Acta Odontologica Scandinavica* 2008;**66**(6):368-73.

Steele 2004
Steele JG, Sanders AE, Slade GD, Allen PF, Lahti S, Nuttall N. How do age and tooth loss affect oral health impacts and quality of life? A study comparing two national samples. *Community Dentistry and Oral Epidemiology* 2004;**32**: 107–14.

Steele 2009
Steele J. Adult Dental Health Survey. http://content.digital.nhs.uk/pubs/dentalsurveyfullreport09 2009.

Tan 2010
Tan HP, Lo ECM, Dyson JE, Luo Y, Corbet EF. A randomized trial on root caries prevention in elders. *Journal of Dental Research* 2010;**89**(10):1086–90.

Thomson 2012
Thomson WM. Social inequality in oral health. *Community Dentistry and Oral Epidemiology* 2012;**40 Suppl 2**:28-32.

Thomson 2014
Thomson M. Epidemiology of oral health conditions in older people. *Gerodontology* 2014;**31 (Suppl. 1)**:9-16.

Touger-Decker 2007
Touger-Decker R, Mobley CC. Position of the American Dietetic Association: oral health and nutrition. *Journal of the American Dietary Association* 2007;**107**:1418–28.

Tsakos 2011
Tsakos G, Demakakos P, Breeze E, Watt RG. Social gradients in oral health in older adults: findings from the English longitudinal survey of aging. *American Journal of Public Health* 2011;**101**(10):1892-9.

van der Putten 2014
van der Putten G-J, de Baat C, Visschere L, Schols J. The challenge of setting - from community to residential care. *Gerodontology* 2014;**31 (Suppl. 1)**:17-24.

Vanobbergen 2005
Vanobbergen JN, De Visschere LM. Factors contributing to the variation in oral hygiene practices and facilities in long-term care institutions for the elderly. *Community Dental Health* 2005;**22**(4):260–5.

Walls 2004
Walls AW, Steele JG. The relationship between oral health and nutrition in older people. *Mechanisms of Ageing and Development* 2004;**125**:853–7.

Walls 2012
Walls AW, Meurman JH. Approaches to caries prevention and therapy in the elderly. *Advances in Dental Research* 2012;**24**(2):36-40.

Walls 2014
Walls A. Challenges of the dentate. *Gerodontology* 2014;**31 (Suppl. 1)**:25-30.

Wardh 2013
Wårdh I, Jonsson M, Wikström M. Attitudes to and knowledge about oral health care among nursing home personnel - an area in need of improvement. *Gerodontology* 2012;**29**(2):787-92.

WHO 2008
Kanström L, Zamaro G, Sjöstedt C, Green G (eds). Healthy ageing profiles: guidance for producing local health profiles of older people. World Health Organisation,

www.euro.who.int/en/publications/abstracts/healthy-ageing-profiles.-guidance-for-producing-local-health-profiles-for-older-people 2008 (accessed 17 September 2016).

WHO 2011
World Health Organisation. Global health and aging. www.who.int/ageing/publications/global_health/en/ 2011 (accessed 17 September 2016). [NIH Publication no. 11–7737]

WHO 2012
World Health Organisation. Policies and priority interventions for healthy aging. www.euro.who.int/en/health-topics/Life-stages/healthy-ageing/publications/2012/policies-and-priority-interventions-for-healthy-ageing 2012.

Widstrom 2004
Widstrom E, Eaton KA. Oral healthcare systems in the extended European union. *Oral Health and Preventive Dentistry* 2004;**2**:155–94.

Wilson 1968
Wilson JM, Jungner YG. *Principles and Practice of Screening for Disease*. Geneva: World Health Organisation, 1968. [Public Health Papers No. 34]

Wong 2011
Wong MC, Clarkson J, Glenny AM, Lo EC, Marinho VC, Tsang BW, et al. Cochrane reviews on the benefits/risks of fluoride toothpastes. *Journal of Dental Research* 2011;**90**(5): 573-9.

* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present

No.	Search terms
1	exp tooth diseases/pc
2	exp mouth diseases/pc
3	halitosis/pc
4	oral health/
5	((dental or tooth or teeth or enamel or root*) and (decay* or caries or carious or white spot* or plaque or reminerali* or demineralı* or erosion* or abrasion* or wear)).ti,ab
6	(denture* and (clean* or clens*)).ti,ab.
7	(periodont* or gingivi* or gingiva*).ti,ab.
8	(stomatitis or mouth ulcer* or oral ulcer* or (oral adj3 candidi*) or (mouth* adj3 candidi*) or aphthous ulcer* or (aphthae adj3 ulcer*) or (mucositis adj3 mouth*) or (mucositis adj3 oral) or xerostomi* or dry mouth*).ti,ab
9	((oral adj3 health*) or (mouth adj3 health*) or (dental adj3 health*)).ti,ab
10	leukoplak*.ti,ab.

(*Continued*)

11	hairy tongue*.ti,ab.
12	(halitosis or mouth odour* or mouth odor* or mouth malodour* or mouth malodor* or oral malodour* or oral malodor* or (breath adj5 malodour*) or (breath adj5 malodor*) or (breath adj5 odour*) or (breath adj5 odor*)).ti,ab
13	or/4-12
14	or/1-3
15	aged/
16	"aged, 80 and over"/
17	frail elderly/
18	(geriatric? or senior? or elderly).ti,ab.
19	(old* adult? or old* person? or old* people or old* patient?).ti,ab
20	geriatrics/
21	"health services for the aged"/
22	geriatric dentistry/
23	or/15-22
24	prevent*.ti,ab.
25	exp preventive dentistry/
26	exp cariostatic agents/
27	(fluoride? or fluoridation).ti,ab.
28	exp dentifrices/
29	exp mouthwashes/
30	exp oral hygiene/
31	(oral adj4 care).ti,ab.
32	(oral hygiene or mouth* care or dental care or (care adj3 teeth) or (mouth* adj3 hygiene) or (plaque adj3 control*) or (plaque adj3 remov*)).ti,ab

(*Continued*)

33	(toothbrush* or tooth-brush* or toothpaste* or dentifrice* or mouthwash* or mouth-wash* or mouthrinse* or mouth-rinse*).ti,ab
34	(floss* or interdental brush* or inter-dental brush* or (tooth adj2 clean*) or (teeth adj2 clean*) or (denture* adj2 hygien*) or (denture* adj2 clean*) or (tongue* adj2 scrap*) or (tongue* adj2 brush*) or (chewing adj2 stick*) or (chewing adj2 gum*)).ti,ab
35	health education, dental/
36	exp health promotion/
37	mass screening/
38	screen*.ti,ab.
39	((dental or dentist? or oral* or mouth or gum? or tooth or teeth) adj5 (instruct* or advise* or advice or educat* or promot* or teach* or train*)).ti,ab
40	or/24-39
41	or/25-39
42	13 and 40 and 23
43	14 and 41 and 23
44	or/42-43
45	randomized controlled trial.pt.
46	controlled clinical trial.pt.
47	multicenter study.pt.
48	pragmatic clinical trial.pt.
49	(randomis* or randomiz* or randomly).ti,ab.
50	groups.ab.
51	(trial or multicenter or multi center or multicentre or multi centre).ti
52	(intervention? or effect? or impact? or controlled or control group? or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment* or quasi experiment* or pseudo experiment* or pseudoexperiment* or evaluat* or time series or time point? or repeated measur*).ti,ab
53	non-randomized controlled trials as topic/

(*Continued*)

54	interrupted time series analysis/
55	controlled before-after studies/
56	or/45-55
57	exp animals/
58	humans/
59	57 not (57 and 58)
60	review.pt.
61	meta analysis.pt.
62	news.pt.
63	comment.pt.
64	editorial.pt.
65	cochrane database of systematic reviews.jn.
66	comment on.cm.
67	(systematic review or literature review).ti.
68	or/59-67
69	56 not 68
70	44 and 69

Appendix 2. Risk of bias for non-randomised studies

Non-randomised controlled trials (NRCTs) and controlled before-after (CBA) studies will be judged according to the following criteria (EPOC 2015; Higgins 2011):

1. **Was the allocation sequence adequately generated?** "Low risk" will be scored if a random component in the sequence generation process is described. "High risk" will be scored if a non-random method is used. NRCTs and CBA studies will be scored "High risk". "Unclear risk" will be scored if the allocation sequence method is not specified in the paper.

2. **Was the allocation concealed?** "Low risk" will be scored if the unit of allocation was by institution, team or professional and allocation was performed on all units at the start of the study; or if the unit of allocation was by patient or episode of care and there was some form of centralised randomisation scheme, an on-site computer system or sealed opaque envelopes were used. CBA studies will be scored "High risk". "Unclear risk" will be scored if allocation concealment is not specified in the paper.

3. **Were baseline outcome measurements similar?** "Low risk" will be scored if performance or patient outcomes were measured prior to the intervention, and no important differences were present across study groups. In RCTs, "Low risk" will be scored if imbalanced but appropriate adjusted analysis was performed (e.g. analysis of covariance). "High risk" will be scored if important

differences were present and not adjusted for in analysis. "Unlcear risk" will be scored if there were no baseline measure of outcome in an RCT.

4. **Were baseline characteristics similar?** "Low risk" will be scored if baseline characteristics of the study and control providers are reported and similar. "Unclear risk" will be used if it is not clear in the paper (e.g. no data are presented). "High risk" will be scored if there is no report of characteristics in text or tables or if there are differences between control and intervention providers.

5. **Were incomplete outcome data adequately addressed?** "Low risk" will be scored if missing outcome measures were unlikely to bias the results. "High risk" will be scored if missing outcome data were likely to bias the results. "Unclear risk" will be scored if this is not specified in the paper (we will not assume 100% follow up unless stated explicitly).

6. W**as knowledge of the allocated interventions adequately prevented during the study?** "Low risk" will be scored if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. "High risk" will be scored if the outcomes were not assessed blindly. "Unclear risk" will be scored if this is not specified in the paper.

7. **Was the study adequately protected against contamination?** "Low risk" will be scored if allocation was by community, institution or practice and it is unlikely that the control group received the intervention. "High risk" will be scored if it is likely that the control group received the intervention. "Unclear risk" will be scored if professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred.

8. **Was the study free from selective outcome reporting?** "Low risk" will be scored if there is no evidence that outcomes were selectively reported. "High risk" will be scored if some important outcomes are subsequently omitted from the results. "Unclear risk" will be scored if this is not specified in the paper.

9. **Was the study free from other risks of bias?** "Low risk" will be scored if there is no evidence of other risk of biases.

Based on the recommendations of EPOC (EPOC 2015), we will assess the risk of bias of interrupted time series (ITS) studies according to the following domains:

1. **Was the intervention independent of other changes?** "Low risk" will be scored if there are compelling arguments that the intervention occurred independently of other changes over time and the outcome was not influenced by other confounding variables/ historic events during the study period. If events/variables are identified, we will note what they are. "High risk" will be scored if it is reported that the intervention was not independent of other changes in time.

2. **Was the shape of the intervention effect prespecified?** "Low risk" will be scored if the point of analysis is the point of intervention, or a rational explanation for the shape of intervention effect was given by the author(s). Where appropriate, this should include an explanation if the point of analysis is not the point of intervention. "High risk" will be scored if it is clear that the condition above criterion is not met.

3. **Was the intervention unlikely to affect data collection**? "Low risk" will be scored if it is reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention). "High risk" will be scored if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported).

4. **Was knowledge of the allocated interventions adequately prevented during the study?** "Low risk" will be scored if the authors state explicitly that the primary outcome variables were assessed blindly, or the outcomes are objective, e.g. length of hospital stay. Primary outcomes are those variables that correspond to the primary hypothesis or question as defined by the authors. "High risk" will be scored if the outcomes were not assessed blindly. "Unclear risk" will be scored if this is not specified in the paper.

5. **Were incomplete outcome data adequately addressed?** "Low risk" will be scored if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the pre- and post-intervention periods or the proportion of missing data was less than the effect size, i.e. unlikely to overturn the study result). "High risk" will be scored if missing outcome data were likely to bias the results. "Unclear risk" will be scored if this is not specified in the paper (we will not assume 100% follow up unless stated explicitly).

6. **Was the study free from selective outcome reporting?** "Low risk" will be scored if there is no evidence that outcomes were selectively reported (e.g. all relevant outcomes in the methods section are reported in the results section). "High risk" will be scored if some important outcomes are subsequently omitted from the results. "Unclear risk" will be scored if this is not specified in the paper.

7. **Was the study free from other risks of bias?** "Low risk" will be scored if there is no evidence of other risk of biases. If the ITS study has ignored secular (trend) changes and performed a simple t-test of the pre- versus post-intervention periods without further justification, we will exclude the study from the review unless re-analysis is possible.

Appendix 3. 'Summary of Findings' and GRADE

Patients or population: **Settings:** **Intervention:** **Comparison:**			
Outcome	**Impact**	**Number of participants**	**Quality of the evidence (GRADE)**

CONTRIBUTIONS OF AUTHORS

Development of the protocol based on the latest Cochrane guidance: PRB

Identification of studies: PRB, LW, KJ

Assessment of risk of bias: PRB, LW, ZH, KJ, Martina Hayes (MH)

Data input/synthesis: PRB, LW, ZH

Discussion and recommendations for practice: PRB, LW, KJ, MH, Richard G Watt (RGW), George Tsakos (GT), Gerry McKenna (GMc), Ivor Chestnutt (IC), Iain Pretty (IAP), Christopher Burton.

DECLARATIONS OF INTEREST

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PRB: none known

LW: none known

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