

BMJ Open

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Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-011159
Article Type:	Protocol
Date Submitted by the Author:	14-Jan-2016
Complete List of Authors:	Hoben, Matthias; University of Alberta Faculty of Nursing, Kent, Angelle; University of Alberta Faculty of Nursing Kobagi, Nadia; University of Alberta Faculty of Medicine and Dentistry, School of Dentistry Yoon, Minn; University of Alberta Faculty of Medicine and Dentistry, School of Dentistry
Primary Subject Heading:	Dentistry and oral medicine
Secondary Subject Heading:	Nursing, Evidence based practice, Geriatric medicine, Health services research
Keywords:	Oral Health Care, Dementia < NEUROLOGY, Nursing Homes, Responsive Behaviours, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Manuscripts

Effective strategies to motivate nursing home residents in oral health care and to prevent or reduce responsive behaviours to oral health care – a systematic review protocol

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Keywords

Oral Health Care, Dementia, Nursing Homes, Responsive Behaviours, Quality in Health Care

Word count

2,535

ABSTRACT

Introduction

Oral health care in nursing homes is less than optimal, with severe consequences for residents' health and quality of life. To provide the best possible oral health care to nursing home residents, care providers need strategies that have been proven to be effective. Strategies can either encourage and motivate residents to perform oral health care themselves or can prevent or overcome responsive behaviours from residents when care providers assist with oral health care. This systematic review aims to identify studies that evaluate the effectiveness of such strategies and to synthesize their evidence.

Methods and analysis

We will conduct a comprehensive search in the databases Medline, EMBASE, Evidence Based Reviews – Cochrane Central Register of Controlled Trials, CINAHL, and Web of Science for quantitative intervention studies that assess the effectiveness of eligible strategies. Two reviewers will independently screen titles, abstracts and retrieved full-texts for eligibility. In addition, contents of key journals, publications of key authors, and reference lists of all studies included will be searched by hand and screened by two reviewers. Discrepancies at any stage of the review process will be resolved by consensus. Data extraction will be performed by one research team member and checked by a second team member. Two reviewers will independently assess methodological quality of studies included using three validated checklists appropriate for different research designs. We will present a narrative synthesis of study results.

Ethics and dissemination

We did not seek ethics approval for this study, as we will not collect primary data and data from studies included cannot be linked to individuals or organizations. We will publish findings of this review in a peer-reviewed paper and present them at an international peer-reviewed conference.

Protocol registration number

This review is registered with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) database: CRD42015026439.

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INTRODUCTION

Providing oral health care to nursing home residents is complex and challenging for care staff. Baby boomers are entering nursing homes with more of their natural teeth and with more complex prostheses and bridges than previous generations, leading to increased and different care needs.[1] The large and rapidly growing number of nursing home residents with dementia[2] further elevates those challenges. In Western countries, between three and eight percent of people aged 65 years or older receive nursing home care.[3, 4] For example, total numbers of nursing home residents are 350 thousand in Canada,[5] 1.3 million in the USA,[6] and 2.9 million in Europe,[3] and the demand for these services will increase in the future.[3, 7, 8]

Providing the necessary extra assistance in oral care to these residents is time consuming and responsive behaviours of dementia often complicate oral health care.[9] Most of the direct care in nursing homes is provided by care aides with little or no formal training.[10-12] Even regulated care providers often lack training in oral health care.[13-17] International evidence-based best practice guidelines for oral health care of older adults are available[18-21] and outline clearly what care providers should do, including regularly assessing residents’ oral health status and providing, or supervising the provision of, oral care at least once daily. However, oral health care practices in nursing homes are less than optimal – up to 62% of nursing home residents have unacceptable oral hygiene.[22-24] Barriers to providing appropriate oral health care in nursing homes include low priority of oral health care, insufficient resources, sub-optimal organization of care processes, deficient policy and documentation, caregivers’ attitudes and lack of knowledge, disgust expressed by care providers, and responsive behaviours by residents.[24-26]

Poor oral health can have serious consequences: increased health care costs; decreased quality of life for residents through unnecessary pain and suffering; elevated risk of malnutrition, aspiration pneumonia,

atherosclerosis, and premature death;[26-29] and psychological and social repercussions from problems such as bad breath, changed dental aesthetics, and altered speech.[30, 31] Between 44% and 76% of dentate nursing home residents have caries.[32-38] Dental pain is present in 5%–8% of all residents,[35, 39] 32%–49% need periodontal treatment,[35, 36, 39] 66%–74% have gingivitis,[35, 38] and 3.4% report pain or discomfort in their gums.[36]

Improving oral health care of nursing home residents is therefore a pressing concern. Systematic reviews reveal numerous studies on the effectiveness of education programs[40, 41] and implementation strategies[42] in changing care providers' oral health care practices and promoting or improving residents' oral health. Overall, these interventions are potentially effective but study quality is generally low and comparability of results is limited due to heterogeneous interventions and study methods. In one review, Weening-Verbree et al.[42] found that none of the studies included deliberately and systematically tailored their strategies in response to identified barriers, although such tailored change strategies are potentially effective.[43]

Lack of cooperation by residents is a major barrier to provision of oral health care by nursing home care staff.[17, 44-46] In particular, residents with dementia may resist care by refusing to open their mouth, turning away their head, verbally assaulting the caregiver, spitting at or hitting the caregiver, etc. Evidence syntheses are available on the effectiveness of communication strategies[47, 48] and psychosocial treatments[49] to reduce behavioural symptoms in residents with dementia. While some of these interventions effectively improve care providers' communication skills, evidence on intervention ability to change residents' behaviours is weak and inconclusive. Many of the interventions were not applied in daily care situations, but rather within planned sessions at defined times. Interventions applied in daily care situations did not refer specifically to situations of oral health care.[47-49] Individual studies have assessed interventions to prevent or overcome responsive behaviours in situations of oral health care[50, 51] but no systematic reviews have synthesized their evidence.

Care providers may also encounter challenges with residents who are physically and cognitively capable of performing their own oral health care but cannot be easily convinced to do so. Although the

majority of the general adult population brushes teeth regularly, up to 27% do not regularly brush teeth at least twice a day[52, 53] and oral health literacy of the public is generally low.[54] Especially in older adults with low socio-economic status, the lack of a history of dental care and negative attitudes towards oral health result in low priority for oral health; specific strategies to promote their oral health are required.[55-59] Renz et al.[60] synthesized the evidence on psychological interventions to improve adherence to oral hygiene instructions in adults with periodontal diseases. Although the four studies included are low quality and results could not be pooled due to great heterogeneity of models and outcomes used, they provide tentative evidence that psychological interventions can positively influence behaviours related to oral hygiene. Cascaes et al.[61] assessed the evidence from studies that applied motivational interviewing to improve oral health outcomes. However, none of the 10 studies included focus specifically on older adults or nursing home residents and the evidence is inconclusive. Four studies indicate positive effects of motivational interviewing on oral health outcomes, four studies show no effect, and two studies do not report sufficient detail to draw any conclusion.

To provide the best possible oral health care to nursing home residents, care providers need strategies with proven effectiveness to either encourage and motivate residents in performing oral health care themselves or to prevent or overcome responsive behaviours from residents when care providers assist them with oral health care. This review aims to identify and synthesize the evidence from studies assessing the effectiveness of interventions that meet these needs.

METHODS AND ANALYSIS

Review design

We will conduct a systematic review of quantitative intervention studies, then generate a narrative synthesis of the available evidence on the effectiveness of strategies that nursing home care providers can apply to

- (a) encourage and motivate residents in performing their own oral health care

(b) prevent or overcome responsive behaviours from residents when care providers assist them with oral health care.

Our review methods and presentation of results will follow the Cochrane Handbook of Systematic Reviews of Interventions[62] and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[63] The review is scheduled to be completed between October and December 2016.

Search strategy

We will search the databases Medline, EMBASE, Evidence Based Reviews – Cochrane Central Register of Controlled Trials, CINAHL, and Web of Science. A search strategy combining terms related to oral health with terms related to care providers and residents in residential long term care facilities (nursing homes) was developed and pre-tested with an expert scientific librarian for each database (see supplementary file 1 for details). We will limit our search to studies published in English but will not limit year of publication; we will retrieve all findings starting with the earliest reference available in the respective database. We will further select three to five key journals and eight to ten key authors based on the number and relevance of their published papers to our research topic. We will search contents of key journals and publications of key authors by hand. Finally, we will screen reference lists of studies included to ensure that all articles relevant to this review are retrieved.

Data management

Results of the literature searches will be imported into Zotero – an open source literature management software that allows online collaboration of researchers. All references including abstracts and retrieved full texts will be managed using Zotero, and we will do the title, abstract and full text screenings, using this software. Before the screening process all review team members will receive training in using Zotero, and we will undertake a calibration exercise to improve application of the inclusion and exclusion criteria.

Inclusion and exclusion criteria

Table 1 lists our inclusion and exclusion criteria. We will not exclude any reference based on year of publication. We will include all types of published works listed in the databases searched, including articles published in peer-reviewed journals and ‘gray’ literature such as non-peer-reviewed articles, textbooks, reports, and thesis publications. We will limit works to quantitative studies assessing effectiveness of an eligible intervention (see Table 1 for details on eligible study types and eligible interventions). We will include intervention studies with or without a control group. Control interventions can be either usual care (no control intervention) or any kind of placebo intervention, such as unspecific communication in the control group versus a specific motivational communication strategy in the intervention group. We will include studies that assess outcomes of residents’ oral health (such as tooth decay, tooth status, periodontal issues, and oral hygiene status), outcomes indicating an increase in residents’ self-performed oral health care (such as number of times residents brush or floss teeth, or clean dentures), or outcomes indicating a decrease in residents’ responsive behaviours towards oral health care provided by staff (such as voluntarily opening mouth, acceptance of staff brushing or flossing teeth, acceptance of staff taking out or putting back dentures, not showing verbally or physically aggressive behaviour during oral care, or not being anxious or nervous during oral care). Details on eligible settings and participants are given in Table 1. We refer to eligible institutions as nursing homes, but various terms are used across countries and jurisdictions to describe these facilities.[64] Important criteria to define them are:[64-66]

- they accommodate mainly older people with complex health and care needs, who are unable to remain at home or in a supportive living environment
- they provide 24-hour support and assistance with activities of daily living and nursing care
- they typically deliver health service over an extended time period (often until the resident dies).

Table 1: Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Study type	<ul style="list-style-type: none"> Primary, empirical, quantitative studies (survey studies, randomized controlled trials, non-randomized trials with or without control group, cohort or case control studies, cross-sectional studies) assessing the effectiveness of an eligible strategy Mixed-methods studies assessing the effectiveness of an eligible strategy quantitatively Systematic reviews and meta-analyses on the effectiveness of an eligible strategy 	<ul style="list-style-type: none"> Non-empirical work (editorials, opinion texts, theoretical discussions) Non-systematic (selective) reviews, qualitative studies (qualitative interviews, focus groups, ethnographic observations, qualitative case studies)
Intervention	<ul style="list-style-type: none"> Strategies that formal care providers can apply to motivate nursing home residents in performing oral health care themselves Strategies that formal care providers can apply to prevent or overcome nursing home residents' responsive behaviours towards oral health care provided by formal care staff 	<ul style="list-style-type: none"> Oral health care tools such as tooth brushes, flossing tape, inter-dental brushes Tooth pastes, fluorides, and other substances Oral health care techniques such as brushing, flossing, or rinsing
Setting	<ul style="list-style-type: none"> Residential facilities that provide care for frail older adults over a prolonged time period (nursing homes, personal care homes, special or complex care homes, residential long term care facilities, residential facilities, skilled nursing facilities, etc.) 	<ul style="list-style-type: none"> Residential facilities providing care for relatively healthy and independent residents (assisted living, supportive living, retirement homes, senior housing) Day or night care facilities Hospitals, home care, primary care, care housing
Participants	<ul style="list-style-type: none"> Formal, paid care providers providing oral health care in nursing homes (care aides, registered nurses, licensed practical nurses, dental hygienists, etc.) Nursing home residents 	<ul style="list-style-type: none"> Unpaid caregivers, volunteers, family members

Study identification

1) After removal of duplicate studies, two review team members will independently screen titles and abstracts of all retrieved studies for inclusion. Each reviewer will assign screened studies to one of three categories: inclusion, exclusion, or full text needed to decide. At all screening steps, reviewers will discuss discrepancies in assignment of screened studies until consensus is reached. Full texts will be retrieved for all studies included based on their titles and abstracts and for screened studies with insufficient information in titles or abstracts to decide on inclusion. Two review team members will screen full texts independently for inclusion. 2) Hand search of key author publications will be carried out

using the same method for inclusion or exclusion of studies retrieved. 3) Hand search of key journals will be carried out by one review team member and a second team member will independently check the studies included. 4) Two team members will independently screen the reference lists of all included studies.

Quality appraisal

Two members of the review team will independently assess methodological quality of studies (risk of bias). They will discuss discrepancies until consensus is reached. The full research team will discuss results of this step for each study in detail. To evaluate study quality we will apply validated checklists as appropriate to study design.

- Systematic reviews and meta-analyses – Assessment of Multiple Systematic Reviews (AMSTAR) tool.[67] AMSTAR is a reliable and valid instrument[68-70] that assesses study quality in the categories of definition of an a priori design, study selection and data extraction, literature search, inclusion and exclusion criteria, list of studies included and excluded, characteristics and scientific quality of studies included, appropriateness of conclusions and methods used to combine findings, publication bias, and conflict of interest.
- Clinical studies with or without control group and with or without randomized allocation of participants – Quality Assessment Tool for Quantitative Studies (QATQS).[71] Reliability and validity of the QATQS have been demonstrated.[71, 72] It assesses the categories of selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity, and analyses.
- Cross-sectional studies – Estabrooks’ Quality Assessment and Validity Tool for Cross-Sectional Studies. This tool was developed based on Cochrane guidelines[73] and other evidence-based criteria.[74, 75] Reviewers assess methodological quality of studies on 12 items in the categories of sampling, measurement, and statistical analyses.

All three tools have been used and described in detail in previous systematic reviews.[76-80] We will rate the overall quality of each study with a scoring method developed by de Vet et al.[81] that was also used in those previous reviews. We will calculate the ratio of the obtained score to the maximum possible score, which varies with the checklist used and the number of checklist items applicable. Based on this quality score with a possible range of 0–1, we will rank studies as weak (≤ 0.50), low moderate (0.51–0.66), high moderate (0.67–0.79), or strong (≥ 0.80).

Data extraction

One team member will extract the following study details into an Excel spread sheet template: first author, year of publication, title, journal (or type of reference e.g., thesis, report, text book), country of study, study purpose(s), study design, study sample (numbers and types of facilities, care providers, and residents included), strategies studied (including control conditions, if applicable), outcomes assessed (including assessment tools, if applicable), and main results. A second team member will double-check data extraction for each study and discrepancies will be resolved by consensus.

Analyses

We will statistically pool results of quantitative studies, using random-effects meta-analysis if we are able to include a sufficient number of studies reporting similar outcomes. We will then use the χ^2 test for homogeneity (significance level set at $\alpha = .10$) and the I^2 statistic to assess statistical heterogeneity (variation beyond chance) and inconsistency of study results.[82] To assess if a small sample bias is present in the published literature (i.e., higher effect sizes in studies with smaller samples), we will compare the estimates of fixed and random effects models, as the latter ones are more accurate when small sample bias is present. To assess reporting bias we will check if for randomized controlled trial a study protocol was published before participants were recruited. We will compare those study protocols to the published studies. In case we are able to include 10 or more comparable studies (e.g., similar

designs, settings, outcomes) we will use funnel plots to assess publication bias. If the included studies are too heterogeneous to pool results statistically, we will construct a narrative synthesis of the outcomes reported in the selected studies. This will include a summary of the study designs used, the interventions and control interventions (if applicable) assessed, the resident and provider outcomes studied, and the effect sizes found. Our pre-tests of the search strategies and our preliminary findings in the title and abstract screenings indicate that we will very likely not be able to conduct statistical syntheses of study findings due to a small number of eligible studies and great heterogeneity of study interventions and outcomes.

ETHICS AND DISSEMINATION

We will not collect primary data from individuals or organizations in this study. Data in studies included in this systematic review will be de-identified and cannot be linked to individuals or organizations. Therefore, we did not seek ethics approval for this study. We will publish findings of this review in a peer-reviewed journal article and present findings at an international peer-reviewed conference. Results of this review will significantly contribute to improving oral health care practices in nursing homes – either by suggesting effective strategies that care providers can use to improve residents’ daily oral health care routines or by demonstrating the need for such interventions and informing their development.

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FOOTNOTES

Acknowledgments

We would like to thank Dr. Carole Estabrooks for her support of this study.

Authors' contributions

MH and MNY developed the research question, the systematic review design, planned and designed the study protocol, and are leading the systematic review project; MH wrote the first draft of the manuscript; AK and NK assisted with drafting parts of the manuscript and will carry out the abstract and full text screening. All authors critically read and commented on the manuscript and have approved its submission.

Funding

This research has been supported by intramural funds from the School of Dentistry, University of Alberta, and the Faculty of Nursing, University of Alberta; MH holds an Alberta Innovates – Health Solutions

(AIHS) Post Doctoral Fellowship. None of the funders has played any role in developing the systematic review protocol.

Competing interests

None declared.

For peer review only

Supplementary file 1: Search strategy

MEDLINE 1946 to Present, MEDLINE(R) In-Process & Other Non-Indexed Citations, EBM Reviews - Cochrane Central Register of Controlled Trials (platform OVID)

1. exp Dentistry/
2. exp Tooth Diseases/
3. Oral Health/
4. Oral Hygiene/
5. ((oral or dental or mouth) adj (health or care or hygiene)).mp.
6. or/1-5
7. Geriatric Nursing/ or nursing homes/ or Intermediate Care Facilities/ or skilled nursing facilities/ or homes for the aged/ or "Institutionalization"/
8. (nursing adj (home* or center* or centre* or facilit*)).tw.
9. ((extended or long term or intermediate or skilled) adj care).tw.
10. ((extended or long term or intermediate or skilled) adj facilit*).tw.
11. ((elderly or senior* or geriatric or veteran*) adj3 (institution* or home* or facilit* or unit* or center* or centre*)).tw.
12. (rest adj2 home*).tw.
13. convalescen* home*.tw.
14. assisted care facilit*.tw.
15. continuing care.tw.
16. residential care.tw.
17. or/7-16
18. 6 and 17
19. exp Child/
20. (child* or boy* or girl* or p?ediatric* or teen* or youth* or adolescen*).mp.
21. 19 or 20
22. exp aged/
23. (senior* or elder* or geriatric* or gerontolog*).mp.
24. 22 or 23
25. 21 and 24
26. 21 not 25
27. 18 not 26
28. 27 or 6
29. remove duplicates from 28

CINAHL (platform EBSCOhost)

- S1 (MH "Dentistry+") OR (MH "Tooth Diseases+") OR (MH "Oral Health") OR (MH "Oral Hygiene+") OR (MH "Dental Hygiene")
-
- S2 (oral W0 (health or care or hygiene)) OR (dental W0 (health or care or hygiene)) OR (mouth W0 (health or care or hygiene))
-
- S3 S1 OR S2
-
- S4 (MH "Gerontologic Nursing+") OR (MH "Nursing Homes+")
-
- S5 (MH "Nursing Home Patients") OR (MH "Institutionalization+")
-
- S6 nursing W0 (home* or center* or centre* or facilit*)
-
- S7 "extended care" or "long term care" or "intermediate care" or "skilled care"
-
- S8 (extended or "long term" or intermediate or skilled) W2 facilit*
-
- S9 ((elderly or senior* or geriatric or veteran*) N3 institution*) OR ((elderly or senior* or geriatric or veteran*) N3 home*) OR ((elderly or senior* or geriatric or veteran*) N3 facilit*) OR ((elderly or senior* or geriatric or veteran*) N3 unit*) OR ((elderly or senior* or geriatric or veteran*) N3 center*) OR ((elderly or senior* or geriatric or veteran*) N3 centre*)
-
- S10 "rest home*" OR "convalescen* home*" OR "assisted care facilit*" OR "continuing care" OR "residential care"
-
- S11 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
-
- S12 S3 AND S11
-
- S13 S3 AND S11
-
- Limiters - Research Article
-
- S14 senior* or older* or gerontolog* or geriatric* or elder*
-
- S15 S13 AND S14
-
- S16 S3 AND S11
-
- S17 S15 OR S16

Web of Science Core Collection

- #1

TS=("oral health" OR "oral care" OR "oral hygiene" OR dentistry OR "dental health" OR "dental care" OR "dental hygiene")
-
- #2

TS=("nursing home*" or "residential care" or "continuing care" or facilit* or residence or residential or "long term care" or institution*)
-
- #3

#1 AND #2

For peer review only

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review (Page 1 [title page] and page 3)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such (N/A)
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number (Page 2)
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author (Page 1 [title page] for corresponding author, information on all others entered during online submission)
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review (Page 14/15)
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments (N/A)
Support:		
Sources	5a	Indicate sources of financial or other support for the review (Page 14)
Sponsor	5b	Provide name for the review funder and/or sponsor (Page 14)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol (Page 14)
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known (Introduction, begins on page 3)
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) (Questions of the review page 5/6, table 1 on page 8 addresses participants, intervention, comparators and outcomes)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review (Page 6 language, publication, year; page 7/8 for PICO, study design, setting)
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage (Search strategy, page 6)
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be

		repeated (Supplementary file 1)
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review (Data management, page 6)
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) (Study identification, page 8)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators (Data extraction, page 10)
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications (Data extraction, page 10 and table, page 8)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale (inclusion, starts page 7)
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis (Quality appraisal, page 8/9, Analyses, page 10/11)
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised (Analyses, page 10/11)
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ) (Analyses, page 10/11)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) (Analyses, page 10/11)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned (Analyses, page 10/11)
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) (Analyses, page 10/11)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) (Quality appraisal, page 9, Analyses, page 10/11)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Effective strategies to motivate nursing home residents in oral health care and to prevent or reduce responsive behaviours to oral health care – a systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-011159.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Feb-2016
Complete List of Authors:	Hoben, Matthias; University of Alberta Faculty of Nursing, Kent, Angelle; University of Alberta Faculty of Nursing Kobagi, Nadia; University of Alberta Faculty of Medicine and Dentistry, School of Dentistry Yoon, Minn; University of Alberta Faculty of Medicine and Dentistry, School of Dentistry
Primary Subject Heading:	Dentistry and oral medicine
Secondary Subject Heading:	Nursing, Evidence based practice, Geriatric medicine, Health services research
Keywords:	Oral Health Care, Dementia < NEUROLOGY, Nursing Homes, Responsive Behaviours, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Effective strategies to motivate nursing home residents in oral health care and to prevent or reduce responsive behaviours to oral health care – a systematic review protocol

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Keywords

Oral Health Care, Dementia, Nursing Homes, Responsive Behaviours, Quality in Health Care

Word count

2,535

ABSTRACT

Introduction

Oral health care in nursing homes is less than optimal, with severe consequences for residents' health and quality of life. To provide the best possible oral health care to nursing home residents, care providers need strategies that have been proven to be effective. Strategies can either encourage and motivate residents to perform oral health care themselves or can prevent or overcome responsive behaviours from residents when care providers assist with oral health care. This systematic review aims to identify studies that evaluate the effectiveness of such strategies and to synthesize their evidence.

Methods and analysis

We will conduct a comprehensive search in the databases Medline, EMBASE, Evidence Based Reviews – Cochrane Central Register of Controlled Trials, CINAHL, and Web of Science for quantitative intervention studies that assess the effectiveness of eligible strategies. Two reviewers will independently screen titles, abstracts and retrieved full-texts for eligibility. In addition, contents of key journals, publications of key authors, and reference lists of all studies included will be searched by hand and screened by two reviewers. Discrepancies at any stage of the review process will be resolved by consensus. Data extraction will be performed by one research team member and checked by a second team member. Two reviewers will independently assess methodological quality of studies included using three validated checklists appropriate for different research designs. We will present a narrative synthesis of study results.

Ethics and dissemination

We did not seek ethics approval for this study, as we will not collect primary data and data from studies included cannot be linked to individuals or organizations. We will publish findings of this review in a peer-reviewed paper and present them at an international peer-reviewed conference.

Protocol registration number

This review is registered with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) database: CRD42015026439.

STRENGTHS AND LIMITATIONS

- Rigorous protocol for a systematic review of intervention studies, following PRISMA-P guidelines
- Review will provide evidence for the effectiveness of strategies care providers can use in their daily practice to a) encourage residents to perform oral health care themselves or b) to prevent or overcome residents’ responsive behaviours to oral health care
- Review will identify need for additional research
- Effective, evidence-based strategies are crucial to improving quality of oral health care in nursing homes
- Limited number, heterogeneity and low quality of eligible studies may make it challenging to pool data

Effective strategies to motivate nursing home residents in oral health care and to prevent or reduce responsive behaviours to oral health care – a systematic review protocol

INTRODUCTION

Providing oral health care to nursing home residents is complex and challenging for care staff. Baby boomers are entering nursing homes with more of their natural teeth and with more complex prostheses and bridges than previous generations, leading to increased and different care needs.[1] For example, regular and effective provision of oral hygiene care to residents with dental implants is crucial to prevent inflammations and to ensure long-term maintenance of these implants.[2] The large and rapidly growing number of nursing home residents with dementia[3] further elevates those challenges. In Western countries, between three and eight percent of people aged 65 years or older receive nursing home care.[4, 5] For example, total numbers of nursing home residents are 350 thousand in Canada,[6] 1.3 million in the USA,[7] and 2.9 million in Europe,[4] and the demand for these services will increase in the future.[4, 8, 9]

Providing the necessary extra assistance in oral care to these residents is time consuming and responsive behaviours of dementia often complicate oral health care.[10] Responsive behaviours are defined as physical or verbal actions (such as grabbing onto people, general restlessness, agitation, resisting care) that can be challenging, disruptive and distressing for care providers.[11, 12] The term responsive behaviours highlights that those behaviours are meaningful responses to environmental stress or unmet needs rather than just neuropathological symptoms.[11, 12] Most of the direct care in nursing homes is provided by care aides with little or no formal training.[13-15] Even regulated care providers often lack training in oral health care.[16-20] International evidence-based best practice guidelines for oral health care of older adults are available[21-24] and outline clearly what care providers should do, including regularly assessing residents' oral health status and providing, or supervising the provision of, oral care at least once daily. However, oral health care practices in nursing homes are less than optimal – up to 62% of nursing home residents have unacceptable oral hygiene.[25-27] Barriers to providing

appropriate oral health care in nursing homes include low priority of oral health care, insufficient resources, sub-optimal organization of care processes, deficient policy and documentation, caregivers' attitudes and lack of knowledge, disgust expressed by care providers, and responsive behaviours by residents.[27-29]

Poor oral health can have serious consequences: increased health care costs; decreased quality of life for residents through unnecessary pain and suffering; elevated risk of malnutrition, aspiration pneumonia, atherosclerosis, and premature death;[29-32] and psychological and social repercussions from problems such as bad breath, changed dental aesthetics, and altered speech.[33, 34] Between 44% and 76% of dentate nursing home residents have caries.[35-41] Dental pain is present in 5%–8% of all residents,[38, 42] 32%–49% need periodontal treatment,[38, 39, 42] 66%–74% have gingivitis,[38, 41] and 3.4% report pain or discomfort in their gums.[39]

Improving oral health care of nursing home residents is therefore a pressing concern. Systematic reviews reveal numerous studies on the effectiveness of education programs[43, 44] and implementation strategies[45] in changing care providers' oral health care practices and promoting or improving residents' oral health. Overall, these interventions are potentially effective but study quality is generally low and comparability of results is limited due to heterogeneous interventions and study methods. Available studies often exclude residents with dementia, especially those with responsive behaviours, and educational programs often focus on techniques and tools to provide oral health care while not systematically addressing management of responsive behaviours.[43, 46] In one review, Weening-Verbree et al.[45] found that none of the studies included deliberately and systematically tailored their strategies in response to identified barriers, although such tailored change strategies are potentially effective.[47]

Lack of cooperation by residents is a major barrier to provision of oral health care by nursing home care staff.[20, 46, 48, 49] In particular, residents with dementia may resist care by refusing to open their mouth, turning away their head, verbally assaulting the caregiver, spitting at or hitting the caregiver, etc. Evidence syntheses are available on the effectiveness of communication strategies[50, 51] and

1
2
3 psychosocial treatments[52] to reduce behavioural symptoms in residents with dementia. While some of
4 these interventions effectively improve care providers' communication skills, evidence on intervention
5 ability to change residents' behaviours is weak and inconclusive. Many of the interventions were not
6 applied in daily care situations, but rather within planned sessions at defined times. Interventions applied
7 in daily care situations did not refer specifically to situations of oral health care.[50-52] Individual studies
8 have assessed interventions to prevent or overcome responsive behaviours in situations of oral health
9 care[53, 54] but no systematic reviews have synthesized their evidence.

10
11
12 Care providers may also encounter challenges with residents who are physically and cognitively
13 capable of performing their own oral health care but cannot be easily convinced to do so. Although the
14 majority of the general adult population brushes teeth regularly, up to 27% do not regularly brush teeth at
15 least twice a day[55, 56] and oral health literacy of the public is generally low.[57] Especially in older
16 adults with low socio-economic status, the lack of a history of dental care and negative attitudes towards
17 oral health result in low priority for oral health; specific strategies to promote their oral health are
18 required.[58-62] Renz et al.[63] synthesized the evidence on psychological interventions to improve
19 adherence to oral hygiene instructions in adults with periodontal diseases. Although the four studies
20 included are low quality and results could not be pooled due to great heterogeneity of models and
21 outcomes used, they provide tentative evidence that psychological interventions can positively influence
22 behaviours related to oral hygiene. Cascaes et al.[64] assessed the evidence from studies that applied
23 motivational interviewing to improve oral health outcomes. However, none of the 10 studies included
24 focus specifically on older adults or nursing home residents and the evidence is inconclusive. Four studies
25 indicate positive effects of motivational interviewing on oral health outcomes, four studies show no
26 effect, and two studies do not report sufficient detail to draw any conclusion.

27
28 To provide the best possible oral health care to nursing home residents, care providers need strategies
29 with proven effectiveness to either encourage and motivate residents in performing oral health care
30 themselves or to prevent or overcome responsive behaviours from residents when care providers assist

them with oral health care. This review aims to identify and synthesize the evidence from studies assessing the effectiveness of interventions that meet these needs.

METHODS AND ANALYSIS

Review design

We will conduct a systematic review of quantitative intervention studies, then generate a narrative synthesis of the available evidence on the effectiveness of strategies that nursing home care providers can apply to

- (a) encourage and motivate residents in performing their own oral health care
- (b) prevent or overcome responsive behaviours from residents when care providers assist them with oral health care.

Our review methods and presentation of results will follow the Cochrane Handbook of Systematic Reviews of Interventions[65] and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[66] The review is scheduled to be completed between December 2016 and March 2017.

Search strategy

We will search the databases Medline, EMBASE, Evidence Based Reviews – Cochrane Central Register of Controlled Trials, CINAHL, and Web of Science. A search strategy combining terms related to oral health with terms related to care providers and residents in residential long term care facilities (nursing homes) was developed and pre-tested with an expert scientific librarian for each database (see supplementary file 1 for details). We will limit our search to studies published in English but will not limit year of publication; we will retrieve all findings starting with the earliest reference available in the respective database. We will further select three to five key journals and eight to ten key authors based on the number and relevance of their published papers to our research topic. We will search contents of key

journals and publications of key authors by hand. Finally, we will screen reference lists of studies included to ensure that all articles relevant to this review are retrieved.

Data management

Results of the literature searches will be imported into Zotero – an open source literature management software that allows online collaboration of researchers.[67] All references including abstracts and retrieved full texts will be managed using Zotero, and each of two review team members will independently carry out the title, abstract and full text screenings, using this software (details see study identification). Before the screening process all review team members will receive training in using Zotero, and we will undertake a calibration exercise to improve application of the inclusion and exclusion criteria.

Inclusion and exclusion criteria

Table 1 lists our inclusion and exclusion criteria. We will not exclude any reference based on year of publication. We will include all types of published works listed in the databases searched. This will primarily include articles published in peer-reviewed journals. ‘Non-peer-reviewed articles, textbooks, reports, and thesis publications (i.e., ‘gray’ literature) identified in the search (electronic data bases, hand search of key journal contents and key author publications, reference lists of included publications) . Will be included if they report quantitative studies assessing effectiveness of an eligible intervention (see Table 1 for details on eligible study types and eligible interventions). We will include intervention studies with or without a control group. Control interventions can be either usual care (no control intervention) or any kind of placebo intervention, such as unspecific communication in the control group versus a specific motivational communication strategy in the intervention group. We will include studies that assess outcomes of residents’ oral health (such as tooth decay, tooth status, periodontal issues, and oral hygiene status), outcomes indicating an increase in residents’ self-performed oral health care (such as number of times residents brush or floss teeth, or clean dentures), or outcomes indicating a decrease in residents’

responsive behaviours towards oral health care provided by staff (such as voluntarily opening mouth, acceptance of staff brushing or flossing teeth, acceptance of staff taking out or putting back dentures, not showing verbally or physically aggressive behaviour during oral care, or not being anxious or nervous during oral care). Details on eligible settings and participants are given in Table 1. We refer to eligible institutions as nursing homes, but various terms are used across countries and jurisdictions to describe these facilities.[68] Important criteria to define them are:[68-70]

- they accommodate mainly older people with complex health and care needs, who are unable to remain at home or in a supportive living environment
- they provide 24-hour support and assistance with activities of daily living and nursing care
- they typically deliver health care over an extended time period (often until the resident dies).

Table 1: Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Study type	<ul style="list-style-type: none">• Primary, empirical, quantitative studies (survey studies, randomized controlled trials, non-randomized trials with or without control group, cohort or case control studies, cross-sectional studies) assessing the effectiveness of an eligible strategy• Mixed-methods studies assessing the effectiveness of an eligible strategy quantitatively• Systematic reviews and meta-analyses on the effectiveness of an eligible strategy	<ul style="list-style-type: none">• Non-empirical work (editorials, opinion texts, theoretical discussions)• Non-systematic (selective) reviews, qualitative studies (qualitative interviews, focus groups, ethnographic observations, qualitative case studies)
Intervention	<ul style="list-style-type: none">• Strategies that formal care providers can apply to motivate nursing home residents in performing oral health care themselves• Strategies that formal care providers can apply to prevent or overcome nursing home residents' responsive behaviours towards oral health care provided by formal care staff	<ul style="list-style-type: none">• Oral health care tools such as tooth brushes, flossing tape, inter-dental brushes• Tooth pastes, fluorides, and other substances• Oral health care techniques such as brushing, flossing, or rinsing
Setting	<ul style="list-style-type: none">• Residential facilities that provide care for frail older adults over a prolonged time period (nursing homes, personal care homes, special or complex care homes, residential long term care facilities, residential facilities, skilled nursing facilities, etc.)	<ul style="list-style-type: none">• Residential facilities providing care for relatively healthy and independent residents (assisted living, supportive living, retirement homes, senior housing)• Day or night care facilities• Hospitals, home care, primary care, care housing

Participants	<ul style="list-style-type: none"> Formal, paid care providers providing oral health care in nursing homes (care aides, registered nurses, licensed practical nurses, dental hygienists, etc.) and Nursing home residents 	<ul style="list-style-type: none"> Unpaid caregivers, volunteers, family members
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Study identification

1) After removal of duplicate studies, two review team members will independently screen titles and abstracts of all retrieved studies for inclusion, using Zotero. Each reviewer will assign screened studies to one of three categories: inclusion, exclusion, or full text needed to decide. At all screening steps, reviewers will discuss discrepancies in assignment of screened studies until consensus is reached. Full texts will be retrieved for all studies included based on their titles and abstracts and for screened studies with insufficient information in titles or abstracts to decide on inclusion. Two review team members will screen full texts independently for inclusion. 2) Hand search of key author publications will be carried out using the same method for inclusion or exclusion of studies retrieved. 3) Hand search of key journals will be carried out by one review team member and a second team member will independently check the studies included. 4) Two team members will independently screen the reference lists of all included studies.

Quality appraisal

Two members of the review team will independently assess methodological quality of studies (risk of bias). They will discuss discrepancies until consensus is reached. The full research team will discuss results of this step for each study in detail. To evaluate study quality we will apply validated checklists as appropriate to study design.

- Systematic reviews and meta-analyses – Assessment of Multiple Systematic Reviews (AMSTAR) tool.[71] AMSTAR is a reliable and valid instrument[72-74] that assesses study quality in the categories of definition of an a priori design, study selection and data extraction, literature search,

inclusion and exclusion criteria, list of studies included and excluded, characteristics and scientific quality of studies included, appropriateness of conclusions and methods used to combine findings, publication bias, and conflict of interest.

- Clinical studies with or without control group and with or without randomized allocation of participants – Quality Assessment Tool for Quantitative Studies (QATQS).[75] Reliability and validity of the QATQS have been demonstrated.[75, 76] It assesses the categories of selection bias, study design, confounders, blinding, data collection methods, withdrawals and drop-outs, intervention integrity, and analyses.
- Cross-sectional studies – Estabrooks’ Quality Assessment and Validity Tool for Cross-Sectional Studies. This tool was developed based on Cochrane guidelines[77] and other evidence-based criteria.[78, 79] Reviewers assess methodological quality of studies on 12 items in the categories of sampling, measurement, and statistical analyses.

All three tools have been used and described in detail in previous systematic reviews.[80-84] We will rate the overall quality of each study with a scoring method developed by de Vet et al.[85] that was also used in those previous reviews. We will calculate the ratio of the obtained score to the maximum possible score, which varies with the checklist used and the number of checklist items applicable. Based on this quality score with a possible range of 0–1, we will rank studies as weak (≤ 0.50), low moderate (0.51–0.66), high moderate (0.67–0.79), or strong (≥ 0.80). We will not exclude studies based on their quality scores. We will report quality scores for each study and discuss study results in context of the study’s quality score.

Data extraction

One team member will extract the following study details into an Excel spread sheet template: first author, year of publication, title, journal (or type of reference e.g., thesis, report, text book), country of study, study purpose(s), study design, study sample (numbers and types of facilities, care providers, and

residents included), strategies studied (including control conditions, if applicable), outcomes assessed (including assessment tools, if applicable), and main results. A second team member will double-check data extraction for each study and discrepancies will be resolved by consensus.

Analyses

We will statistically pool results of quantitative studies, using random-effects meta-analysis if we are able to include a sufficient number of studies reporting similar outcomes. We will then use the χ^2 test for homogeneity (significance level set at $\alpha = .10$) and the I^2 statistic to assess statistical heterogeneity (variation beyond chance) and inconsistency of study results.[86] To assess if a small sample bias is present in the published literature (i.e., higher effect sizes in studies with smaller samples), we will compare the estimates of fixed and random effects models, as the latter ones are more accurate when small sample bias is present. To assess reporting bias we will check if for randomized controlled trial a study protocol was published before participants were recruited. We will compare those study protocols to the published studies. In case we are able to include 10 or more comparable studies (e.g., similar designs, settings, outcomes) we will use funnel plots to assess publication bias. If the included studies are too heterogeneous to pool results statistically, we will construct a narrative synthesis of the outcomes reported in the selected studies. This will include a summary of the study designs used, the interventions and control interventions (if applicable) assessed, the resident and provider outcomes studied, and the effect sizes found. Our pre-tests of the search strategies and our preliminary findings in the title and abstract screenings indicate that we will very likely not be able to conduct statistical syntheses of study findings due to a small number of eligible studies and great heterogeneity of study interventions and outcomes.

ETHICS AND DISSEMINATION

We will not collect primary data from individuals or organizations in this study. Data in studies included in this systematic review will be de-identified and cannot be linked to individuals or organizations.

Therefore, we did not seek ethics approval for this study. We will publish findings of this review in a peer-reviewed journal article and present findings at an international peer-reviewed conference. Results of this review will significantly contribute to improving oral health care practices in nursing homes – either by suggesting effective strategies that care providers can use to improve residents’ daily oral health care routines or by demonstrating the need for such interventions and informing their development.

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FOOTNOTES

Acknowledgments

We would like to thank Dr. Carole Estabrooks for her support of this study.

Authors' contributions

MH and MNY developed the research question, the systematic review design, planned and designed the study protocol, and are leading the systematic review project; MH wrote the first draft of the manuscript; AK and NK assisted with drafting parts of the manuscript and will carry out the abstract and full text screening. All authors critically read and commented on the manuscript and have approved its submission.

Funding

This research has been supported by intramural funds from the School of Dentistry, University of Alberta, and the Faculty of Nursing, University of Alberta; MH holds an Alberta Innovates – Health Solutions (AIHS) Post Doctoral Fellowship. None of the funders has played any role in developing the systematic review protocol.

Competing interests

None declared.

Supplementary file 1: Search strategy

MEDLINE 1946 to Present, MEDLINE(R) In-Process & Other Non-Indexed Citations, EBM Reviews - Cochrane Central Register of Controlled Trials (platform OVID)

1. exp Dentistry/
2. exp Tooth Diseases/
3. Oral Health/
4. Oral Hygiene/
5. ((oral or dental or mouth) adj (health or care or hygiene)).mp.
6. or/1-5
7. Geriatric Nursing/ or nursing homes/ or Intermediate Care Facilities/ or skilled nursing facilities/ or homes for the aged/ or "Institutionalization"/
8. (nursing adj (home* or center* or centre* or facilit*)).tw.
9. ((extended or long term or intermediate or skilled) adj care).tw.
10. ((extended or long term or intermediate or skilled) adj facilit*).tw.
11. ((elderly or senior* or geriatric or veteran*) adj3 (institution* or home* or facilit* or unit* or center* or centre*)).tw.
12. (rest adj2 home*).tw.
13. convalescen* home*.tw.
14. assisted care facilit*.tw.
15. continuing care.tw.
16. residential care.tw.
17. or/7-16
18. 6 and 17
19. exp Child/
20. (child* or boy* or girl* or p?ediatric* or teen* or youth* or adolescen*).mp.
21. 19 or 20
22. exp aged/
23. (senior* or elder* or geriatric* or gerontolog*).mp.
24. 22 or 23
25. 21 and 24
26. 21 not 25
27. 18 not 26
28. 27 or 6
29. remove duplicates from 28

CINAHL (platform EBSCOhost)

S1	(MH "Dentistry+") OR (MH "Tooth Diseases+") OR (MH "Oral Health") OR (MH "Oral Hygiene+") OR (MH "Dental Hygiene")
S2	(oral W0 (health or care or hygiene)) OR (dental W0 (health or care or hygiene)) OR (mouth W0 (health or care or hygiene))
S3	S1 OR S2
S4	(MH "Gerontologic Nursing+") OR (MH "Nursing Homes+")
S5	(MH "Nursing Home Patients") OR (MH "Institutionalization+")
S6	nursing W0 (home* or center* or centre* or facilit*)
S7	"extended care" or "long term care" or "intermediate care" or "skilled care"
S8	(extended or "long term" or intermediate or skilled) W2 facilit*
S9	((elderly or senior* or geriatric or veteran*) N3 institution*) OR ((elderly or senior* or geriatric or veteran*) N3 home*) OR ((elderly or senior* or geriatric or veteran*) N3 facilit*) OR ((elderly or senior* or geriatric or veteran*) N3 unit*) OR ((elderly or senior* or geriatric or veteran*) N3 center*) OR ((elderly or senior* or geriatric or veteran*) N3 centre*)
S10	"rest home*" OR "convalescen* home*" OR "assisted care facilit*" OR "continuing care" OR "residential care"
S11	S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
S12	S3 AND S11
S13	S3 AND S11 Limiters - Research Article
S14	senior* or older* or gerontolog* or geriatric* or elder*
S15	S13 AND S14
S16	S3 AND S11
S17	S15 OR S16

Web of Science Core Collection

- #1 TS=("oral health" OR "oral care" OR "oral hygiene" OR dentistry OR "dental health" OR "dental care" OR "dental hygiene")
-
- #2 TS=("nursing home*" or "residential care" or "continuing care" or facilit* or residence or residential or "long term care" or institution*)
-
- #3 #1 AND #2

For peer review only

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review (Page 1 [title page] and page 3)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such (N/A)
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number (Page 2)
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author (Page 1 [title page] for corresponding author, information on all others entered during online submission)
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review (Page 14/15)
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments (N/A)
Support:		
Sources	5a	Indicate sources of financial or other support for the review (Page 14)
Sponsor	5b	Provide name for the review funder and/or sponsor (Page 14)
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol (Page 14)
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known (Introduction, begins on page 3)
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) (Questions of the review page 5/6, table 1 on page 8 addresses participants, intervention, comparators and outcomes)
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review (Page 6 language, publication, year; page 7/8 for PICO, study design, setting)
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage (Search strategy, page 6)
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be

		repeated (Supplementary file 1)
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review (Data management, page 6)
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) (Study identification, page 8)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators (Data extraction, page 10)
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications (Data extraction, page 10 and table, page 8)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale (inclusion, starts page 7)
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis (Quality appraisal, page 8/9, Analyses, page 10/11)
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised (Analyses, page 10/11)
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ) (Analyses, page 10/11)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) (Analyses, page 10/11)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned (Analyses, page 10/11)
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) (Analyses, page 10/11)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) (Quality appraisal, page 9, Analyses, page 10/11)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.