PROTOCOL

Caring Optimally: promoting effective Mouth MInuTes in care homes (COMMIT Study)

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Summary of Research (abstract)
A carer, in our ongoing work with people living and working in care homes, asked how she could help residents with mouth care, particularly when someone resisted such care. The compassion and curiosity of this carer led to discussions across our research partnership. This is a significant area of concern for care home staff, residents and relatives and we have worked together to develop this proposed research study.

The teeth and gums of people living in care homes are often in poor condition even though there have been many studies looking into how to maintain mouth care for this population. It is clear that there are problems in implementing the findings. Work is needed, therefore, to find out how to get research into practice. Good mouth health not only helps with eating and speaking but also helps people to feel good about themselves. Poor mouth health, on the other hand, might decrease a person's quality of life and play a part in life-threatening problems, such as chest infections. In addition, it can distress family and friends to witness their relative (or friend) with 'dirty' teeth and may increase concern about other missed care. Our research will investigate this important area of personal care with a view to developing practical solutions to improve oral care in care homes.

Care home staff have many duties during their working day, so mouth health may not get as much time as is needed. Many care home residents need help from staff because often they are unable to carry out, and sometimes resist, personal care (including mouth care) due to their physical and/or mental health and abilities. Care home staff may not always have the skills, knowledge and understanding to be able to provide adequate oral care. This research aims, in partnership with care homes, to find out how best to keep residents' mouths healthy by supporting staff to promote, in their day-to-day work, effective 'mouth minutes' of care for residents.

In Phase 1 we will review existing research evidence and then work with care home staff, residents and families to consider what might work best from their perspectives and experiences. We will look specifically at: what has been shown to work in some care homes to help keep residents' mouths healthy; what factors get in the way of care staff helping to keep mouths healthy; what factors might make it easier; and what might help influence staff to engage in this area. While most of the evidence will be on oral care, there might be important lessons from other care settings (e.g. hospices). We will use a theoretical approach (the theoretical domains framework) to help us better understand this area and the influences on staff behaviour and to capture elements related to organisational constraints. This will enable us to identify potential areas to target for behaviour change.

In Phase 2 we will 'co-produce' (with care home residents, relatives and staff) a simple guide which will bring together past research findings and practical input from the care homes to determine the best ways to spend valuable mouth minutes on residents' care and to help care staff choose what fits best with them and each resident's needs. We will also determine (with people living and working in care homes) what, if any, future research needs to be developed to address this important area of care.

The main contribution of this work is its focus on an enduring issue for care home residents (oral care) and a key strength of the team is our existing relationships and partnership working with the sector to address and offer practical solutions for important aspects of care in care homes.

Background and Rationale

This study originates from a question asked by Dawn, a carer working in a NICHE-Leeds care home. NICHE-Leeds[25] is an established partnership between academia and care homes working together to co-produce evidence-based sustainable solutions to areas of care that matter most for people living or working in care homes. In a collaborative meeting, Dawn asked: "how can I help residents with their mouth care, particularly when they resist this care?" This question resonated with other carers in this care home and our partnership but is an international concern for many staff working in long-term care settings.

Care homes offer care and support to a population with high support needs, particularly in later life. Circa 433,000 people live in care homes (nursing and residential) in the UK[1] and this population is getting older and frailer, living with co-morbidities and/or cognitive impairment[2]. Care home residents are often not able to carry out personal care (including oral care) due to their physical or cognitive states and depend on care staff to help them meet these needs[3]. However, care home staff may not have the skills, knowledge and understanding to be able to support adequate oral care, particularly when a resident resists such care. Care homes employ registered nurses and/or care staff. Quality provision needs a workforce with the competence, compassion and preparedness to deliver personalised care. Many care staff have no formal qualifications, minimal training and receive a low wage, yet are expected to offer high quality care which is often physically and emotionally demanding. Many residents have complex care needs, where oral health may seem a low priority; encouraging time focused on oral health (effective mouth minutes) is vital. This raises a number of important questions related to effective strategies and interventions for promoting oral care, as well as approaches for implementation in care homes. This forms the focus of our proposed study and falls within the remit of the HS&DR programme to produce evidence for promoting quality of care in care homes.

In the UK, care homes are an integral part of the health and social care system, especially for society's most frail and vulnerable older people. Care home residents have complex care needs: living with on average six co-morbidities, taking eight different medicines, and the majority living with cognitive impairment[2]. The majority also have poor oral health[4]. This creates significant challenges for the sector in meeting the needs of this population. Yet, it is critical to address these challenges with sustainable solutions as the number of people living in care homes with complex care needs increases[5]. Associations between residents' oral health and quality of life, respiratory tract infections, and nutritional status have been reported. Removal of teeth for people aged 65+ in hospitals was estimated to cost the NHS between £27 and £57 million[2]. Poor oral health is linked to early mortality[8], malnutrition[9], and myocardial infarction[10]. The prevention of oral disease is more important than ever, as most adults keep their natural teeth into old age and often require more complex dental treatments[11]. Adequate oral care for the care home population is therefore a vital function. Oral care in this proposal will be defined as any measure taken on a daily basis by the people living or working in care homes to maintain or improve the health of the teeth, gums and soft tissues of the mouth, and for some residents this will include denture care. In addition, we will define oral care in the care home setting as including timely onward referral for professional dental care where appropriate.

Literature searches were conducted in January and August 2020 to inform this proposal and check for overlap with existing studies. Searches in Ovid Medline (1946 onward) and PROSPERO (International prospective review of systematic reviews) used MeSH terms, search terms and synonyms for 'mouth care', 'care homes' and 'systematic reviews' to identify relevant systematic reviews and primary studies, while scoping the potential size the planned overview and scoping review. The search strategy in Appendix 1 illustrates our comprehensive search used to explore this field of research. Within the results of the search we looked specifically for existing overviews of reviews; at the numbers and topic areas of

systematic reviews; and among a sample of 100 results from the search assessed the body of evidence on barriers and enablers to oral care in the care home setting. One applicant (GVAD) reviewed the titles and abstracts of papers identified. This initial scoping of the literature shows that our proposal addresses a gap in the current literature, there are no overviews of reviews synthesising the diverse body of evidence on maintaining or improving oral health in the care home setting, nor any ongoing overviews in this area registered in PROSPERO. The published literature falls into three broad categories (some examples are referenced):

(i) effective interventions to improve oral care in care homes[6-8];
(ii) effective implementation strategies that influence staff behaviours to promote oral care[9-11]; and
(iii) barriers and facilitators which influence oral care in care homes[12] or oral care in physically compromised individuals[13].

Our scoping search found 57 systematic reviews; around half were deemed likely to be relevant to our topic as well as a further 11 ongoing reviews of relevance registered in PROSPERO. Examples of the diverse interventions reported in the reviews included: managing resistance to personal care; oral care in the prevention of pneumonia; denture disinfection; influencing staff or resident behaviours; and educational interventions. A number of reviews specifically considered only people with dementia. The search also allowed for the identification of systematic reviews relating to oral care of dependent adults in other settings which may be relevant to the care home setting (for example hospice care). We found examples of papers considering interventions to improve oral care for people with stroke[14] and cardiovascular disease[15] which were considered relevant for care home populations and the setting. It is likely that such reviews could consider interventions that have not been researched within the care home setting and stimulate discussion with stakeholders about whether these have potential application for this setting. We will therefore include terms in our search strategy to capture such literature to inform our stakeholder engagement discussions. In considering the body of published evidence on addressing barriers and enablers to oral care in the care home setting we found that around one quarter of our sample of 100 search results covered this area. This confirms the value of our proposed scoping review to synthesise these findings.

Evidence explaining why this research is needed now
There is extensive research on oral health in care homes and the National Institute for Health and Care Excellence (NICE) has issued guidance[12]. However, an extensive lack of awareness of these NICE guidelines in care homes has been highlighted[1] and oral health continues to be an enduring issue in the sector. Recently, the Care Quality Commission (CQC) raised concerns about oral care in care homes, highlighting that practices and policies do not always incorporate NICE guidance[16], as well as a lack of access to dental care for residents[17]. They noted: 73% of residents' care plans either did not include or adequately address oral health; 52% had no oral health care policy; and 47% did not provide oral health training for staff[1]. Recently, the James Lind Alliance has also highlighted the need for further research on how basic oral hygiene can best be achieved for people who live with other additional care needs[18].

Poor oral health creates pain and discomfort[19, 20], makes communicating (verbally and facially) difficult[21], and limits being able to eat a varied and balanced diet which impacts on general health outcomes. Poor oral health reduces the ability to live a healthy life[20], increases social isolation[22] and can cause premature death[23]. Public Health England urge future research exploring daily mouth care practices in care homes to ensure older residents' oral health-related quality of life[24].

Care home staff, residents and relatives in our ongoing NICHE-Leeds partnership[25] have identified oral care as a priority but that not all care staff are equipped (personally) or supported (organisationally) to meet this care need. Following consultation, we propose it is timely to 'take stock' of existing evidence and to work with stakeholders to 'make sense' of this extensive evidence. Our experience of working with the sector is that being actively engaged helps ensure the acceptability and feasibility of proposed solutions. Our care home partners indicate that there should first be focus on supporting staff (and their behaviours) to commit to effective 'mouth minutes' of care for residents.

Our proposed research is a synthesis of published evidence of effective interventions to improve oral care and strategies to influence staff behaviours to promote oral care in care homes, as well as understanding the barriers and enablers influencing oral care in this setting. We will use our evidence synthesis findings to inform qualitative investigation with care home residents, relatives and staff to explore effective 'mouth minutes' of care for residents. The outputs of this work will include co-produced guidance for the sector, as well as informing the direction of future research.

Aims and objectives

Our overall aim is to develop theory- and research-informed guidance for care homes to promote staff behaviours to improve oral health (committing to effective 'mouth minutes') in care home residents.

Our objectives are to:

1. evaluate effective strategies for use by care home staff to improve oral care for residents
2. evaluate the effectiveness of behaviour change (or implementation) strategies on staff behaviours related to oral care for residents
3. understand individual (micro), organisational (meso) and wider social and political (macro) barriers and facilitators influencing oral care in care homes
4. consult with residents, relatives and staff to 'sense-check' current evidence and explore what matters most to those living and working in care homes
5. develop guiding principles and a logic model of strategies and contexts which promote staff behaviours to improve residents' oral care
6. refine outputs with residents, relatives and staff to ensure effective dissemination and translation of this work (longer-term plan)

Research Plan / Methods

When determining how to influence staff behaviours to improve oral health practices in care homes it is imperative to work with people living or working in this unique context. NICHE-Leeds[25] is an established partnership between academia and care homes working together to co-produce evidence-based sustainable solutions to areas of care that matter most. Our care home partners identify oral care as a priority area and will work with us throughout the proposed research.

We recognise this is a complex area, as even though there has been extensive research, oral care in care homes remains a concern. Rather than 'imposing' new solutions to address this concern, it is timely to 'take stock' of the evidence to date and to work in partnership with the sector to determine the content, acceptability and feasibility of approaches identified in published research. We will collate existing evidence and work with residents, relatives and staff to: (i) understand the key issues, needs, and challenges associated with potential solutions for improving oral care and to consider gaps in the evidence; (ii) develop guiding principles and a logic model informed by this understanding (which can make an immediate contribution to the sector); (iii) provide theoretical and empirical foundations to inform future

development of acceptable and feasible interventions aimed at staff behaviours for improving this aspect of care in care homes.

We will use the Theoretical Domains Framework (TDF)[26] as a lens for our evidence synthesis to provide a comprehensive, theory-informed approach for extracting and organising determinants of staff behaviour (individual, social and environmental) related to the provision of oral care in care homes. The TDF is a framework for understanding behaviour change, developed from a number of psychological theories.[27] It can be used to identify determinants of health professionals' and patients' behaviours[28] and employing it in evidence synthesis can facilitate linking modifiable determinants to targets for behaviour change29. If the TDF social influences and environmental context and resource domains highlight the importance of organisational and systems factors, then as per TDF guidance[28] we will use the Consolidated Framework For Implementation Research[48] to map a more granular understanding of these likely barriers and enablers.

Taking this approach will enable us to base any future intervention design not only on existing evidence but on a theoretically informed approach to behaviour change that makes explicit the hypothesised mechanisms of change for any intervention.

This will be an 18-month study, working with relevant stakeholders, in two phases: (1) INVESTIGATION of key issues, needs and challenges associated with improving oral care in care homes; and (2) DEVELOPMENT of guiding principles and logic model of staff behaviours to promote oral care in this setting.

PHASE 1: INVESTIGATION (Objectives 1 to 4; Months 0 to 12)
Phase 1 employs evidence syntheses and qualitative research to investigate key issues, needs, and challenges associated with improving oral care in care homes and possible ways to influence staff behaviours for this aspect of personal care. We will achieve this in two sequential stages:

i. Evidence syntheses to establish state of published knowledge for improving oral care for care home residents; and
ii. Stakeholder consultations to explore the review findings and to understand what matters to those living and working in care homes.

We provide the detail of these stages below.

(i) UNDERSTANDING CURRENT EVIDENCE TO ESTABLISH STATE OF KNOWLEDGE FOR IMPROVING ORAL CARE FOR CARE HOME RESIDENTS (Objectives 1-3)
We plan to synthesise and understand the current evidence base in three important related areas for improving oral care for care home residents: (i) ***effective interventions for use by care home staff*** to maintain or improve oral care for residents; (ii) ***effective strategies that target staff behaviours*** to promote oral care; and (iii) ***barriers and enablers*** for effective oral care. We consider these three areas as crucial to inform the development of guiding principles that will have relevance for the sector and to inform our logic model of what works, why and how, as well as the interactions between the constituent parts that maintain and/or improve oral care in care homes (Phase 2). This will require syntheses of a diverse body of literature across these three areas. Our proposed methods support this ambition. We will:

- conduct an overview of reviews of (i) ***effective interventions*** and (ii) ***strategies to influence staff behaviours***; and
- scoping review of (iii) ***barriers and enablers*** for promoting oral care for care home residents.

The review questions necessitate these different review methods: further justification and detail of these methods are described below. Ethics approval is not required for these reviews.

Search methods for both reviews

One comprehensive literature search will identify studies for both the overview of reviews and the scoping review. We will ensure that diversity is considered within the searches by not limiting review terms by any population characteristics other than care home residence to ensure that such diverse research populations as those with co-morbidities, disabilities and cognitive difficulties are not excluded.The search results will be sifted during the screening process into systematic reviews relevant for the overview and studies relevant for the scoping review. This comprehensive approach will reduce the risk of missing relevant studies and be more efficient than undertaking separate searches for each review. Our proposal scoping search and screening work indicates we will find approximately 6000 records to sift. We estimate 150 systematic reviews will be identified during abstract screening, and approximately half of these would be considered in the overview. For the scoping review we estimate the 750 abstracts will be classed as potentially relevant.

A comprehensive search strategy (Appendix 1) was developed for searching Medline using subject headings and free-text words that describe oral care, care home and other directly relevant settings and populations. This strategy will be adapted to other databases and information sources as necessary. No date or language restrictions will be placed on our search. The following databases will be searched: Medline, Embase, Cochrane Library, CINAHL, PsycINFO, Epistemonkos[1], and Web of Science Core Collection. Further completed and ongoing reviews will be identified in Joanna Briggs Institute (JBI) Register of Systematic Reviews, International Health Technology Assessment (HTA) Database, NIHR Journals Library and the international prospective register of systematic reviews (PROSPERO) and Europe PubMed Central Grantfinder. Where there is insufficient data presented in studies deemed potentially relevant then we will contact the authors to request if data can be released to us.

Unpublished literature will be identified in Social Care Online, Web of Science Conference Indexes and organisation websites e.g. CQC. We will search trade journals (for example Nursing Standard, Caring Times, and Care Management Matters) as these may contain articles or editorials to inform the scoping review and explain why oral care interventions may not be working. We will also search abstracts of relevant conferences, for example the British Association for the Study of Community Dentistry, British Gerodontic Society (BGS) and British Society for Oral and Dental Research, where we might identify relevant unpublished care home studies that we can follow up with the authors. We will consult with our stakeholders to advise us on further grey literature sources and we will test out a range of possible sources of grey literature to inform our decisions about which to search.

References will be managed using Endnote X9 (https://endnote.com/).

Overview of reviews of interventions

We will conduct an overview of reviews to summarise systematic reviews that assess the effects of interventions, or combinations of interventions, for use by care home staff and strategies to influence staff behaviours to promote oral care for people living in care home settings (with and without nursing). In the background section of this detailed research plan we offered our definition of oral care for this study. To recap: this includes activities (or techniques) that are (or could be) used by staff employed by the care home with the purpose of preserving health and function of the oral cavity, as well as promoting personal resident well-being. Oral care includes screening of residents' needs for onward referral for professional dental attention, this however does not include care home staff assessing or

diagnosing oral diseases which is within the scope of practice of trained oral health professionals only. We have developed our methods for the overview of reviews based on criteria in the Cochrane Handbook of Systematic Reviews of Interventions Methods[30]. Specifically, we will use explicit and systematic methods to search for and identify multiple systematic reviews on related research questions in this topic area for the purpose of extracting and analysing results across important outcomes. We will register the protocol on PROSPERO (https://www.crd.york.ac.uk/prospero/).

Our focus on a defined population (people living in care homes) and on interventions or strategies aimed at maintaining or improving oral care in this population makes an overview of reviews appropriate[30]. Our literature searches will not be restricted to interventions in the care home setting, as research involving the effectiveness of oral care of dependent adults in any setting may be valuable to reflect upon within stakeholder consultations - Phase 1(ii). We will synthesise non-care home reviews separately. We will not draw inferences about the comparative effectiveness of multiple interventions but synthesise the current body of systematic review evidence in the field to address our objectives.

This work is timely and necessary. There are multiple systematic reviews in this field that require synthesis and our work represents a novel contribution to this area. There are no published or ongoing overviews of reviews in this area.

Types of reviews

We will include peer-reviewed systematic reviews and meta-analyses of original randomised controlled trials (RCTs) that examine the effects of any interventions, or combination of interventions, on oral care provision for care home residents or strategies to influence staff behaviours to promote oral care for this population. We will also include (as a separate overview of reviews) systematic reviews and meta-analyses of original RCTs that examine the effects of any interventions, or combination of interventions, in these areas in settings or with populations which have direct relevance for the care home population (for example hospice or stroke care).

Current guidance does not recommend combining data from variable study designs (such as RCTs and observational studies)[31]. We will focus on systematic reviews rather than original trials in order to utilise the widest range of relevant international evidence and compare the best estimates of effectiveness of different interventions. We will only include reviews that identify an intervention for the provision of oral care for care home residents or to influence staff behaviours OR reviews in settings or with populations relevant for the care home population. Reviews that include studies of different designs (for example RCTs and observational studies) will only be included if results of the RCTs are presented in a distinct subgroup.

If there are multiple reviews of the same intervention with care home residents then we will select the most recent and highest quality review. We will carefully examine all included studies to ensure we analyse and report the most recent review of interventions and strategies. There is a possibility that two or more reviews of the same intervention or strategies for behaviour change are published in a short time period (<2 years) but with conflicting results. In these cases we will explore the similarities and differences in the full texts of the reviews and lists of included studies. We will descriptively report the results of our comparisons and outline the rationale for our selection of reviews to include.

Types of interventions

We will include reviews of any oral care interventions or strategies with the purpose of maintaining or improving oral health for care home residents. Interventions may include organisational and/or supportive systems in the care home, as well as practical strategies

used to improve oral care for this population or to influence staff behaviours with oral care. Reviews of interventions or strategies in other related settings or populations will be managed in separate overviews. Interventions or strategies must be compared to "usual care".

Types of participants

The population of interest for this overview is adults (≥18 years of age) who reside in a care home setting (with or without nursing). If reported results of a review include both older people residing in care homes and their own home in the community then we will only include the review if these groups are reported separately. Such reviews and those involving other non-care home settings will still be of interest for use within stakeholder consultations and synthesised separately but should have relevance for the care home population (as described above in 'Types of reviews').

Search methods for identification of reviews

See 'search methods for both reviews' (previously described).

Selection of reviews

Two investigators will independently screen titles and abstracts to identify relevant systematic reviews for full-text review and will independently screen full texts for final inclusion. The inclusion criteria are detailed in Table 1. Any discrepancies in the inclusion of abstracts or full-text articles will be resolved by discussion and reaching a consensus. If a consensus cannot be reached a third investigator will arbitrate. It is possible that the same studies may appear in several different reviews and so these will be identified and a "decision tool" used to make inclusion decisions (see Appendix 2).

Quality criteria

To ensure the included reviews are 'systematic' and meet a minimum level of methodological rigour, we will assess the reviews using the Assessment of Multiple Systematic Reviews 2 tool (AMSTAR 2)[31]. Two authors will independently assess the quality of the reviews for inclusion. We will also extract risk of bias assessments from each included trial in the included reviews, or if other measures of quality were utilised (for example Jadad scale[32]), we will report the tool used and record the quality score for each relevant trial. Discrepancies in the ratings of the systematic reviews and quality of evidence will be resolved by consensus between two investigators and, if necessary, arbitration with the wider research team.

Table 1: Inclusion criteria for overview of reviews

Population:	People aged 18 years and over
Intervention:	Interventions, or combinations of interventions, for use by care home staff to maintain or improve oral care or strategies to influence staff behaviours to promote oral care for people living in care home settings (including systematic reviews of interventions or strategies in other settings and with populations relevant for care homes)
Comparator:	Systematic reviews and meta-analyses of original RCTs of interventions of strategies compared with "usual care"
Outcome:	Measures of oral care maintenance of improvement

Data extraction and management

Two investigators will independently perform data extraction for each review and populate a predefined table. Discrepancies in the data extracted will be resolved by discussion and reaching a consensus, and if necessary, arbitration by a third investigator. For all reviews

selected for inclusion, we will obtain the following information: details of the review including first author name, year of publication, number of included studies; details of the population and setting where the intervention or strategies are implemented; category of the intervention (or combination of interventions) or strategies, including (for example) provision or teaching of information/education/self-management, practical strategies, or organisational tools /strategies; and a description of the outcome measures used. This information will be valuable in order to map the existing evidence. It will also be necessary to identify potential discrepancies in the results of similar reviews.

For reviews showing a significant effect on outcomes, we will extract the report effect estimates (and corresponding 95% confidence intervals) and details of tests for heterogeneity and or other sources of bias for the primary and secondary outcome measures and for any additional predetermined outcomes. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) will also be extracted (https://training.cochrane.org/grade-approach). Where reported, any details of barriers and enablers will also be captured.

Reporting

Presentation of results of the overview of reviews will align with guidelines in the Cochrane Handbook of Systematic Reviews of Interventions[33] and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement[34]. A PRISMA flow diagram will be used to summarise study selection. We will summarise the characteristics of included reviews in Tables. Mapping the evidence in this way will provide a concise overview of the nature of the evidence base and highlight gaps in the evidence relating to practical interventions. We will map the interventions to the 14 domains of the TDF (see Scoping Review Stage 5, page 10).

Overviews of reviews have unique limitations that we will address in the discussion of our report including:

- whether all relevant systematic reviews were identified and included in the overview
- any gaps in coverage of existing reviews (and potential priority areas for systematic reviews)
- whether all relevant data could be obtained (and implications for missing data), and
- whether the methods used (for example, searching, study selection, data collection and analysis at both the systematic review and overview levels) could have introduced bias.

Scoping review of barriers and enablers

Understanding barriers and enablers for oral care provision for older people in care homes is essential if interventions are to be fully realised (and operationalised) in this setting. These may exist at the individual (residents or care staff), organisational and or socio-political levels. Studies considering barriers and enablers often use descriptive methods (both quantitative and qualitative), and seldom RCTs, which precludes a systematic review. We will follow scoping review methodology to identify and appraise the body of literature (volume, scope and quality) on this topic[35]. This systematic approach adopts six-stages[36] which we detail below. We will register the protocol for this scoping review with Open Science Framework (OSF) (https://osf.io/).

Stage 1: Identifying the research question

The question to be addressed by this scoping review is:

> *What are the individual (micro), organisational (meso) and wider social and political (macro) barriers and facilitators influencing oral care in care homes?*

Stage 2: Searching for relevant studies
See 'search methods for both reviews' (previously described).

Stage 3: Screening and selection of studies
The titles and abstracts of references will be independently screened by two investigators and selected for potential inclusion based on our criteria (Table 2). The full text of these studies considered relevant will be retrieved and independently screened by two investigators to confirm inclusion in the review. Any disagreements between the two investigators when screening or selecting studies will be resolved by discussion and where consensus cannot be reached then a third investigator will be consulted to make an independent decision. When screening the results of the search for the scoping review we will include studies or reviews conducted in the last 10 years. Any relevant reviews identified through the overview of reviews which provide evidence of barriers and enablers will also be included.

Table 2: Inclusion and exclusion criteria

Studies will be **included** if they satisfy the following criteria: - Focus on oral care for people (aged 18 years and over) residing in care homes - Study the barriers and enablers of oral care provision for this population - Primary study using quantitative, qualitative or mixed methods - Process evaluation embedded within an intervention trial - Systematic review (which may include studies pre-2010) - Conducted in last 10 years (2010 onwards) Studies will be **excluded** if: - Focused on oral care provision in other care settings (for example own home or hospital) - An opinion piece (rather than primary study) of oral care provision for this population - Conducted before 2010

Stage 4: Charting the data
We will extract data of included studies to include year, authors, publication title, research question or study purpose, study design, context, participants, sample size, theoretical/conceptual framework, detail of intervention (if relevant), methods, results and relevant discussion points. We acknowledge this list may be updated during the data extraction process. We will pilot the data extraction form and make necessary alterations (discussed among team) prior to commencing full data extraction. One investigator will extract data from all included studies, with other authors double-checking a sample of the extraction. Any disagreements will be resolved through discussion. We will quality assess the included studies using appropriate tools as recommended by the EQUATOR network (https://www.equator-network.org/). No studies will be excluded based on quality, but our review conclusions will appraise and report the quality of the included studies.

Stage 5: Collating, summarising and reporting the results
We will provide a description of the included studies (including number of studies, countries, study populations, study design and methods (including intervention description if relevant), years of publication). We will initially describe identified barriers and enablers at the individual (micro), organisational (meso) or socio-political (macro) levels. These will then be mapped to the 14 domains of the TDF: (1) Knowledge, (2) Skills, (3) Social Influences, (4) Memory, Attention and Decision Processes, (5) Behavioural Regulation, (6) Professional/Social Role and Identity, (7) Beliefs about Capabilities, (8) Belief about Consequences, (9) Optimism, (10) Intentions, (11) Goals, (12) Emotion, (13) Environmental Context and Resources and (14) Reinforcement. We will use constructs within the domains and construct definitions to inform mapping decisions[28]. Any barriers and enablers that do not fit within the existing domains will be documented.

The evidence sourced for improving oral care for care home residents will be combined and summarised to provide a concise overview of the nature of the existing evidence base and will highlight potential strategies, barriers and enablers to uptake organised by TDF constructs as well as any gaps.

Stage 6: Consulting with stakeholders
The results of the scoping review will be prepared alongside the results of the overview of reviews, for broader input through our Phase 1(ii) stakeholder consultations (see below).

(ii) STAKEHOLDER CONSULTATIONS TO EXPLORE WHAT MATTERS FOR PEOPLE LIVING OR WORKING IN CARE HOMES (Objective 4)
We will explore the findings of the reviews in depth with key stakeholders from around the UK. Focus groups will provide an opportunity to explore the review findings with representatives of the target audience for this research to gather qualitative data focused on:

1. resonance and relevance of the review findings for stakeholder groups; and
2. additional issues stakeholders consider pertinent for improving oral care for care home residents.

Participants will include a diverse mix of people living in care homes, their relatives, care home staff, and wider stakeholders in healthcare with a role in promoting oral care for care home residents. Where feasible and acceptable we will invite participants to a focus group discussion. We are aware that as society adapts to living with COVID-19, and not knowing how this situation will develop over the next 12 to 24 months, that we need a degree of flexibility in our research plans. We will consider public health guidance at the time of data collection (March to May 2022) and the group discussions will be planned accordingly: face-to-face or virtually. As a team, we have experience of conducting group discussions for care home-related projects using both of these approaches. Regardless of approach, we recognise that a group discussion may pose particular challenges for care home residents and some relatives, and so we will consider conducting interviews with residents or resident-relative pairs[37]. As well as the pandemic concerns, we also recognise the care home sector faces a range of internal and external pressures, such as low staffing levels, staff turnover, staff wellbeing, reduction in funding and increased regulatory demands. These pressures may impact on capacity and ability of managers and staff to participate in this study. We will work closely with care home managers and staff to maximise opportunities for engagement but also to minimise participant burden.

Participants and recruitment
We will recruit up to 40 participants for this exploratory phase, including up to 10 people from the following groups: residents (n=10), relatives (n=10), care home staff (n=10) and healthcare (external to the care home) staff with a role in promoting oral care for care home residents (n=10) and including dentists, both community and general practice, with care home responsibilities. These 40 participants will be invited to one (of up to 4) focus groups. If preferred by an individual, then an interview can be conducted to promote participation (and if taking part in a focus group is not acceptable for an individual). We also acknowledge the importance of this choice to respect participants and maintain their dignity when addressing such a personal topic (mouth care). Further detail is provided below (see Data collection and analysis).

The idea for this work originated through the NICHE-Leeds partnership but the plans for the completion of this work extend beyond the NICHE-Leeds partnership to ensure broader representation of care home characteristics and participants. Purposeful sampling will be used to recruit participants. We will aim to represent in our sample: geographical location (including representation across UK nations); type of care home (with and without nursing); provider organisation (size and ownership); care home staff roles and seniority levels

(including day and night shift care assistants, senior carer assistants, registered nurses and managers); external staff in a range of relevant roles (community dentists and dental nurses, hygiene therapists, GPs, dental public health commissioners and also commissioners from older people's services); personal characteristics of residents (ethnicity, gender, age); and length of time either living or working in a care home. We will recruit these participants via existing networks (including the National Care Forum, Care England, Care Forum Wales, the NIHR Enabling Research in Care Homes Network (ENRICH) (https://enrich.nihr.ac.uk), NICHE-Leeds, Join Dementia Research and local carer support groups), our care home collaborators (including NIHR Applied Research Collaboration (ARCs)), social media and a targeted approach of care homes using publicly available information, for example to recruit from care homes providing care for particular ethnic groups. We will also link with NIHR Clinical Research Network (CRN) Oral and Dental Health speciality (https://www.nihr.ac.uk/explore-nihr/specialties/oral-and-dental-health.htm) to access research expertise and clinical leaders in this field.

We will make contact with potential participants by email, post, telephone or use established contacts within the care home (such as the care home manager) to share information with residents and their relatives, to ensure that participants recruited are representative of the care home. For the purposes of this study, we will only include people who have the mental capacity to consent to taking part: it is unlikely that residents who may lack capacity to participate would put themselves forward for the study and the methods used may not be appropriate for these residents (particularly if we use a virtual approach). However, we will ensure participation of relatives of people with dementia who do not have the capacity to consent as well as staff looking after such residents so that we are able to address the concerns of this important group. For participants whose first language is not English we will work with residents and their relatives to ensure this is conducted appropriately: a researcher who speaks the language will conduct the interview or we will ask a relative (or bilingual care worker) to translate (if this is acceptable for the resident). All participant information materials will be co-developed and written with our PPI co-investigators to ensure their appropriateness for participants, including language. We will develop shorter information sheets for all participants, covering all areas required by ethics committees, but avoiding overburdening potential participants.

We are committed to promoting equality, diversity and inclusion of participants with our work and we will follow the principles advocated by NIHR INVOLVE[38] for this purpose: joint ownership and partnership working; sampling to include a range of perspectives and skills; respecting and valuing the knowledge of all those involved; ensuring reciprocity; building and maintaining lasting relationships.

Data collection and analysis

Participants will be asked to take part in one discussion (or if preferred interview) that will last no longer than 60 minutes to reduce participant burden. We acknowledge the importance of minimising participant burden and fatigue or time pressures due to work demands when conducting interviews in any format: we will accommodate individual needs to support participation. If necessary (particularly for older participants), the discussion could take place in more than one time slot to reduce fatigue. Participants will be encouraged to share their access arrangements with the research team as soon as possible, in order for these to be supported during data collection. We have already outlined above the uncertainties about whether the data collection will occur face-to-face or virtually (due to COVID-19). However, the team are confident that either of these approaches would be feasible and acceptable: during the pandemic, members of the team have successfully conducted a research study with health and care professionals using entirely virtual methods[39]. Regardless of approach, we will include up to 10 participants in each focus group[40] and the researcher will give due consideration to the impact of group mix to promote

discussion (e.g. different stakeholder groups and how they interact with each other)[41]. All participants (other than those in a commissioning or policy role) will be offered a £10 voucher as reimbursement for the time they provide to the study.

We will prepare a one-page visual summary of the review findings to share with participants in advance of the focus group or interview. We will develop a topic guide informed by the reviews. We will develop both of these with our PPI co-investigators for appropriateness and understanding. We will revise and update the topic guide following use with participants in line with the iterative process of qualitative inquiry: if new areas emerge from our discussions, then the topic guide will be updated (as appropriate) to facilitate exploration in subsequent group discussions or interviews.

All focus groups (or interviews) will be audio recorded and fully transcribed word-for-word for analyses. Data will be analysed at a semantic level using thematic analysis to understand individual experience, perceptions and beliefs using a constant comparative technique[42]. The principal qualitative researcher (Research Fellow) will lead data analysis. A proportion of the transcripts will be coded by a second researcher. Emerging codes will be discussed by the research team and amended through consensus agreement. It is anticipated that triangulation of opinion from participants will allow further exploration of differing perspectives and understanding from the participants to explore the challenges and opportunities for oral care for this population from a range of perspectives across the health and care system. A summary of these findings will be sent to participants who express they would like to receive a copy and are willing to provide contact details for this purpose.

At the end of this phase we will have an appreciation of what may and may not work and why, and the opportunities and challenges for embedding staff behaviours to promote oral care in care homes.

PHASE 2: DEVELOPMENT (Obj 4 to 6; Mths 10 to 18)
The findings of Phase 1 will be developed into resources that will have immediate utility for the sector (guiding principles) but that also provide the theoretical and empirical foundations for future intervention studies (a logic model). To achieve this, we recognise the importance of continuing to work alongside care home residents, relatives and staff when developing these resources. Our rationale for this engagement is based on the principles of co-production[43] and our ways of working in NICHE-Leeds[25]. We recognise that those living and working in care homes are an asset (with skills and understanding) that is directly relevant for the development of this work and to influence changes in oral care practice in care homes. Any outputs from this work needs to be relevant and workable for these end-users of the work for this purpose. We will achieve this in two stages.

(i) Resource development: Guiding principles and a logic model (Obj 4 and 5)
Oral care, and the health behaviours associated with maintaining and improving this aspect of care in this setting are complex. This underpins our rationale for using the TDF to frame our analysis and interpretation of the Phase 1 findings (as described above). In Phase 2 we will develop resources based on identifying potentially modifiable determinants of oral health, including the following domains: knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; memory, attention and decision processes; environmental context and resources; social influences; emotions; and behavioural regulation[26]. This will aid the development of guiding principles for care homes, through explicit specification of key features for maintaining or improving oral care in this setting and identifying context-specific staff behavioural issues, needs and challenges.

It will also underpin the development of a logic model[44, 45] to describe the connections between these domains and the "system" in which they operate. This will offer a way of visualizing the underlying theory of what works, why and how, as well as the interactions between the constituent parts that maintain and/or improve oral care in care homes. The logic model will include the following in relation to improving oral care in care homes: PURPOSE (the 'problem' or opportunity); CONTEXT (the conditions necessary); INPUTS (the resources or infrastructure required and any constraints/ barriers); ACTIVITIES (how resources are used); OUTPUTS (indicators that activities are undertaken or resources used as planned); EFFECTS (or outcomes of having taken action (intended and unintended) which can be considered in short-, mid- and long-term). As well as identifying components that help 'embed' oral care in care homes, the logic model will highlight areas for future implementation strategies for the successful improvement of oral care in this population.

ii) Refining resources and outputs: Stakeholder engagement (Obj 5 and 6)
Broader stakeholder engagement will be used to challenge our assumptions, reasoning and thinking. We will ask stakeholders to review the guiding principles and logic model and consider whether: (1) these match their experience (resonance)? (2) the work is useful for them (relevance)? (3) there is anything missing that needs to be added (gaps)? Specifically the consultation will ensure the acceptability, feasibility and wider generalisability of the guiding principles for the care home sector and future strategies for positively influencing oral care in this setting (informed by our logic model). Refining our resources and outputs is an important inductive process to systematically identify what is needed to maintain and improve oral care in this setting (guiding principles), to inform the future direction of research in this field (logic model and promising interventions) and to optimise the dissemination and uptake of our research outputs.

We will host 3 workshops (each lasting up to 90 minutes) with up to 10 participants from each of the following groups: (1) people living in care homes and their relatives; (2) care home staff (including care assistants, senior carer assistants, registered nurses and managers); and (3) wider stakeholders in healthcare with a role in promoting oral care for care home residents (including community dentists and dental nurses, hygiene therapists, GPs, dental public health commissioners and also commissioners from older people's services). We will engage diversity of participants, where possible engaging participants from Phase 1(ii) focus groups that were willing to be contacted about Phase 2. We will purposefully recruit additional participants (with the mental capacity to consent) where there may be gaps in the sample to reflect diversity in the sample (and as described in Phase 1(ii)). The workshops will be hosted to accommodate participant availability and to promote as wide engagement as possible and to accommodate the observation of our PPI consultees who emphasised the importance of including (in particular) care staff who work night shift and relatives working full-time.

We will prepare a draft of the guiding principles and logic model to share with participants in advance of the workshop. We will develop both of these with our PPI co-investigators for appropriateness and understanding. We will audio record the workshop discussions (with participants' permission) with the purpose of using their words when developing the resources, and in particular the guiding principles for the sector. In the workshops we will also explore how to enhance the dissemination of our work and promote wider engagement of the sector. We will invite a graphic artwork designer to these workshops who will create illustrations to sit alongside the guiding principles text and our outputs.

The timing and locations of these workshops (most likely hosted in Leeds, and if possible in care homes, but to be confirmed) will be planned in advance to increase inclusivity and to enhance attendance. The workshops will promote wide engagement and participation by stakeholders from across the nations. The workshops will occur during 2022 (July-Sept). We

would plan for face-to-face workshops but will follow public health guidance at the time and adapt the approach as appropriate. If we conduct virtual workshops, then we will also ensure diversity of participants taking part. Again, we recognise that a virtual workshop may pose particular challenges for residents and relatives and so in these circumstances we would explore (if necessary) how best to engage in paired interviews with these participants. We will promote inclusive engagement of participants whose first language is not English and develop all participant materials with our PPI co-investigators (see Phase 1(ii)). All participants (other than those in a commissioning or policy role) will be offered a £10 voucher as reimbursement for the time they provide to the study.

To ensure that development is guided by stakeholders, after each workshop the feedback gained will be collated and sent to the workshop attendees and made available online for broader stakeholder engagement. This 'sense checking' will enable us to ask of these stakeholders: (1) does this match your experience (resonance)? (2) is this work useful for you (relevance)? (3) is there anything missing that needs to be added (gaps)? This online feedback in conjunction with workshops and SSC input enables co-production to be central to the project throughout[38].

Working with these stakeholders to develop these resources is an important and novel aspect of our work in this field.

Dissemination, Outputs and anticipated Impact

Dissemination will be informed by the Knowledge to Action framework[46] and dialogue with our study participants, PPI, our SSC and our sectoral links (care home and public health). We will produce a range of outputs, each will reach, inform, and engage different audiences and appeal to their information needs and abilities. The different outputs we will produce include:

- Project resources: print-friendly versions of the guiding principles, logic model, and summary sheets will be disseminated to all participants and across the sector. These will be available to download via the NICHE-Leeds webpage. Through our existing links we will approach national organisations (e.g. Skills for Care, Care England, and National Care Forum) to request that the work is disseminated through their existing communication channels (e.g. newsletters). The weblink will also be shared from our Twitter account (@LeedsNiche), and relevant Twitter handles (@CareEngland) and hashtags (e.g. #socialcare) used to attract attention.
- Engagement: We will seek to engage training providers and charitable organisations (such as Age UK, Dementia UK and Alzheimer's Society) with our work and dissemination activities.
- Blogs: to help build awareness of, and interest in, our project we will regularly write blogs which describe project progress. We have successfully used this approach in other NIHR funded care home research (HSDR 15/144/29). We will contact relevant national social care, and community dental related organisations to request these blogs are featured in their blog series or webpages (e.g. National Care Forum, and the British Association for the Study of Community Dentistry (BASCD)). We will liaise with NIHR ENRICH and Oral and Dental Health speciality (NIHR CRN) to explore opportunities for wider reach.
- Presentations: the research team (including PPI co-applicants) will present the study findings at both national, and local care home meetings and forums, such as NIHR ENRICH meetings, local Care Home Manager Forums (the study team have direct links to forums in Leeds, York, and Nottingham) and the 'My Home Life' leadership support programme. We will ensure participants and sector colleagues are aware of these presentations.
- Web presentation: recognising that care home staff may be unable to attend events or conferences we will host a web presentation of findings and implications, to reach broad

audiences, and supplemented by resources produced during this work (e.g. guiding principles, logic model, summary sheets). This will be hosted on our NICHE-Leeds web pages.

- Briefing videos: will be recorded, edited, and hosted on our web pages. These briefings will be presented by a range of stakeholders and focused on the relevance of the findings and outputs from their perspective. The range of stakeholders will be drawn from care homes (e.g. residents/ family members/ staff/ managers/ senior operational and quality managers), national representative organisations for care homes, charitable organisations, training providers, commissioners, regulators, external healthcare and dental staff (e.g. GP/ Geriatrician/ Consultant in Dental Public Health with care home remit/ community dentistry/ general dental practice/ specialist who works with dementia or patients with special needs), and public health leads for oral health in care homes. We will consult with study participants and our SSC to ensure comprehensive representation of stakeholders for the briefing videos and also for dissemination of these resources.
- National conference presentations: the research team (including PPI co-applicants) will submit abstracts to care home and dental related conferences taking place nationally, such as BASCD and The King's Funds care home events. We will also share findings through the NIHR ARC networks for care home and older people research. KS is a co-investigator for the Yorkshire and Humber ARC and closely collaborates with ARC leads from other regions.
- Academic publications: we will register the review protocols with PROSPERO (overview of reviews) and OSF (scoping review), and publish the findings in a high quality, international, relevant, impactful and open access journals focused on care homes, such Journal of the American Medical Directors Association (https://www.jamda.com). This will reach the relevant academic and clinical research community and inform future research in this area of international concern.
- Sector publications: We will publish the findings in a care provider journal such as Care Management Matters (https://www.caremanagementmatters.co.uk), and through this increase our reach to care provider audiences.

Outputs intended for the care home sector (e.g. guiding principles tool, summaries, PowerPoint slides, and blogs) will include engaging and creative graphic drawings and photographs (taken with participant permission during stakeholder engagement work). The text will be developed with EF and KW (PPI team members) to ensure readability and appeal of these outputs. Co-production with care home residents, relatives, staff and managers will promote relevance of our work so that our outputs are more likely to be impactful for the sector to maintain or improve oral care practices in care homes. We acknowledge that different audiences will require the findings and outputs to be provided in different ways and to ensure accessibility, particularly to appeal to an audience whose English literacy levels may be poor. The co-production activities alongside our plans for the findings and resources to be presented in visual, audio and written form will support this ambition. UK-wide stakeholder engagement will mean that outputs are generalisable to all nations. Our engagement with decision makers and policy makers throughout the project (as both participants and SSC members) will further support the pathway for implementation of activities identified by this work. We therefore have an opportunity to maximise links between ongoing policy work with our research, and to generate and share impactful findings for individuals, care home organisations and policy.

The main contribution of this work is partnership working to generate immediate resources and to inform future research on improving residents' oral health. Increasing scrutiny of care quality in care homes makes this study important and timely. Findings will be important to inform policy and organisational (home) level decisions about the best way to improve oral care provision in care home.

Project management
The COMMIT study will be led by co-PIs KS and GVAD who will have joint research management responsibility (finance and governance) and overall leadership for ensuring delivery of the research by the team, liaising with collaborators, supervising research staff, and ensuring the final report and resources are submitted to deadline and with timely outputs. The PIs will report to the funder and the appointed SSC. Clear research management roles for the co-PIs have been discussed and agreed. KS will lead the scoping review and Phase 1 stakeholder discussions. GVAD will lead the overview of reviews and Phase 2 stakeholder engagement. The complementary set of skills and expertise of the co-PIs will be drawn upon for the benefit of the work: having leading experts in care home and dental public health research is a strength of our work.

The team is comprised of thematic and methodological experts who are listed as co-investigators, as well as two part-time research fellows (both @ 60%fte) and information support post (@5% fte) employed to deliver this work. Team members have been allocated responsibilities to maximise their skills and expertise. PW, JC and AG will support the overview of reviews. PW, RD and KVC will support the scoping review. PW and KVC will have a key role in mapping the review findings to the TDF. JW (information specialist) will support both reviews. PPI co-investigators include BD (a care home manager) and EF and KW (members of the public who have experience of a relative living in a care home). RD and AG will lead PPI activities, support our PPI co-investigators, and liaise with (and instruct) the graphic artist. KVC and RD will lead the stakeholder discussions and engagement events. JC and AG will lead the stakeholder engagement online feedback. PW will guide implementation activities. All team members will contribute to reporting, developing resources and outputs. The team will meet two-weekly to discuss any issues arising, plans for the following 2 weeks and to assess progress against the tasks presented in our Gantt chart.

External oversight of the project will be through an appointed SSC. The SSC will assist the co-PIs in reaching strategic decisions, review progress towards key milestones and help to both anticipate and oversee risks. The SSC will comprise of an independent Chair and representatives of all key stakeholders from across the UK. Key stakeholder groups from which the SSC will be appointed include: PPI representatives (care home residents/family members/staff/ managers); methodological experts (information specialist/health psychologist/health economist/statistician); senior operational or quality managers from care provider organisations; commissioner; CQC; medical (GP/Geriatrician); dental (Consultant in Dental Public Health with care home remit/community dentistry/general dental practice and a specialist who works with dementia or patients with special needs); the PHE lead for oral health in care homes (also a member of the NICE Guideline group); representatives of other NIHR-funded research on care homes. As there are many stakeholder groups, we have in mind to appoint some individuals who can represent more than one group, for example a consultant in dental public health who is part of another NIHR funded research team working in the topic of oral health in care homes. The SSC will additionally play an active role in stakeholder engagement in phase 2 of the project.

Ethics / Regulatory Approvals
The team have wide-ranging experience of research with care homes and experience of securing necessary ethical permissions required for this setting. Our research will be registered on the NIHR CRN portfolio and the reviews on the PROSPERO (overview of reviews) and OSF (scoping review) databases. At the commencement of the study (months 0 to 3) we will seek ethics approval for Phase 1 stakeholder consultations and Phase 2 stakeholder engagement. All participant information materials, summaries and topic guides will be developed in conjunction with our PPI co-investigators. We will obtain informed

written consent from all participants. We will recruit participants with the mental capacity to provide informed consent.

Ethics approval
Ethical approval for Phase 1 stakeholder consultations and Phase 2 stakeholder engagement has been provided by the University of Leeds, Faculty of Medicine and Health (School of Healthcare) Research Ethics Committee (HREC 21-004).

Project / research expertise
The existing NICHE-Leeds partnership is a strength of our team and broader collaborators include many key organisations with interest in oral health in care homes. All parties see improving oral care as a priority in care homes. PPI within NICHE-Leeds and broader groups of residents, relatives, and care home staff and managers have informed this proposal (and as detailed in the application form PPI section). Our plain English summary was prepared with relatives and care home staff and a SSC of key stakeholders will be formed to oversee study conduct and dissemination. PPI activities for the study will be coordinated and led by RD and AG.

Our research team has the methodological, subject, sector and clinical expertise required for the effective design, conduct and delivery of the work. It will be co-led by a nurse (KS) with an extensive portfolio of research on the workforce and care homes and a specialist in dental public health (DPH) (GVAD) with a broad range of clinical expertise in oral healthcare, particularly the prevention of oral diseases in community settings. They will lead on different phases but contribute to all of the work (see 'Project management'). PW has expertise in evidence synthesis and implementation science. JW is a senior information specialist and qualified librarian. RD is experienced in care homes research, evidence reviews and knowledge translation with the sector. JC has academic DPH and policy expertise and coauthored Oral Health of Vulnerable Older People[24]. KVC is a health psychologist and qualitative researcher with expertise on behaviour change. AG has expertise in complex interventions for care home residents with dementia. BC is a nurse and care home general manager who along with EF and KW, relatives of care home residents, will promote project relevance. The team, all with evidence review experience, will be supported by dedicated two part-time (60%fte) research fellows and an information scientist. A professional graphic artist has also been costed to support our dissemination activities.

Project timetable

This is an 18-month study. We provide detail of our proposed timetable for this work in the Gantt chart below.

Month number	-3	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Project milestone*							M1							M2				M3		M4		
Study start up tasks																						
Contract																						
Collaboration agreements																						
Ethics approval (for Phases 1 and 2)																						
Set up study steering committee																						
Study oversight: SSC meetings																						
Phase 1: Investigation																						
Overview of reviews and scoping review																						
Searches																						
Screening																						
Data extraction																						
Draft report																						
Re-run searches																						
Amend draft report																						
UK-wide stakeholder consultations																						
Data collection																						
Data analysis																						
Draft report																						
Phase 2: Development																						
Developing guiding principles																						
Developing logic model																						
UK-wide engagement: planning and refining outputs																						
Study reporting (draft to final report)																						
Final report for funder																						
Dissemination activities																						

***Key project milestones**

M1: Study start up tasks completed (month 3)
M2: Draft report of review findings (month 10)
M3: Phase 1 draft report (review and stakeholder consultation) (month 14)
M4: Phase 2 consultation completed (with guiding principles and logic model) (month 16)
M5: Final report for funder (month 18-19) and ongoing dissemination activities (month 18 onwards)

Success criteria and barriers to proposed work

From an output perspective on success, as well as peer reviewed published academic outputs there are two main products which we will deliver:

(1) Co-produced Guiding Principles which map out the knowledge obtained from synthesis of published evidence along with that obtained qualitatively through stakeholder consultation and engagement. These will present a suite of options for care home staff to consider which are considered to promote optimum oral care for residents. Our success criteria for the Guiding Principles is that they be in a format which is easily understood, acceptable and accessible to the target audience and will be meaningful across the UK. Engagement with a broad UK-wide group of stakeholders will help to demonstrate success in these respects.

(2) A logic model will also be derived using the TDF as lens to bring together knowledge about interventions which have been demonstrated to be effective (obtained through the overview of reviews), with what is known about barriers and enablers (from the scoping review) and consultations with stakeholders. The logic model will present the synthesised knowledge in a way which will map out interactions of what works, as well as why and how they work to enable adequate oral care provision and lead to improved protection of oral health. The logic model, along with what we identify as gaps in the published literature will help to guide future work where, including intervention development and implementation as appropriate.

From a process perspective on success, we have already established that there is enough published evidence in this field to draw upon in our reviews and have sufficient expertise to conduct rigorous evidence synthesis within the proposed timeframe. Further, the research team has a track record of successfully recruiting and engaging meaningfully with UK-wide stakeholders involved in oral care in the care home setting at micro, meso and macro levels.

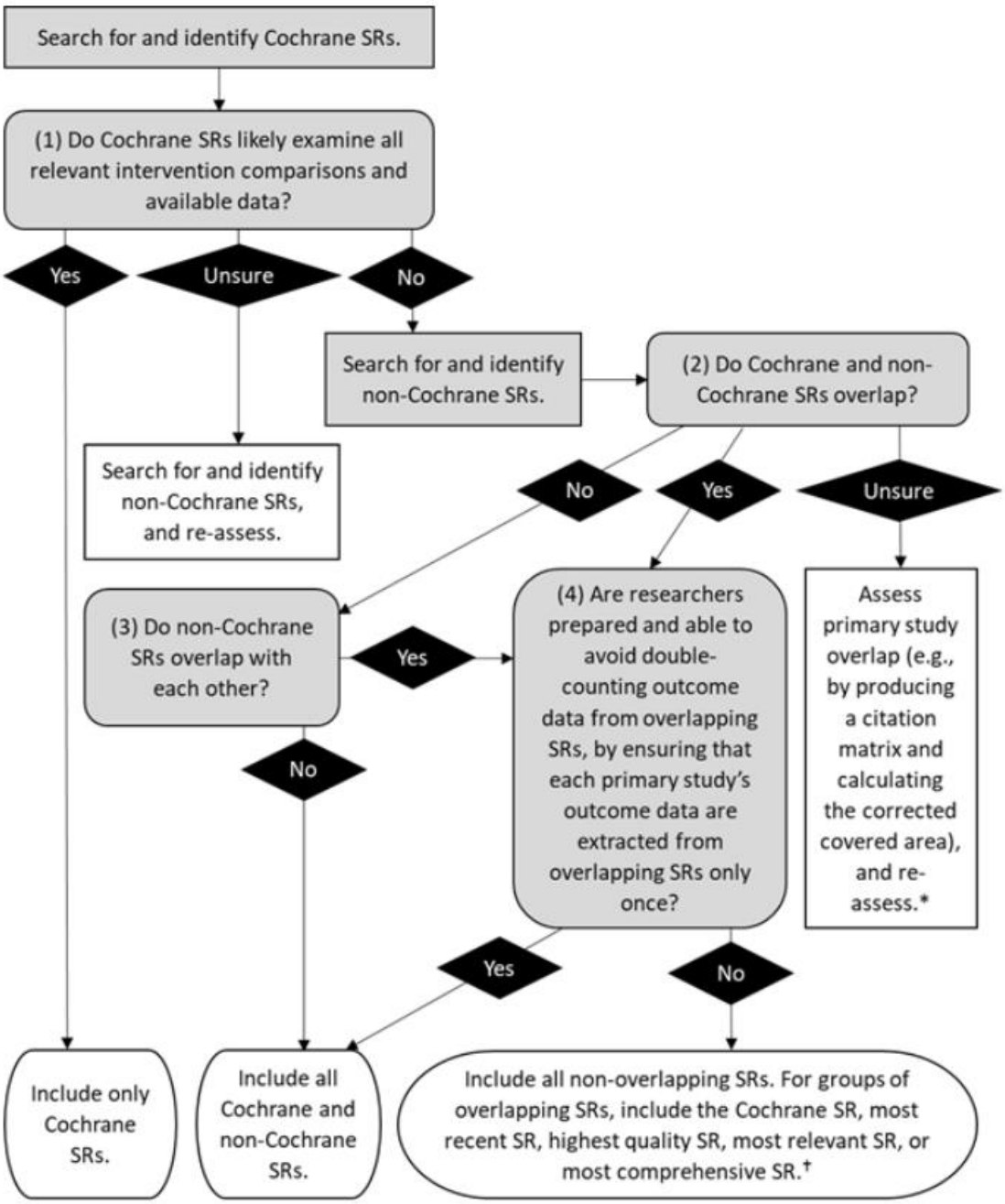
However, COVID-19 has taught us to expect the unexpected. Should there be further similar disruption, research could be of lower priority to many of our intended stakeholders. However, all aspects of our methods are possible to complete remotely. This also means that we are better enabled to engage with the widest group of stakeholders possible, irrespective of geography. As our participant engagement is of a qualitative nature to give depth of understanding to the issues recruitment should not be a difficulty as the numbers of participants is relatively low. We have also considered that remotely engaging with participants could require the use of technology which would possibly not have been available within the care homes prior to COVID-19. Our preparatory discussions and experiences in the team recognise that this would not be a problem: team members have successfully conducted a study with a range of care home staff using video calls. Some staff and residents may require initial assistance in the use of ipads or computers, we will provide for this. Where joining a virtual group discussion may pose challenges for an individual (particularly residents and/or relatives) we will adapt our approach to promote their engagement in paired interviews. Finally, it is acknowledged that there is a high turnover of staff within care homes. We do not require participant involvement of a long-term nature therefore drop-out is not likely to be a barrier. We will take staff turnover into account in relation to the format of Guiding Principles developed to ensure that these are accessible and understandable for those newly appointed in this setting.

APPENDIX 1: Comprehensive search strategy developed for Medline search (25-08-2020)

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to August 25, 2020> Search Strategy:

1 exp Nursing Homes/ (39341)
2 Residential Facilities/ (5452)
3 Homes for the Aged/ (13912)
4 Assisted Living Facilities/ (1391)
5 Long-Term Care/ (25982)
6 Hospices/ (5033)
7 care home?.tw,kw. (4004)
8 ((nursing or residential) adj2 home?).tw,kw. (33384)
9 ((nursing or residential) adj2 facilit*).tw,kw. (6835)
10 ((elderly or "old age" or "older adult?") adj2 home?).tw,kw. (2624)
11 ((elderly or "old age" or "older adult?") adj2 facilit*).tw,kw. (390)
12 ((elderly or "old age" or "older adult?") adj2 institution*).tw,kw. (2634)
13 "home? for the aged".tw,kw. (1486)
14 assisted living facilit*.tw,kw. (763)
15 residential aged care.kw. (130)
16 (residential adj2 (care or setting?)).tw,kw. (5837)
17 (geriatric? adj2 (ward? or unit? or facilit*)).tw,kw. (2831)
18 rest home?.tw,kw. (197)
19 (("long-term care" adj3 (facilit* or setting or resident*)) and older).tw,kw. (1551)
20 (("long-term care" adj3 (facilit* or setting or resident*)) and aged).tw,kw. (631)
21 (("long-term care" adj3 (facilit* or setting or resident*)) and elderly).tw,kw. (1478)
22 hospice?.tw,kw. (12691)
23 or/1-22 [Care Homes or Hospice] (109640)
24 exp Dementia/ (166276)
25 Delirium, Dementia, Amnestic, Cognitive Disorder/ (9204)
26 (dement* or alzheimer*).tw,kw. (222449)
27 exp Delirium/ (9579)
28 exp Cognition Disorders/ (94398)
29 disabled persons/ or amputees/ or mentally disabled persons/ or mentally ill persons/ or persons with hearing
impairments/ or visually impaired persons/ (59641)
30 Vulnerable Populations/ (10664)
31 exp Intellectual Disability/ (96062)
32 exp Learning Disabilities/ (22102)
33 ((physical* or learning or mental* or intellectual*) adj (disorder* or disab* or impair*)).tw,kw. (82772)
34 down* syndrome.tw,kw. (22318)
35 exp Stroke/ (135214)
36 stroke.tw,kw. (244816)
37 or/24-36 [Disabilities] (832830)
38 (residential or home? or facilit*).tw. (935039)
39 (ward? or unit?).tw,kw. (698236)
40 exp Hospital Units/ (111979)
41 Inpatients/ (22102)
42 inpatient?.tw,kw. (108948)
43 or/38-42 (1718774)
44 37 and 43 [Disabilities and Residential homes or hospital wards] (77499)
45 23 or 44 [Care Homes or Disabilities homes for older people] (173168)
46 Preventive dentistry/ (3269)
47 Oral Hygiene/ (12906)
48 Dental Care/ (21302)
49 Toothbrushing/ (7592)
50 Mouthwashes/ (5348)
51 Mouthwashes/ (5348)
52 Health Education, Dental/ (6032)
53 Oral health/ (16613)
54 Dental Care for Chronically Ill/ (2873)
55 Dental Care for Aged/ (2018)
56 Dental Care for Disabled/ (4238)
57 Geriatric Dentistry/ (987)
58 ((access* or availab*) adj2 (dentist* or dental)).tw,kw. (2232)
59 ((oral or dental or mouth or teeth or tooth or gum or periodontal) adj care).tw,kw. (15066)
60 ((oral or dental or mouth or teeth or tooth or gum or periodontal) adj hygiene).tw,kw. (15692)
61 ((oral or dental or mouth or teeth or tooth or gum or periodontal) adj health).tw,kw. (34624)
62 (mouthwash* or mouth-wash* or mouth-rins* or mouthrins* or oral rins* or oralrins*).tw,kw. (6160)
63 (toothpaste* or tooth paste* or dentifrice* or toothbrush* or tooth brush* or fissure sealant* or floss*).tw,kw. (14926)
64 exp Dentifrices/ (6868)
65 (fluorid* adj2 (varnish* or topical or milk)).tw,kw. (2255)
66 Fluorides, Topical/ (4554)
67 exp Stomatognathic Diseases/pc [Prevention & Control] (37267)
68 (dental adj (crown* or implant* or bridge* or inlay*)).tw,kw. (15589)
69 denture?.tw,kw. (24126)
70 ((oral or dental or mouth or teeth or tooth or gum or periodontal) adj1 check*).tw,kw. (728)
71 ((oral or dental or mouth or teeth or tooth or gum or periodontal) adj1 assess*).tw,kw. (2442)
72 ((oral or dental or mouth or teeth or tooth or gum or periodontal) adj1 exam*).tw,kw. (8565)
73 ((oral or dental or mouth or teeth or tooth or gum or periodontal) adj1 screen*).tw,kw. (735)
74 ((tooth or teeth or plaque) adj3 disclos*).tw. (239)
75 or/46-74 [Prevention and Control of Dental Problems] (170418)
76 (oral disease* or oral neoplasm* or oral cancer* or mouth disease* or mouth neoplasm* or mouth cancer*).tw,kw. (30203)
77 (dental disease* or dental decay or dental plaque or oral plaque).tw,kw. (9415)
78 ((tooth or teeth) adj2 (decay* or loss)).tw,kw. (8216)
79 (gum disease* or DMF or caries or gingivitis or periodontal disease* or periodontitis or dry mouth or xerostomia).tw,kw. (102318)
80 or/76-79 [Dental Problems] (139503)
81 (prevent* or control* or reduc*).tw. (7214355)
82 pc.fs. (1289699)
83 81 or 82 (7820767)
84 80 and 83 [Prevention of Dental Problems] (60578)
85 75 or 84 [Oral Care or Prevention of Dental Problems] (204048)
86 45 and 85 [Care homes and Oral Care or Prevention of Dental Problems] (2331)

Appendix 2: Decision tool to make inclusion decisions in Overviews (modified from Pollock 2019)[47]



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