Protocol: CONCEALED Evidence Synthesis

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Project Title: The impaCt Of dietary intake and Nutritional status in CarE homes on orAl heaLth: an EviDence synthesis (CONCEALED)

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Version Control Table

Version	Date
4	15/09/23

Changes from Version 1

Page	Change
23	Addition of section 'Changes to Project Timelines'
25	Inclusion of information on ethical approval

Changes from Version 2

Page	Change
23	Update to 'Project Timetable'

Changes from Version 3

Page	Change
16	In WS2 Groups 3 and 4 have been combined. When recruitment was undertaken a very large degree of overlap was noted between Groups 3 and 4 as many potential recruits were part of both groups. Therefore 60 qualitative interviews will be undertaken.
18	In WS3 Groups 3 and 4 will be combined given the overlap between

	the groups. A total of 15 participants will be invited to take part in the final stakeholder meeting.

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1. FULL TITLE OF PROJECT

The impaCt Of dietary intake and Nutritional status in CarE homes on orAl heaLth: an EviDence synthesis (CONCEALED)

2. SUMMARY OF RESEARCH

2.1 Aim(s) of the research: The aim of this evidence synthesis project is to explore the role of dietary intake and nutritional status as aetiological risk factors for poor oral health in dentate older adults living within residential and nursing care homes.

2.2 Background to the research: It is estimated that approximately half a million older people live in care homes across the UK[1]. This includes residential care homes (health and social care provision by healthcare assistants) and nursing homes (health and social care provision by registered nurses)[2]. Prevention and management of malnutrition in care homes is a significant clinical challenge meaning that residents are often provided with diets rich in complex carbohydrates, including sugars, plus additional sugared medications and oral nutritional supplements to increase caloric intake[3–5]. However, this creates a significant problem for oral health as the causal link between sugar intake and dental caries is well established[6,7]. Epidemiological changes have meant that the majority of older adults within care homes now retain their natural teeth, giving rise to a partially dentate care home population who are very susceptible to dental disease as their ability to manually clean their teeth declines[8–10]. Currently the oral health of care home residents is significantly worse than their community living peers, with a very high prevalence of dental caries and periodontal disease[11]. This results in pain, discomfort and negative impacts on oral function and quality of life[12]. Poor oral health may also exacerbate a range of medical conditions including aspiration pneumonia and delirium, increasing healthcare costs and leading to poorer overall outcomes[13,14]. Despite these high levels of preventable dental diseases, little attention has been paid to oral health prevention including critically examining the role of dietary intake and nutritional status on oral health within this population. Whilst the National Institute for Health and Care Excellence (NICE) have made recommendations to help improve the Oral Health of Adults in Care Homes (NG48) little attention was paid to the role of dietary intake and nutritional status, reflecting the paucity of evidence in this area[15]. NICE, along with the World Health Organisation (WHO), Royal College of Surgeons of England (RCS), Public Health England (PHE) have all called for more high quality research into improving oral health for older adults in care homes[16,17].

This study complements a number of on-going studies being undertaken by many of the same research team:

1. Improving the Oral Health of Older People in Care-homes: a Feasibility Study (TOPIC) NIHR PHR 17/3/11
2. Using role-substitution in Care Homes to improve Oral Health (SENIOR) NIHR128773

3. Development of a Core outcome set for Oral Health Services research involving dependent Older Adults (DECADE) Dunhill Medical Trust
4. STroke friendly Oral health Promoting toolkit to improve oral self-care practices (STOP) NIHR RfPB 16922
5. Visual ethnography for Older people In a Care Home Environment (VOICE) doctoral research
6. BRC551b/OHD/AH/110380 Feasibility and acceptability of an intervention to improve adherence to dietary recommendations and reduce sugar intake among adults living in care homes
7. We also link to the recently funded NIHR131506 'Caring Optimally: promoting effective Mouth MInuTes in care homes (COMMIT Study)' via co-applicant PRB, who is on the advisory board for this study

2.3 Design and methods used: This evidence synthesis will comprise a systematic review to appraise existing published evidence on the impact of dietary intake and nutritional status on the oral health of older adults living within care homes. A scoping review of UK guidelines and policy documents which provide dietary/nutritional advice or recommendations for older adults in care homes will be undertaken, with particular attention on identifying guidance which references oral health. Given the complex nature of this research area, further qualitative evidence will be gathered by undertaking semi-structured interviews with care home staff (including carers, care-assistants, chefs and kitchen assistants), managers and health professionals (including dieticians, nurses and the community dental service) who have an input into the dietary intakes of older adults within care homes. Patients and family members will also be invited to provide qualitative interviews to discuss their experience of links between dietary intake and nutritional status, and oral health. The project will also examine the economic factors which determine the foods and beverages which are provided to care home residents through the semi-structured interviews with care home managers and staff directly involved in food preparation (chefs, kitchen assistants and care assistants). From the evidence produced and synthesised, recommendations will be made on ways to improve dietary intake and nutritional status which do not actively contribute to the development of oral disease and are still effective in terms of nutritional status outcomes. Key stakeholders (including patients, family members and care home staff) will be central to the production of recommendations.

This application focuses on dietary intake and nutritional status, but will link to the evidence syntheses within NIHR131506 via co-applicant PRB.

2.4 Patient and public involvement: The research questions driving this evidence synthesis have come from previous qualitative work with care home residents, family members and carers undertaken by members of this research team as part of the DECADE study[18]. Whilst the focus of DECADE was on developing a core outcome set for oral health services research for dependent older adults, a consistent theme which emerged from the qualitative interviews was the relationship between oral health and

diet within care homes. One carer reported that sugared dietary supplements "are given to all residents in their home routinely" with no consideration of the residents' oral health as it is "not a priority". One family member reported her frustration that care home staff were providing her mother with "sugared juice" and that "the cupboards and drawers in her room were full of biscuits and chocolates from visitors". She reported that her mother entered the care home with "a full set of teeth but the medicines, food and drinks provided in the home had rotted her teeth". One care home resident reported that care home staff "would never ask you if you've brushed your teeth or plate (denture) after a meal".

We have included a PPI representative (NW) as a co-applicant who has previous experience working with this research team. This study has been developed in partnership with BELONG (https://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/PPIGroup/), which is a PPI group consisting of older adults from Northern Ireland, and PARC-Bangor (http://nworth-ctu.bangor.ac.uk/parc-bangor.php.en). Members of BELONG contributed to the DECADE project by participating in qualitative interviews which ultimately gave rise to this application. NW is a member of BELONG who has contributed to the design of this research project, particularly through helping to design the outline topic guide which will be used for the semi-structured interviews. As part of this application NW has helped the research team to write the plain English summary and the plans for widely disseminating the study outcomes, particularly to older patients, family members and the general public. CONCEALED will complement both the TOPIC and SENIOR studies which are focused on oral health interventions, but do not include dietary intake and nutritional status, to improve oral health within care homes.

2.5 Dissemination: This research team have substantive links with national and international academics, clinicians, patient groups and policymakers. GMK is the president of the Geriatric Oral Research Group (GORG) and GT is the president elect of the Behavioural, Epidemiological and Health Services Research (BEHSR) Group within the International Association for Dental Research (IADR). Through JW and CME the research team have links to British Dietetic Association (and the older adults specialist group), European Federation of the Associations of Dietitians, The European Nutrition for Health Alliance (Optimal nutrition for all) and Nutrition Society which all promote nutrition and health amongst older people.
The research team provide undergraduate and postgraduate education for healthcare professionals working within care homes including dentists (GMK, PRB, GT, AH), public health professionals (GT, CON, GMK) nutritionists (JW, SW), dieticians (CME), nurses (GM) and doctors (GMK), and will ensure that the findings of this evidence synthesis are embedded within future training. PRB, GMK and GT work with the All-Wales Faculty for Dental Professionals hosted by Bangor University to provide education, training and support for Dental Care Professionals in Gerodontology via an online Massive Open Online Course (MOOC)(https://awfdcp.ac.uk/moocs/all-moocs/gerodontology). Members of the research team (GMK and SW) also provide

training for care home staff through the My Home Life education programme (http://myhomelife.org.uk). All opportunities for disseminating the outputs from CONCEALED will be explored including linking with the Enhanced Health in Care Homes Team within NHS England and other equivalent bodies throughout the UK. Existing networks will also be utilised including through the South Eastern Health and Social Care Trust (via CL) and the Patient Client Council. This provides a unique opportunity to disseminate the outcomes from CONCEALED directly to care home staff and managers across the United Kingdom.

This team is uniquely positioned to engage with policymakers at a number of levels across the United Kingdom. The team includes the deputy Chief Dental Officer for Wales (PRB) and GMK is currently working updating oral health policy for older adults in Northern Ireland with the acting Chief Dental Officer. GT is a Consultant in Dental Public Health for Public Health England and chair of the Platform for Better Oral Health in Europe (http://www.oralhealthplatform.eu/). GMK is currently a fellow with NICE specifically working on improving oral health for older adults (https://www.nice.org.uk/Get-Involved/Fellows).

3. BACKGROUND AND RATIONALE

3.1 Background: Poor oral health, including dental caries and periodontal disease, is a very common problem for older adults living in care homes (both residential and nursing care homes) with the issue of poor oral health rapidly becoming a significant public health problem[11]. Epidemiological changes have meant that the majority of older adults within care homes now retain their natural teeth, giving rise to a partially dentate care home population[8,9]. Amongst older adults, 40% of the 75-84 age group and 33% of the 85+ age group have dental caries, whilst periodontal disease affects 69% of those over 65 years of age[9]. The oral health of care home residents is much worse than their community living peers, as highlighted by caries prevalence data (73% compared to 40%)[11]. With increasing age, the ability for self-care deteriorates with reduced manual dexterity for mechanical cleaning of teeth and polypharmacy leading to dry mouth / xerostomia which further exacerbates the development of dental disease[19].

Both caries and periodontal disease are preventable chronic destructive dental diseases[20–22]. There is a well-established body of evidence which demonstrates the causal links between diets rich in sugars and the development of dental caries[6,7,23]. Complex carbohydrates within the diet (including oral nutritional supplements) fuel cariogenic bacteria within the mouth leading to dental caries. In the absence of effective manual cleaning, and diminished protective salivary output, caries can develop extremely quickly on both the coronal and root surfaces of teeth particularly in dependent older adults[24]. Caries can cause significant pain and discomfort leading to extraction of remaining natural teeth which in turn has further negative consequences for oral function including speaking, eating and quality of life[25,26].

The care home resident population presents complex nutritional challenges including a high prevalence of malnutrition (>25% of residents)[5]. This has significant consequences for a range of systemic co-morbidities including increased susceptibility to infection, muscle weakness and poor healing, and increases the risk of developing frailty four fold[27,28]. Malnutrition is as a recognised risk factor for cognitive decline and excess mortality[29]. Whilst significant attention is directed towards prevention and management of malnutrition in care homes the nutritional interventions provided are now directly contributing to the aetiology of dental caries in partially dentate care home residents. Care home residents are provided with high energy density foods and beverages which are high in sugars to provide maximum caloric intake and improve the taste. Additionally, many care home residents receive frequent oral nutritional supplements which are often delivered in a sugared suspension thus further promoting development of dental disease[30,31]. Previously, when the vast majority of residents were edentate these nutritional practices had few consequences for oral health, however changing oral epidemiology means that these practices are now directly contributing to development of caries and poor oral health in partially dentate residents. Paradoxically, poor oral health resulting in the loss of any remaining natural teeth will further compound the nutritional challenges which these nutritional practices were intended to target[32].

3.2 Evidence explaining why this research is needed now

Health need: Poor oral health impacts on older adults' quality of life, self-esteem, and general health, including malnutrition[25,33]. Dental service provision for older people who live in care homes in England has recently been described as “particularly deficient” and a pressing public health issue with little attention paid to prevention[34]. For example, a Healthwatch survey in Bolton found that (approaching) 1 in 10 care-homes had resorted to taking a resident to A&E because of preventable dental complications including removal of carious teeth[35]. Need has also been identified in Wales, where previous detailed epidemiological studies have been undertaken[11]. Admission to hospital for dental problems is distressing and very costly for the NHS. The cost of treating oral disease is expected to rise and a significant proportion of this cost in the future will relate to the provision of treatment for dependent older people. The ongoing COVID-19 pandemic has provided a significant opportunity to reshape health services, including dental care throughout the UK towards a prevention based treatment model[36]. Identification and management of all aetiological factors must form part of any effective preventative regime, and for care home residents this must include consideration of dietary intake and nutritional status.

Expressed need: In a pilot Priority Setting Partnership (PSP) led by PRB, older people identified a number of concerns as they anticipated losing their independence[37]. Older people spoke about the importance of preventing and treating oral diseases in their population group and the impact this has upon dignity and activities of daily living. From a care home perspective, access to services is an area where concern has been recently expressed, particularly around oral health, as large proportions of the residents in most homes are reported to be unable to access dental care[34]. These concerns have

been echoed in TOPIC (NIHR PHR 17/3/11), SENIOR (NIHR HS&DR 128773) and DECADE, which are being undertaken by most of the study team. Co-applicant GT's recent study and DECADE have found that determining appropriate models of oral health care, including advice on appropriate dietary intake, is a major discussion issue amongst care home managers, carers, health professionals and family members[38].

Capacity to generate new knowledge: The research team represent the majority of clinical and public researchers working within the field of Gerodontology within the UK. The research team is further strengthened by the inclusion of leading researchers in nutrition and diet, ageing, nursing and health economics. This project would be the first to undertake an evidence synthesis focused on the complex topic of the role of dietary intake and nutrition in poor oral health for care home residents. The proposed project will gather information on all aspects of this complex issue including a review of existing literature and guidelines, and qualitative interviews with stakeholders (including patients) including an examination of financial drivers. As far as we are aware, this will be the first attempt (as a NIHR project application) to robustly examine these research questions and produce recommendations. WHO, PHE and the RCS all argue that the design of long-term care systems need to be fit for purpose and also highlight the paucity in the literature in this area[16,17]. NICE NG48 also argues strongly that more research is needed in this area particularly in developing strategies to prevent oral diseases[15]. Dietary intake and nutritional status are significant aetiological factors in the development of chronic dental diseases in older adults. CONCEALED will synthesize the evidence to produce recommendations to improve dietary intake and nutritional status for older adults in care homes which do not actively contribute to the development of oral disease and are still effective in terms of nutritional status outcomes. Currently NG48 does not include reference to dietary intake and nutritional status, reflecting the lack of current high quality evidence in this area, CONCEALED will address deficiency thus facilitating future updates to the guideline.

Generalisable findings and prospects for change: Poor oral health within care homes care is a rapidly emerging public health issue as highlighted by the Care Quality Commission[34]. Preventative oral health measures are currently underutilised within care homes but managing the major aetiological factors driving dental disease is crucial to ensure success. The links between dietary intake and nutritional status, and poor oral health are well established in adults but care home residents pose additional complex challenges given the need to prevent malnutrition and frailty[33,39–41]. In order to ensure meaningful changes to oral health amongst care home residents it is essential that the evidence in this area be robustly evaluated and made available to policymakers. The applicants have strong links with key policy-makers in Wales, England and Northern Ireland. PRB is the deputy Chief Dental Officer for Wales and GMK is leading work on improving oral health for older patients as part of a fellowship

with NICE. GMK is also a member of the Northern Ireland and nationwide Hospitals Group council of the British Dental Association. CL is the chair of the British Dental Association Northern Ireland Council and represents the Community Dental Service on a national level within the British Dental Association. The team also have strong links with PHE via GT (GT contributed to PHE's Commissioning Better Oral Health for Vulnerable Older People). GM holds the title of Queen's Nurse (QN) with the Queen's Nursing Institute where he provides thought leadership on care home nursing. GM is also an elected member of the Royal College of Nursing's Older People Forum and represents 12,500 nurses specialising in care of older people (many of whom practice in care homes).

The research team have also developed a strong track record in developing research and outputs in partnership with care homes and patients. As part of the TOPIC study we have developed resources on improving oral cleanliness for care homes residents through a co-production process with care home staff and residents: https://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/HealthServicesGlobalHealth/OralHealthCare/TOPIC/TOPICinterventionmaterialsandtrainingvideo/

The evidence collected to date (through a process evaluation of the ongoing TOPIC study) on the uptake of these resources have been very positive from care home staff and managers. We intend to employ a similarly inclusive approach with CONCEALED to ensure buy in from care home staff and encourage positive change.

Building on existing work: As highlighted above, the research team are already active within the care home sector where they are currently undertaking a feasibility study on the NICE guidelines (NG48) for care homes (TOPIC: NIHR PHR 17/03/11) and examining innovative ways of delivering oral healthcare for residents with Dental Care Professionals (SENIOR NIHR: 128773). The team have also worked together on a number of projects examining links between oral health and nutrition including dietary intervention alongside natural tooth replacement (DENHAB: NI HSC R&D and HSE Awards on Ageing) and analysis of the UK National Diet and Nutrition Survey in older adults[26,32,42–45]. We will link to the evidence syntheses within NIHR131506 via co-applicant PRB.

The research team have just completed the DECADE study funded by the Dunhill Medical Trust. This work was focused on developing a Core Outcome Set (COS) for oral health services research with dependent older adults, including a series of qualitative interviews with care home residents, family members and care home staff[18]. Whilst dietary intake and nutritional status were not a primary focus within the DECADE interviews discussions around oral function, chewing and eating often fed into conversations around the diet of care home residents. Within the thematic analysis of the qualitative interviews dietary intake and nutritional status of care home residents emerged as a consistent theme. Family members expressed their concerns about the

diet provided to care home residents particularly around “sugared juices” and “biscuits and chocolates” provided by staff and visitors. Care home staff raised the issue of sugared dietary supplements which were “given to all residents in their home routinely” with no consideration of the residents’ oral health as it is “not a priority”. Care home staff and family members expressed frustration at a lack of clear guidance around diet for care home residents as they were aware of the negative impacts that sugar consumption could have on natural teeth. These views were echoed very strongly by the oral health professionals included within the study and they emphasised that “diet needed to be part of any preventative strategy” to improve oral health in this population.

4. AIMS AND OBJECTIVES

Research questions: The following are our research questions, derived from our PPI group:

1. According to published literature, how does dietary intake and nutritional status impact on oral health amongst older adults living in care homes?
2. What do care home staff (including carers, care assistants, chefs, kitchen assistants and care home managers), health professionals, residents and their family members identify as the main influences on dietary intake and nutritional status amongst older adults living in care homes? How do these groups feel that dietary intake and nutritional status impact on oral health for older adults living in care homes?
3. What are the economic drivers of food and beverage provision for older adults living in care homes?

Aims: To undertake an evidence synthesis to investigate the relationship between dietary intake and nutritional status, and oral health amongst older adults living in care homes.

Objectives: The objectives of the study are to:

1. Undertake a systematic review of the impact of dietary intake and nutritional status on the oral health of older adults living in care homes;
2. Undertake a scoping review of available policy documents and dietary guidelines for care homes in the UK to identify guidance where both dietary intake and nutritional status, and oral health are optimized;
3. Use semi-structured interviews to gather information from care home staff (carers, care assistants, care home managers), health professionals, residents and family members on: influences and drivers of dietary intake and nutritional status amongst older adults in care homes; the impact of dietary intake and nutritional status on oral health amongst older adults living in care homes.
4. Examine the economic drivers of preparing and providing food and beverages for older adults in care homes through semi-structured interviews with relevant care home staff (including care home managers, chefs and kitchen assistants).
5. Synthesize the evidence to produce recommendations, with input from key stakeholders, to improve dietary intake and nutritional status for older adults in

care homes which do not actively contribute to the development of oral disease and are still effective in terms of nutritional status outcomes.

5. RESEARCH PLAN / METHODS

Three work streams (WS) are proposed:

Work stream 1 (WS1) – Review of the scientific literature and current nutritional guidelines

Work stream 1 has two parts and will be led by GMK and GM. The first part is to undertake a systematic review of the scientific literature to determine the impact of dietary intake and nutritional status on oral health in older adults living care homes. The second part of WS1 is to conduct a scoping review of available dietary guidelines and policy documents for older adults in care homes throughout the UK and to identify guidance where both dietary intake and nutritional status, and oral health are optimized.

Systematic review

The review will consider studies that have examined the relationship between dietary intake and nutritional status, and oral health of older adults living in care homes. We will link to the evidence syntheses within NIHR131506 via co-applicant PRB, but this study will focus specifically on dietary intake and nutritional status. As mentioned previously, the proportion of edentate older adults has fallen over the past few decades, giving rise to a partially dentate older population within care homes[11]. As this is a relatively new phenomenon, little attention has been paid to the role of dietary intake and nutritional status with regards to oral health amongst older adults living in care homes, reflecting the paucity of high-quality studies in this area. Therefore, to increase the strength of evidence, all relevant data from experimental (randomised and non-randomised trials) and observational studies will be considered in the review. The focused question for this systematic review is: “In older patients living in care homes, what is the impact of dietary intake and nutritional status on oral health?”.

Protocol and registration

This systematic review will be conducted and reported according to the PRISMA guidelines[46]. A protocol describing the process of the systematic review has been submitted to PROSPERO: International prospective register of systematic reviews. A previous search of PROSPERO did not reveal any previous or ongoing systematic reviews focused on this subject.

Eligibility criteria

Studies will be included if participants are aged 60 years or over, dentate and reside in a care home (nursing or residential). Studies which include information reporting on both dietary intake and nutritional status, and oral health outcomes will be included. Dietary interventions which target the whole diet, food or nutrient intake will be included; this includes oral nutritional supplement interventions. Studies will be included if dietary intake was assessed by food frequency questionnaire, 24 hour dietary recall, food records or similar instruments. We will include studies that have assessed clinical dental outcomes (including decayed, missing and filled teeth [DMFT]; active root and coronal caries;

intraoral swelling and discharge), as well as person centred oral health outcomes such as oral health related quality of life, pain, social outcomes and reduced function (eating and speaking). We will also include studies which report on operative dental interventions which arise as a result of dental disease including direct restorations, extractions, modifications to removable dentures as well as events such as hospital attendance or emergency treatment (Table 1).

Information sources

The following online databases and trial registries will be searched: MEDLINE, CINAHL, Web of Science, EMBASE, WHO International Clinical Trials Registry Platform (ICTRP), International Standard Randomised Controlled Trials Number (ISRCTN), UK Clinical Trials Gateway (UKCTG) and ClinicalTrials.gov. Hand searches will be performed for records not accessible electronically or those records with an electric abstract available. Further searches resulting from reference cross-checks will be performed to identify studies not discovered online. Further attempts to maximize the pool of relevant studies and avoid any erroneous exclusion will involve posting queries on research community websites (https://www.researchgate.net/) and personal communications sent to relevant corresponding authors.

Search strategy

The search strategy has been designed by the research team and set up by PRB who has extensive previous experience working with the Cochrane Oral Health Group (Table 1). A preliminary search has been run in MEDLINE (1946-present), which generated 582 papers (Table 2). The initial electronic search will be performed by a single reviewer (SW) and then repeated by a second reviewer (GMK) to confirm the number of discovered articles by the search strategy. The search terms employed will be either medical subject headings (MeSH) terms or keywords classified under general (all fields) category. The search terms will be combined with an “OR,” and PICO categories will be combined using “AND” to create a final search query.

Study selection

All relevant studies will be included in this review if they fulfil the inclusion criteria. A title and abstract screening will be performed by two investigators independently (SW and GMK). The reviewers will use Covidence software (https://www.covidence.org) as the primary screening and data extraction tool. A final list of studies will be generated for full-text analysis and data extraction, only after a mutual agreement between the two investigators; disagreements, if any, will be resolved by means of a consensus discussion with input from a third reviewer (PRB). In cases of identified studies reporting on the same cohort at different time points, only the most recent publication will be included in the systematic review.

Data extraction process

The two investigators will extract data from the included studies independently and will be reciprocally blinded. During data extraction, for any uncertainty involving the extracted data, a consensus will always be reached by both investigators before finalising the extracted data. In cases of significant doubts, corresponding authors will be contacted via email for confirmation of the extracted information.

Table 1. Exemplar Systematic Search and Strategy		
Focused question	In older patients living within residential care homes, what is the impact of nutritional and dietary factors on oral health	
Search Terms	**Population**	# 1 – ((Aged) OR (Frail Elderly) OR (Geriatrics) OR (Senior Centers) OR (Adult Day Care Centers) OR (Housing for the Elderly))
	Intervention or exposure	#2 – ((“Diet, Food and Nutrition”) OR (Diet) OR (Digestion) OR (Eating) OR (Feeding Behavior) OR (Nutritional Status) OR (Nutritional Requirements) OR (Nutritive Value) OR (Dietary supplements) OR (Food) OR (Beverages) OR (Fermented Foods and Beverages) OR (Sustenance) OR (Food Assistance) OR (Diet, Cariogenic)) OR (Diet, healthy)
	Comparison	#3 – ((“Diet, Food and Nutrition”) OR (Diet) OR (Digestion) OR (Eating) OR (Feeding Behaviour) OR (Nutritional Status) OR (Nutritional Requirements) OR OR (Nutritive Value) OR (Dietary supplements) OR (Food) OR (Beverages) OR (“Fermented Foods and Beverages”) OR (Sustenance) OR (Food Assistance) OR (Diet, Cariogenic) OR (Diet, Healthy))
	Outcome	#4 – (Oral Health) OR (Dental Caries) OR (Tooth Diseases) OR (Tooth Demineralization) OR (“Root Caries”) OR (Dental Caries Susceptibility) OR (Tooth Mobility) OR (Tooth Loss) OR (Toothache) OR (Tooth Extraction) OR (Dental Amalgam) OR (Dental Materials) OR (Emergency Service, Hospital)
Filters applied	**Language**	#5 – (English [lang])
	Species	#6 – (Human [Species])
Search Combination	#1 AND #2 AND #3 AND #4 AND #5 AND #6	
Database search	**Electronic**	MEDLINE, CINAHL, Web of Science, EMBASE, WHO International Clinical Trials Registry Platform (ICTRP), International Standard Randomised Controlled Trials Number (ISRCTN), UK Clinical Trials Gateway (UKCTG) and ClinicalTrials.gov.

	Journals	All peer reviewed dental, nutrition and nursing journals available in PubMed, Embase and CENTRAL. No filters will be applied for the journals

Table 2: Results from Preliminary Search in MEDLINE(R) ALL <1946 to 01 June 2021>

	Search term	Search results
1	Aged/	3204897
2	Frail Elderly/	12469
3	Geriatrics/	30483
4	Senior Centers/	90
5	Adult Day Care Centers/	123
6	Housing for the Elderly/	1638
7	Diet, Food, and Nutrition/	2
8	Diet/	166942
9	Digestion/	22811
10	Eating/	54502
11	Feeding Behavior/	85897
12	Nutritional Status/	47161
13	Nutritional Requirements/	19741
14	Nutritive Value/	14608
15	Food/	34384
16	Beverages/	15490
17	Fermented Foods and Beverages/	740
18	Sustenance/	4
19	Dietary Supplements/	62383
20	Food Assistance/	1307
21	Diet, Cariogenic/	1269
22	Diet, Healthy/	4985
23	Oral Health/	17735
24	Dental Caries/	46691
25	Tooth Diseases/	6759
26	Tooth Demineralization/	2382
27	Root Caries/	862
28	Dental Caries Susceptibility/	2367
29	Tooth Mobility/	2617
30	Tooth Loss/	4064
31	Toothache/	2838
32	Tooth Extraction/	19774
33	Dental Amalgam/	8402
34	Dental Materials/	17502
35	Emergency Service, Hospital/	74191

36	1 or 2 or 3 or 4 or 5 or 6	3224424
37	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22	442953
38	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35	190382
39	36 and 37 and 38	617
40	limit 39 to (english language and humans)	582

Missing data

Information will be requested via email from the corresponding authors of included studies for missing or unclear data. In the case of an initial non response, email reminders will be sent. Whilst every effort will be made to retrieve missing data a non response from the corresponding author will ultimately result in the exclusion of the study from the review.

Risk of bias and quality assessment of the included studies

The certainty of the evidence will be assessed using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system[46]. The risk of bias (ROB) for included randomised studies will be assessed using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions, while the ROBINS-I tool (Risk of Bias In non-randomized Studies of Interventions) will be used for included non-randomised studies and the ROBINS-E tool will used for included observational studies[47,48].

Scoping review of UK dietary guidelines and policy documents

We will use Arksey and O'Malley's (2005) framework for conducting a scoping review of guidelines and policy documents related to dietary intake and nutritional status, and oral health in older adults living in care homes throughout the UK[49]. Documents from UK government organisations, charities and professional bodies will be considered. As these documents are not indexed by standard bibliographic databases, we will also use a modified version of Godin's et al. strategy for searching the grey literature[50]. This will include four search strategies: grey literature databases, advanced Google search and NICE Evidence Search (via GMK), targeted websites and consultation with UK experts/stakeholders in dietary intake and nutritional status, and oral health. The research team will utilise existing relationships that have been established through collaborative working to identify content experts across the UK. These individuals will be contacted by email and asked to identify or send any potentially relevant documents, as well as forward the message to colleagues who could also provide assistance. We will continue to contact experts until data saturation is reached (i.e. when the addition of other experts is unlikely to uncover additional documents).

We will include documents that provide dietary/nutritional advice or recommendations which optimize dietary intake and nutritional status and include reference to oral health of older adults living in care homes. A narrative synthesis of all guidelines and recommendations will be undertaken. Ultimately, we will provide a synopsis of the dietary advice for older adults living in care homes which also consider oral health. We will identify any gaps within existing guidelines, including those which do not consider oral health. These gaps will be explored further in WS3.

Work stream 2 (WS2) – Qualitative interviews with key stakeholders

WS2 will be led by PRB and AH who have extensive expertise in qualitative methodology. Semi-structured interviews with key stakeholders will be undertaken either by telephone, videocall or face-to-face at a suitable location. The research team are aware of the challenges of carrying out this work within the ongoing restrictions imposed by COVID-19. If these restrictions remain in place during the delivery of WS2 then only telephone or videocall options will be offered to the participants. The research team have engaged with the Project Echo NI management team about utilising existing video conferencing technology within care homes in the event that access is restricted: https://echonorthernireland.co.uk Project ECHO NI is funded by the Health and Social Care Board in Northern Ireland and facilitates a series of networks based on a spoke and hub arrangement including care homes. Project ECHO NI offers opportunities for education, video consultations and communication and could facilitate semi-structured interviews with care home residents, staff and managers if required. Similar Project ECHO networks exist across the UK.

An outline topic guide consisting of semi-structured open-ended questions has been developed in collaboration with our BELONG PPI group facilitated by NW and GMK Appendix 1). This will link with two on-going NIHR funded studies (17/3/11; 128773). The topics to be covered will be sense checked with the group with an opportunity for further input into the topic guide. The findings from the systematic review and scoping review (WS1) will help to refine the topic guide. The topic guide will be piloted with two members of BELONG prior to recruitment to ensure that the questions are clear and easy to understand for older adults living in care homes.

Stakeholders will be purposively sampled, and will include:

Group 1: Care home residents and family members (n=20)

Group 2: Care home staff including care home assistants, chefs, kitchen assistants and care home managers (n=20).

Group 3: Healthcare professionals with specific experience of working in the care home environment, including Dieticians and Nutritionists, Community Dentists, General Dental Practitioners, Nurses, General Medical Practitioners and Geriatricians. Researchers and experts, including researchers specialised in ageing, nutrition or oral health research, dental commissioners, Consultants in Dental Public Health and healthcare policy makers will also be included in this group (n=20)

A total of 60 stakeholders from across the UK will be recruited initially. It is expected that this number will be sufficient to achieve the aforementioned aims; however, if saturation of ideas and opinions is not reached with this sample size, further interviews will be conducted as necessary. Data saturation will be defined as the point in which no new themes emerge.

Stakeholders in Group 1 (Care home residents and family members) and Group 2 (Care home staff) will be recruited from a broad range of care homes and care home providers across the UK to ensure the generalisability and external validity of the study results. As mentioned previously, the research team have established strong links with the care home sector across the UK and with the ENRICH networks through various research projects (TOPIC, SENIOR and DECADE). The research team will work with a number of patient organisations including the Patient and Client Council, Age Sector Platform and Age UK to convey information about CONCEALED to their members. We will also with the Relatives & Residents Association (http://www.relres.org) who have previously contributed to work on oral health in care homes led by AH. We will work with the My Home Life programme to recruit care home staff and GM will utilise existing networks

within care homes including those already established with the Queen's Nursing Institute and the British Geriatrics Society Special Interest Group for Care Homes. An invitation will be provided to each organisation which can be distributed to encourage interested participants to contact the study team where they will receive further information about CONCEALED, including a Participant Information Sheet (PIS). Participants who are interested can then contact the research team to discuss the study in more detail, or if consent is given, the research team will contact them. Potential participants will be given at least 48 hours from discussing the study with the research team to decide whether they wish to take part. This recruitment strategy has been used very successfully with the recent DECADE study.

We plan to use a purposive sampling method for the identification and selection of stakeholders for the qualitative interviews. This sampling method will facilitate the selection of key stakeholders who are knowledgeable of the research area, and have the ability to communicate their opinions and experiences in an articulate manner. The range of stakeholders in the four groups including care home residents, family members, care staff, health professionals and experts will allow the collection of different perspectives.

A purposive sampling method was used in the DECADE study, and although recruitment was successful, it was clear certain demographic groups were underrepresented (e.g. 26% male participants). Furthermore, as this is a UK-wide study it is imperative that participants from the four nations are included. Therefore, we will employ a quota sampling strategy by using minimum quotas for the following categories:

1) At least 40% of the sample is male

2) At least 15% of the sample is from each constituent UK nation (England, Scotland, Wales and Northern Ireland)

The decision to recruit twenty participants for each of the four groups (n=80) is to ensure all stakeholder views within each group are captured and equally represented. However, an iterative process of data collection and provisional data analysis will be undertaken. Therefore, if data saturation occurs before reaching the *a priori* sample size estimation, recruitment will be terminated. Likewise, if saturation of ideas and opinions is not reached with this sample size, recruitment will continue as necessary.

Stakeholders in Group 3 (Healthcare professionals, researchers and experts) will also be recruited via UK-wide professional bodies including the British Dietetics Association, the Association for Nutrition, British Geriatrics Society, the Royal College of Nursing, Queen's Nursing Institute, the British Dental Association, British Society of Gerodontology and via links that have already been established through collaborative working. Again, these recruitment strategies were successful in the DECADE project led by GMK, where a similar range of stakeholders was recruited. Members of the research team have close links to many of these professional bodies across the disciplines of oral health, nutrition and nursing. Every effort will be made to recruit a diverse participant pool, with involvement from each major stakeholder group.

Interviews will last between 30-45 minutes and will be recorded and transcribed verbatim. Data will be anonymised, fully transcribed by a commercial transcription service, and analysed by researchers under the supervision of co-applicants PRB and AH. The transcripts will be line numbered for thematic analysis to develop a coding frame. Overarching themes will be developed from the coded transcripts by organising them into clusters based on the similarity of their meaning. These will then be checked against the coded extracts and the raw data to ensure that they form a coherent pattern and are representative of what the participants were trying to convey. Further refinement of the themes will be achieved through critical dialogue with the entire research team[51].

Work stream 3 (WS3) – Synthesis of evidence and production of recommendations

Having produced evidence in WS1 and WS2, the final WS within CONCEALED aims to synthesise this evidence into a series of recommendations which have input from all stakeholders to address the impact of dietary intake and nutritional status on oral health in care homes. WS3 will also develop a logic model to guide future research in this area.

The stakeholders who participated in WS2 will be invited to attend an online workshop (using videocall technology) to consider the evidence generated. The workshop will last no longer than three hours with refreshment breaks in between. We will aim to recruit 15 stakeholders, which is a sufficient sample size to manage and co-ordinate an online meeting and at the same time generate useful discussion. The stakeholders included will be:

Group 1: Care home residents and family members (n=5)

Group 2: Care home staff including care home assistants, chefs, kitchen assistants and care home managers (n=5)

Group 3: Healthcare professionals with specific experience of working in the care home environment, including Dieticians and Nutritionists, Community Dentists, General Dental Practitioners, Nurses, General Medical Practitioners and Geriatricians. Researchers and experts, including researchers specialised in ageing, nutrition or oral health research, dental commissioners, Consultants in Dental Public Health and healthcare policy makers will also be included (n=5).

Every effort will be made to recruit a heterogeneous sample, with similar numbers of stakeholders recruited from each stakeholder group. A researcher will facilitate the workshop, and NW, as a PPI representative, will chair the meeting to avoid a 'top-down' approach, i.e. the recommendations will not just be expert-driven but also patient-centred.

The findings from WS1 and WS2 will inform the development of a detailed protocol for the workshop. The workshop will include a presentation of key findings, open discussion and a voting/ranking activity, which will involve the stakeholders ranking the recommendations by importance using the scale proposed by GRADE[52]. In addition to information from WS1 and WS2, publicly available information on financial information relevant to care homes will be presented. Efforts will be made to source data from local council areas and through engagement with the National Care Association.
The outcome of the workshop will be to reach consensus among the stakeholders on a series of recommendations to ensure that oral health is considered within dietary guidelines for older patients within care homes. These recommendations will propose ways to improve dietary intake and nutritional status which do not actively contribute to the development of oral disease and are still effective in terms of nutritional status outcomes. This approach has been adopted successfully in the DECADE project.

WS3 will also develop a logic model to graphically depict where future clinical research could impact on dietary intake and nutritional status to have a positive impact on oral health in care homes. Logic models are a core component of intervention planning and development. The logic model produced by this evidence synthesis will highlight any theoretical and practical gaps, identify important intervention features, define intervention outcomes, define how the intervention is to bring about change in the intended outcomes and will highlight target areas for future implementation strategies.

Ultimately, it will provide a road map for the successful introduction of interventions in care homes, which aim to improve the oral health, dietary intake and overall nutritional status of older adults. Once the evidence synthesis has been completed the research team will decide the most appropriate type of logic model to use[53]. The logic model will be constructed to include the following elements:

Purpose - the relevance of the intervention, including a description of the 'problem' or 'opportunity' and who is affected (population);

Context – external factors that might influence the intervention (social, political, or physical);

Inputs – the resources or infrastructure required, including human resources, knowledge, skills or expertise, facilities and equipment, and any constraints/ barriers);

Activities – includes the processes, tools, technology and actions that will produce an output. How the resources are used;

Outputs - indicators that activities are undertaken or resources have been used as planned; and

Outcomes - the results or intended and unintended impacts of the intervention.

6. DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

What do you intend to produce from your research? What do you think the impact of your research will be and for whom?

The aim of this evidence synthesis project is to explore the role of dietary intake and nutritional status as aetiological risk factors for poor oral health in dentate older adults living within residential and nursing care homes. The main outputs are listed thematically below.

Patients
The CONCEAL project has been developed in response to the significant public health concern around poor oral health in care homes. Despite clear guidelines developed by NICE and other professional bodies the 2019 CQC report made for extremely concerning reading including the fact that 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[34]. These statistics illustrate why the oral health of care home residents is significantly worse than their community living peers[11]. Whilst this research team is already undertaking work to generate evidence around oral health interventions and delivery of operative dental care within care homes, CONCEALED will be the first project to critically examine the role of nutrition and diet in contributing to poor oral health in this population. This work will generate a systematic review on this topic plus a scoping review of existing guidelines. It will also provide qualitative and economic evidence from all stakeholders on the decision making around food and beverage provision in relation to oral health in care homes. This work will produce recommendations on improving dietary intake and nutritional status which can also have positive impacts on oral health in care homes. This work will ultimately lead to the development of an intervention to be trialled in a future clinical study utlising the logic model produced in WS3. By ensuring that we address diet and nutrition as a major aetiological factor in the development of oral disease we can prevent pain and suffering in dependent older adults and improve oral health related quality of life.

Academia
Existing links to the International Association of Dental Research (IADR) Geriatric Oral Research Group (GORG) and the European College of Gerodontology (ECG) will be made via GMcK who is President of GORG and past president of the ECG. The ECG aims to foster international co-operation, influence European policy and curriculum development. GT is also Past President of the European Association of Dental Public Health (EADPH) and Chair of the Platform for Better Oral Health in Europe, a joint initiative between the EADPH, CECDO, Association for Dental Education in Europe and the Oral Health Foundation, where GMcK also represents the ECG. GT is also the incoming president of the IADR Behavioural Epidemiologic and Health Services Research group. The research team is well connected to academic bodies within Nutrition (Association for Nutrition), Dietetics (British Dietetics Association) and Nursing (the Royal College of Nursing, Queen's Nursing Institute). All of these academic connections will be utilised to disseminate the results of CONCEALED.
We will publish the academic outputs from CONCEALED in Dental, Nutrition and Nursing journals. We will disseminate our results at the ECG, the International Association of Dental Research, the British Association for the Study of Community Dentistry and the British Society of Gerodontology.

Changes to practice
The research team are already embedded within the care home sector in the UK. They are currently working on two projects focused on preventative oral health practices

(TOPIC) and operative dental care for care home residents (SENIOR). CONCEALED would address the significant gap in oral health prevention by addressing the vitally important issues around current diet and nutrition practices which are impacting negatively on oral health for residents. The outputs from CONCEALED will be incorporated into training packages provided for care home staff and managers as delivered by GMK within the My Home Life programme. In his role as a NICE Fellow, GMK is working on improving oral health for older people. Within the current NICE guideline: Improving oral health for adults in care homes (NG48), the role of diet and nutrition in preventing oral disease is not addressed despite the committee highlighting the need to address poor oral health. GM sits on the Royal College of Nursing's Older People Forum and ensure that a summary of the findings from CONCEALED will be communicated to its membership of 450,000 nurses. GMK will work with NICE to ensure that the outputs from CONCEALED are included within future updates of NG48 to effect change within the care home sector.

Care Home Staff and Managers
The results of the study will feed directly into an existing educational programme, My Home Life where GMK provides training for care home staff and managers. All avenues for disseminating these results will be explored including working with Enhanced Health in Care Homes Team within NHS England and other equivalent bodies throughout the UK. Outputs developed as part of the TOPIC study have already been made available to care home staff and managers through this programme and the same model would be followed with CONCEALED. A user friendly infographic displaying a summary of the findings from CONCEALED will be produced and disseminated through the care home networks already established by the research team. The infographic would also be shared via social media (including Twitter) to maximise exposure.

Changes to policy
PRB, GMK and GT have strong links to national and international policy-makers as PRB is the Deputy Chief Dental Officer in Wales. This gives the research team a direct line to policy-makers for dissemination of CONCEALED. In Northern Ireland, GMK is working closely with the acting Chief Dental Officer on a focused update to oral health policy for older adults following an 'Oral Health Matters' event organised by the British Dental Association. This drew together policy-makers, Chief Dental Officers, the British Dental Association and Assembly Ministers in Northern Ireland. The decision was taken to focus on older people's health as a priority and this will form an important channel for the dissemination of the results of the study. PRB, GMcK and GT have also initiated the formation of a new network linking policymakers and researchers together called: RETHINK oRal hEalTH In aging research NetworK. The research team are in active discussions with Public Health England about RETHINK and they are keen to work with the research team to learn from the results of the studies being undertaken by the research group. GMcK, PRB and GT are key figures in a number of International and European organisations: ECG, IADR's GORG, CECDO and PBOHE. GMcK is a co-author on the 2019 National Oral Health Policy for the Republic of Ireland: https://health.gov.ie/blog/publications/smile-agus-slainte-national-oral-health-policy/. GT has links with the Public Health England "Vulnerable Older Adults" group and has an on-going collaboration with the Centre for Policy on Ageing (CPA) that promotes the interests of older people through research, policy analysis and knowledge transfer (http://www.cpa.org.uk/). From a nutrition/dietetics perspective, JW is a Trustee for the Nutrition Society, one of the largest learned societies for the study if nutrition science globally, whilst CME has active networks with dietetic colleagues locally, nationally and internationally (e.g. European Federation of the Association of Dietitians (EFAD) and The European Nutrition for Health Alliance (ENHA)).

Regulators
The research team has collaborative links with the Regulation and Quality Improvement Authority (RQIA) (https://www.rqia.org.uk/) via the TOPIC project. This is the independent body responsible for monitoring and inspecting the availability and quality of health and social care services in Northern Ireland, including care-homes, and encouraging improvements in the quality of those services. The research team will share the outputs from CONCEALED with RQIA, the Care Quality Commission (CQC) and Care Inspectorate Wales as well as the Northern Ireland Social Care Council.

How will you inform and engage patients, NHS and the wider population about your work?

The research team have strong links (via PRB) with ENRICH-Cymru in Wales (https://www.swansea.ac.uk/enrich-cymru/) (e.g. VOICE) and Care Forum Wales (https://www.careforumwales.co.uk/), which represents over 450 care-homes, nursing homes and other independent health and social care providers across Wales. As highlighted on their website, Care Forum Wales actively share best practice and resources. The research team will also utilise existing relationships that have developed with a number of other organisations in Wales, including the Centre for Ageing and Dementia (http://www.healthandcareresearch.gov.wales/centre-for-ageing-and-dementia-research/) and the largest third sector organisation in Wales: Age Cymru (http://www.ageuk.org.uk/cymru/). In Northern Ireland collaborative links have been formed with Age Sector Platform which represents a strong unified voice for older people in Northern Ireland (https://www.agesectorplatform.org/). It is the charity responsible for the Northern Ireland Pensioners Parliament. Age Sector Platform has a membership of individuals and older people's groups across Northern Ireland, representing approximately 200,000 people. Members of Age Sector Platform contributed to the plain language summary of this document. These networks will complement BELONG (https://www.qub.ac.uk/researchcentres/CentreforPublicHealth/Research/PPIGroup/) and PARC-Bangor (http://nworthctu.bangor.ac.uk/parc-bangor.php.en), to ensure strong PPI representation.
Informal dissemination networks will be made by these PPI groups, who will also link to the Patient and Client Council http://www.patientclientcouncil.hscni.net), which collaborated on HS&DR 14/19/12. This will ensure dissemination of information directly to dependent older people and their carers/relatives and care-home managers/staff. Our PPI co-applicants will also ensure a strong patient-facing dissemination strategy.

What further funding or support will be required if this research is successful?

The ultimate aim of this research is to improve the oral health of older adults within care homes. It is widely accepted that current oral health provision in this sector is lacking, with a focus on symptomatic relief of oral discomfort rather than an evidence-based policy driven approach centred around prevention for an increasingly partially dentate population. The outputs from CONCEALED will inform a future clinical study to test an co-designed intervention to improve dietary intake and nutritional status for older patients in care homes which does not actively contribute to the development of oral disease, but is still effective in terms of nutritional status outcomes. The logic model produced in WS3 will guide the design of this research to focus on the intended outcome of improving oral health for older adults in care homes.

What are the possible barriers for further research, development, adoption and implementation?

Working within the care home sector we are aware of the challenges of implementing changes in this environment. This has been demonstrated with the introduction of the NG48 guideline which has required additional resources to be developed to encourage implementation[15]. A 2019 report from the Care Quality Commission (CQC) highlighted that 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, despite clear recommendations on these issues within NG48[34].

The CONCEALED project has been designed to be inclusive of care home staff and managers as well as patients. Within WS2 care home staff and managers will have the opportunity to discuss their views on nutrition and diet in relation to oral health including the financial drivers of food and beverage provision with care homes. WS3 will also include key stakeholders, including those responsible for implementing change, in development of recommendations. These activities will ensure that we include care home staff and management within the project outputs and that any proposals for change are realistic and financially achievable. The clear pathways to education and training for care home staff and managers offered by the My Home Life programme will ensure that the outputs from CONCEALED are disseminated to those responsible for effecting change.

7. PROJECT / RESEARCH TIMETABLE

The total time scheduled for the project is 24 months. This is detailed in the table below:

Milestones	Workstream	Start Date	End Date	Duration (months)
Systematic Review: In patients living within care homes, what is the impact of dietary intake and nutritional status on oral health	1	1/4/22	31/1/23	10
Scoping Review of UK Dietary Guidelines and Policy Documents	1	1/6/22	31/1/23	8
Development and refinement of topic guide	2	1/10/22	31/1/23	4
Recruitment of Participants	2	1/2/23	30/6/23	5
Qualitative Interviewing	2	1/3/23	31/7/23	5
Transcription and analysis of qualitative interviews	2	1/4/23	31/10/23	7
Development of recommendations, including workshop with stakeholders	3	1/10/23	31/10/23	1
Dissemination and write up	1, 2, 3	1/4/22	31/1/24	10

Changes to Project Timelines
The project is on track to complete during the proposed timeframe. The start date for the qualitative aspects of WS2 were delayed as a result of COVID-19 regulations within care homes preventing engagement and localised outbreaks of further COVID infections during winter 2022. In consultation with care homes it was guided best to actively start engagement in Spring 2023. This has now commenced.

8. PROJECT MANAGEMENT

CONCEALED will be led by GMK as PI who is an experienced clinical researcher and internationally renowned gerodontologist. He is currently President of the Geriatric Oral Research Group at the International Association for Dental Research and past president of the European College of Gerodontology. He is a Co-PI on one NIHR funded study (17/03/11) and Co-I on a second (NIHR128773). He is supported by an extremely strong research team with extensive experience of leading and delivering NIHR funded research including PRB (11/1025/04; 14/19/12; NIHR/CS/010/004; NIHR128773; 16/01/79, 17/03/11), GT (17/03/11; NIHR128773), JW (14/67/20; NIHR131509) and CON (08/14/19; NIHR129125; NIHR128773; NIHR131817; 17/03/11). This group has an established track record of research collaboration resulting in high quality outputs.

The research team is made up of the majority of oral health researchers within the UK focused on gerodontology. In order to explore the complexities of the research questions posed with CONCEALED a multidisciplinary research team has been assembled to provide additional expertise in nutrition and dietetics, nursing and health economics. WS1 will be led by GMK with input from PRB, GT, AH, JW and CME. GM will co-lead WS1 and can call on his clinical background as a nurse within the care home sector and his training as a Fellow with Evidence Synthesis Ireland. WS2 will be led by AH and PRB with input from GT, GMK, JW and CME. AH and PRB have extensive experience in qualitative research methods including working with older people. CON will contribute to WS2 where the financial costs of providing food and beverages to care home residents will be explored. WS3 will be led by JW and CME with input from all members of the research team. They will ensure that the recommendations produced in partnership with key stakeholder prioritise both nutritional and oral health outcomes in an achievable manner. PPI input will be provided at all stages of the project by NW who is a member of BELONG and has worked with this research team previously. Research team meetings will be scheduled on a fortnightly basis via Microsoft Teams hosted by the Centre for Public Health at Queen's University Belfast. Given the ongoing restrictions around COVID-19, videoconferencing will be planned for all research team meetings during the CONCEALED project, this approach has been adopted successfully in other ongoing projects involving this team including TOPIC, SENIOR and DECADE. Queen's University Belfast will act as sponsor for the CONCEALED project and GMK will be responsible for overall delivery of the project and reporting to NIHR.

In order to provide external oversight of the CONCEALED study, a Study Steering Committee (SSC) will be established to oversee the progress of the project and provide external advice to the PI. The SSC will oversee the running of CONCEALED on behalf of the sponsor and funder. The SSC will consist of national and international experts who represent key stakeholders in care home provision for older adults. Those invited to join the SSC include Dr Milli Doshi (past president of the British Society for Gerodontology), Mrs Wendy Grudgings (Manager, Faith House Residential Home Belfast), Professor Denis O'Mahony (Consultant Medical Geriatrician, Cork University Hospital), Professor Ashely Adamson (Professor of Public Health Nutrition, Newcastle University), and a PPI representative from PARC-Bangor (http://nworthctu.bangor.ac.uk/parc-bangor.php.en). The SSC will meet every six months with the PI and all meetings will be via Microsoft Teams hosted by the Centre for Public Health at Queen's University Belfast.

9. ETHICS / REGULATORY APPROVALS

Due to the nature of the activities planned in WS1, this element of CONCEALED does not require ethical or regulatory approval. Ethical approval for WS2 and WS3 has been provided by the Faculty of Medicine, Health and Life Sciences Ethics Committee, Queen's University Belfast.

As part of the ethics application all participant information was be developed, read and sense checked by NW, PPI co-applicant and the members of BELONG. Queen's University Belfast will act as the sponsor for the CONCEALED study.

10. PATIENT AND PUBLIC INVOLVEMENT

The research questions driving this evidence synthesis have come from previous qualitative work with care home residents, family members and carers undertaken by members of this research team as part of the DECADE study. Whilst the focus of DECADE was on developing a core outcome set for oral health services research for dependent older adults, a consistent theme which emerged from the qualitative interviews was the relationship between oral health and diet within care homes. One carer reported that sugared dietary supplements "are given to all residents in their home routinely" with no consideration of the residents' oral health as it is "not a priority". One family member reported her frustration that care home staff were providing her mother with "sugared juice" and that "the cupboards and drawers in her room were full of biscuits and chocolates from visitors". She reported that her mother entered the care home with "a full set of teeth but the medicines, food and drinks provided in the home had rotted her teeth". One care home resident reported that care home staff "would never ask you if you've brushed your teeth or plate (denture) after a meal".

We have included a PPI representative (NW) on the research team who has previous experience working with this research team. This study has been developed in partnership with BELONG (https://www.qub.ac.uk/research-centres/CentreforPublicHealth/Research/PPIGroup/), which is a PPI group consisting of older adults from Northern Ireland, and PARC-Bangor (http://nworth-ctu.bangor.ac.uk/parc-bangor.php.en). Members of BELONG contributed to the DECADE project by participating in qualitative interviews which ultimately gave rise to this application. NW is a member of BELONG who has contributed to the design of this research project, particularly through helping to design the outline topic guide which will be used for the semi-structured interviews. As part of this application NW has helped the research team to write the plain English summary and the plans for widely disseminating the study outcomes, particularly to older patients, family members and the general public. CONCEALED will compliment both the TOPIC and SENIOR studies which are focused on oral health interventions, but do not include dietary intake and nutritional status, to improve oral health within care homes.

11. PROJECT / RESEARCH EXPERTISE

GMK is a Clinical Reader / Consultant in Restorative Dentistry and a gerodontologist with experience of clinical trials in older adults (PHR 17/03/11; NIHR128773: SENIOR). He is president of the Geriatric Oral Research Group within the International Association for Dental Research and a Fellow with NICE focused on improving oral

health for older patients. He will act as PI for the overall study. JW is Professor of Human Nutrition at QUB and specialises in the conduct of dietary intervention studies and the development of interventions to encourage long term behaviour change. She is the PI of the Genius School Food Network which partners with government, professional bodies and academia to encourage a more health-promoting food and nutrition system in UK schools. CME is a dietitian and lecturer in Human Nutrition and Ageing Research at QUB. CME has an active portfolio of research projects in the area of nutrition for prevention of age-related complex diseases including NIHR128729. PRB is Professor of Health Services Research at Bangor University and the Deputy Chief Dental Officer for Wales. He is an experienced NHIR PI (NIHR/CS/010/004; HS&DR 11/1025/04; HS&DR 16/01/79; NIHR128773: SENIOR), and is Director of NWORTH CTU. GT is a Professor in Dental Public Health with experience in the relationship between oral and general health among older populations. CON is Professor of Health Economics focused on application of economics to healthcare including oral health and gerontology. PRB, GMK, GT and CON are currently working together on NIHR PHR 17/03/11: TOPIC and NIHR128773: SENIOR. AH has experience in both quantitative and qualitative research methods with a particular interest in the oral health of older people. NW is a member of the BELONG PPI group and has a long track record of working with GMK and JW on research projects. SW is a research fellow who works with GMK, GT and PRB on TOPIC, SENIOR and DECADE. Her research is focused on evaluating interventions aimed at improving oral health of dependent older adults. GM is a qualified nurse working as a lecturer in nursing and midwifery at QUB. His research interests centre around caring for older people and he is active in nursing education. He was previously the national research coordinator for Four Seasons Healthcare and a trustee for Age NI. GM is a current Fellow with Evidence Synthesis Ireland and the Pathway Lead for Nursing Care of Older People with the School of Nursing at QUB. NMC has extensive experience in delivering research in care homes, hospices and with older adults, including those with cognitive decline. Her recent research has focused on co-production of resources for older adults with dementia in care homes.

12. SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK

The CONCEALED study will deliver the following:

1. A high quality systematic review based on the focused PICO question: In patients living within care homes, what is the impact of dietary intake and nutritional status on oral health.
2. A scoping review of current guidelines on UK guidelines and policy documents related to dietary intake and nutritional status for older adults living in care homes in the UK. Particular attention will drawn to guidelines which consider oral health as well as dietary intake and nutritional status.
3. A qualitative examination of key stakeholders views on the impact of dietary intake and nutritional status on oral health for patients living in care homes including an examination of the financial drivers for food and beverage provision.

4. Recommendations, based on the evidence gathered, for improving dietary intake and nutritional status for older adults in care homes which also reduce the aetiological impacts on oral disease.
5. A logic model to guide future clinical research aimed at improving both dietary intake and nutritional status, and oral health for older adults in care homes.

The research team are aware of the challenges of carrying out this work within the ongoing restrictions imposed by COVID-19. If these restrictions remain in place during the delivery of WS2 then only telephone or videocall options will be offered to the participants. The research team have engaged with the Project Echo NI management team about utilising existing video conferencing technology within care homes in the event that access is restricted: https://echonorthernireland.co.uk Project ECHO NI is funded by the Health and Social Care Board in Northern Ireland and facilitates a series of networks based on a spoke and hub arrangement including care homes. Project ECHO NI offers opportunities for education, video consultations and communication and could facilitate semi-structured interviews with care home residents, staff and managers if required.

Appendix 1: Outline Topic Guide
The impaCt Of dietary intake and Nutritional status in CarE homes on orAl heaLth: an EviDence synthesis (CONCEALED)

Interview Protocol

The interviewer will introduce him/herself and reiterate the purpose of the interview.

1. Use semi-structured interviews to gather information from care home staff (carers, care assistants, care home managers), health professionals, residents and family members on: influences and drivers of dietary intake and nutritional status amongst older adults in care homes; the impact of dietary intake and nutritional status on oral health amongst older adults living in care homes.
2. Examine the economic drivers of preparing and providing food and beverages for older adults in care homes through semi-structured interviews with relevant care home staff (including care home managers, chefs and kitchen assistants).

To explore:
1) The views and perceptions of care home staff, health professionals, residents and family members on the influences and drivers of dietary intake and nutritional status amongst older adults in care homes.
2) The views and perceptions of care home staff, health professionals, residents and family members on the impact of dietary intake and nutritional status, on oral health amongst older adults in care homes.

The interviewer will reiterate that the interview will be tape-recorded and transcribed for research purposes, but transcripts will be anonymised i.e. will not contain participant names. Also the audio tapes will be destroyed when the typed transcripts have been prepared. In addition, it will be made clear to participants that they can inform the facilitator if there are any particular statements they do not wish to be transcribed at the end of the session.

The interviewer will explain to the participants that they are free to stop the interview at any stage if they feel uncomfortable with any of the discussions or do not wish to participate further.

The interviewer will ask if participants have any questions before starting the discussion.

Interviewer guide:

Care home residents and family members (Group 1 and Group 2):

- Tell me how you feel about your current diet? *(Probe: consumption of sugar foods/beverages and if take dietary supplements).*
- What do you feel are the main factors that influence your dietary intake and/or nutritional status? (*Probe: main barriers and facilitators, i.e. health status, oral health, medication use, mobility issues, appetite, type of meals/snacks provided in the care home and assistance provided*).

- How do you feel about your teeth and mouth care? (*Probe: general oral hygiene, daily routine mouth care, visits to the dentist and care worker support*).
- Do you feel your oral health has improved, has worsened or has remained the same since entering the care home? *(Ask for details, i.e. any oral health (dental) problems that required treatment since being in care? I.e. dental caries, gum disease, extractions, toothache).*
- Since entering the care home, do you feel that your diet (foods consumed) has had an impact on your oral health? *(Probe – has your consumption of sugary foods/beverages increased/decreased, how often would you consume these types of foods, consumption of dietary supplements high in sugar).*
- Would you be willing to change your diet in order to improve your oral (dental) health? *(I.e. reduce intake of sugar foods and beverages, substitute for healthier versions).*

Care home staff (Group 3):

- What do you feel are the main factors that influence the dietary intake and/or nutritional status of older adults in your care home? (*Probe: main barriers and facilitators, i.e. health status, cognitive function, oral health, medication use, mobility issues, appetite, type of meals/snacks provided in the care home and assistance provided*).
- Do you follow any nutritional guidelines for your residents when meal planning? (Ask for details).
- Is oral health considered when planning meals for care home residents? *(Probe: sugar content of foods).*
- What is your care home's policy regarding visitors bringing in foods and beverages for residents?
- What is the current oral healthcare practice for older adults in your care home? *(Probe: assessment on arrival, daily mouth care routines and access to dental services)*
- Do you feel the dietary intake (foods consumed) of older adults living in care homes has an impact on their oral health? *(Probe –consumption of sugary foods/beverages and dietary supplements high in sugar).*
- What do you suggest the care home could do to reduce the intake of sugary foods and beverages? What help and resources would you require?

- What are the financial constraints on preparing foods and beverages for older adults in care homes? (*Probe – time available for food preparation, staff availability for food preparation, types of meals prepared including preparation of fresh ingredients vs premade products)*
- What are the financial costs of providing foods and beverages for older adults in care homes? (*Probe – budgetary constraints, cost of food and beverages, source of food and beverages)*

Healthcare Professionals and researchers (Group 4):

- What do you feel are the main factors that influence the dietary intake and/or nutritional status of older adults living in care homes? (*Probe: main barriers and facilitators, i.e. health status, cognitive function, oral health, medication use, mobility issues, appetite, type of meals/snacks provided in the care home and assistance provided*).
- Are you aware of any nutritional guidelines for older adults living in care homes? (*Ask for details*) If yes, is oral health considered? (Ask for details)
- How do you feel about the oral health status of older adults living in care homes? (Is it poor, why? Probe: oral hygiene, access to dental services, knowledge and training of care home staff)
- Do you feel the dietary intake (foods consumed) of older adults living in care homes has an impact on their oral health? *(Probe –consumption of sugary foods/beverages and dietary supplements high in sugar).*
- What do you suggest care homes could do to reduce the intake of sugary foods and beverages? What help and resources would they require?

Conclusion:

- Do you have anything else you would like to add that we haven't already discussed?
- Thank you for your contribution.
- Ask the participant if there are any particular statements that they do not wish to be transcribed.

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