STUDY PROTOCOL

Title: Improving the Oral Heal**T**h of **O**lder **P**eople **I**n **C**are Homes: A Feasibility Study (TOPIC)

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1. Background

Poor oral health is an increasingly common problem for older adults (defined as those over 65 years of age). Approximately 40% of the 75-84 age group and 33% of the 85+ age group have dental caries with periodontal disease affecting 69% of those over 65 years of age [1]. Oral conditions impact on the quality of life of older adults [2, 3], their general health and diet [4, 5]. Access to domiciliary services is difficult and hospital admission for dental problems can be distressing and costly [1]. Income-related inequality in oral health of older adults is a major issue [6, 7]; therefore, the effective prevention of oral diseases is paramount.

Four per cent of people aged over 65 and one fifth of those aged over 85 live in care homes [8]. Care homes is a broad term that refers to both residential and nursing care homes. About half of all care home residents have their own natural teeth [9] but their oral health is much worse than their peers living in the community (e.g. caries prevalence was 73% vs. 40%) [10]. Good daily oral hygiene is essential for the maintenance of complex dental restorations. With increasing age, the ability to care for oral health (including dental restorations) can deteriorate; poly-pharmacy can lead to an experience of having a dry mouth; and, diets can become rich in sugars [11]. All these factors increase the risk of oral disease and directly impact on comorbidities.

Strategies for this population are to prevent disease, reduce pain and co-morbidity [12]. However, a Public Health England (PHE) survey showed current provision and service in care homes to be poor [13]. A Priority Setting Partnership (PSP) led by a Co-Principal Investigator (CO-PI) (PRB) found that maintaining function, dignity and the fear of losing the ability to look after your own teeth were key issues among older adults [14]. The World Health Organisation has focused on healthy ageing and prioritised the designing of health and long-term care systems that are fit for ageing populations [15]. However, no relevant systematic reviews have been published (scoped as part of a Cochrane Effective Practice and Organisation of Care Review, led by CO-PI (PRB). The evidence for interventions on promoting oral health among care home residents is weak [16] since there is uncertainty about effect size estimates, recruitment and retention of participants, intervention fidelity and appropriate outcome measures. This makes the design of a full trial problematic at this stage.

The National Institute for Health and Care Excellence (NICE) recently issued guideline NG48 [17], which aims to maintain and improve the oral health of care home residents. The aim of this study is to assess the feasibility of promoting oral hygiene and preventing oral diseases in older people in care homes, following the NICE guideline recommendations.

2. Aim

The aim of this study is to determine the feasibility of a multi-centre cluster randomised controlled trial of a complex intervention based on a recent NICE guideline for the oral health of older people in care homes.

2.1 Objectives:

1. Undertake semi-structured interviews and co-design workshops (**Work Stream 2) (WS2)** to refine a complex intervention to promote oral health in care home residents (guided by the framework of Stirman et al. and the Davidson et al. toolkit [18, 19]) in order to:
    a) Ensure the intervention is clinically and culturally acceptable;
    b) Understand the context and mechanisms for delivery; and
    c) Work with the Patient and Public Involvement (PPI) group and stakeholder group to determine how the intervention could be optimised.

2. Determine the feasibility of undertaking a definitive trial to evaluate the complex intervention to promote oral health (**WS1**) to determine the:
    a) Proportion of care homes that agree to participate;
    b) Number of residents that are eligible and able to consent;

c) Proportion of eligible residents that agree to participate;
d) Proportion of participating residents that receive the intervention per the protocol;
e) Proportion of care homes and residents that remain in the study (at least 75% completion rate required);
f) Proportion of completed measures used in the study (at least 75% completion rate required): i) oral health assessments; ii) quality of life questionnaires; iii) clinical measurement records; iv) oral symptoms checklist diaries; and
g) Impact on recruitment of varying the 6-CIT screening tool [20] threshold;

3. Undertake a parallel process evaluation using semi-structured interviews to explore how the intervention could be embedded in standard practice guided by Pfadenhauer et al.'s framework [21] to maximise pathway to impact with (**WS2**):

i. Managers and staff to assess the intervention's feasibility and sustainability;
ii. Residents to explore the intervention's acceptability;
iii. Managers and residents that refused participation to explore their reasoning;

4. Develop a cost-consequence model (**WS3**) to determine the relevance and relative importance of the different outcome measures in the decision-making context.

3. Plan of Investigation

This research project has three WSs as outlined below. The different WSs are based on the nature of the work rather than on the chronological order of the stages of the research. Therefore, certain elements of WS2 precede WS1, while other elements of WS2 run in parallel with WS1. For a full description of the time allocation of the different WS, please see the study Gantt chart. All procedures are presented within the relevant WS and where there is overlap, reference is made to the relevant section of the associated WS.

3.1 Work Stream 1 – Feasibility of a Pragmatic Cluster-Randomisation Controlled Trial

WS1 will explore whether a definitive trial is feasible in terms of recruitment and retention of participants, at the care home and participant level. It will also explore the fidelity of the intervention delivery in care homes and its acceptability to care home staff (managers, carers and other staff) and residents. Therefore, the WS1 will address the aforementioned objective no.2.

3.1.1 Study Population

This feasibility study will be undertaken in up to 24 care homes at each site (London and Northern Ireland) with recruitment on both arms of the study in each setting. In order to achieve the overall estimated sample size for the study, we aim to recruit up to twelve care homes at each study site with a minimum of five residents (participants) to be recruited in each home (n=120); 60 participants will receive the co-designed intervention (n=60) and 60 will receive routine practice (n=60). A minimum of five participants will be recruited at each care home. When the care homes are randomised to either the control or intervention arm, they will be stratified according to study site (London and Northern Ireland), so that that there are approximately equal number of intervention and control homes at each study site. The specific inclusion and exclusion criteria for the trial will be:

Cluster level (Care Homes):
Inclusion criteria:

- Care homes must have a minimum capacity of twenty residents (as approximately half are expected to be edentate).

Exclusion criteria:

- Care homes that only provide high-dependency units or end-of-life care.

Individual level (care home residents):

Inclusion criteria:

- 65 years and over;
- Dentate or partially dentate;
- Full-time resident in care home;

Exclusion criteria:

- Residents who are receiving end-of-life or palliative care;
- Residents with severe cognitive impairment (6-CIT score of 10 or higher);
- Residents who are currently taking part in another oral health intervention study;
- Residents who do not have a working level of oral English.

3.1.2 Recruitment

Recruitment will be a two-stage process (Figure 1, p.13). The first stage will be the recruitment of the care homes. The research team will make contact with independent care home providers in London and Northern Ireland to ensure that a broad range of care homes are recruited. The feasibility study will be conducted in up to 24 care homes (with expected 50% recruitment rate, up to 48 homes will be approached). An minimum of 5 residents will be recruited in each home resulting in a recruited sample of 120 participants; a maximum of 20 participants will be recruited at each care home. Recruitment will be restricted to a maximum of 6 months and participants will be followed-up over a 12 months period (unless they choose to withdraw or are lost to follow up).

Eligible care homes will be informed about the study (by letter/email/phone call or in person) and invited to participate. For London, this will be facilitated through the Clinical Research Networks in North Thames and North West London, while also making active use of the ENRICH network (https://enrich.nihr.ac.uk/pages/research-ready-care-home-network). For Northern Ireland, this will be facilitated through the the South Eastern NHS Trust links. If eligible care homes want further information, a member of the research team will arrange a visit in person to provide the care home managers with the relevant Participant Information Sheet for Care Homes (PIS_WS1_CareHomes), further discuss the study and answer any questions about it. Potential care homes will be given at least 48 hours from discussing the study to decide whether or not they wish to take part. Eligible care homes will be contacted by the researcher to confirm whether they would like to take part in the study.

The second stage of recruitment is the recruitment of eligible residents in participating care homes. Eligibility will be determined by a screening process that will comprise of three stages. In Stage One, the care-home manager will identify potentially eligible residents from their home. Potential eligible residents in participating care homes will be identified using their personal information stored in the care home records. Only care home managers (or staff) will have access to care home records. Potentially eligible residents will then be given a Participant Information Sheet (PIS_WS1_Eligibility) by the care-home manager for the two further eligibility tests (as these warrant separate consent). After forty-eight hours (to provide sufficient time for the residents to read PIS_WS1_Eligibility), the research assistant will ask them to consent (ICF_WS1_Eligibility) to undergo two further tests to determine their eligibility (6-CIT and dental examination).

Once consented at this stage (ICF_WS1_Eligibility), the research assistant will undertake the 6-CIT test (Stage Two). Participants with normal cognitive function (6-CIT score of 0-7) and those with mild cognitive impairment (6-CIT score of 8-9) will be included in the study. Participants who score 10 or higher on the 6-CIT will be offered the chance to complete it again on different days and at different times. This approach might facilitate higher rates of inclusion, considering also that cognitive function tends to fluctuate in this population. A record of the 6-CIT score will be kept in a spreadsheet.

In Stage Three, the research assistant will confirm whether the resident is dentate or partially dentate, by performing a simple 'lift-the-lip' exercise. If eligible, the research assistant will provide an overview of the study (aim of the study, what it involves and what we hope to achieve) to the eligible

residents and provide them with a Participant Information Sheet for the feasibility study (PIS_WS1_Feasibility). Fourty-eight hours after the eligible resident has been given the Participant Information Sheet for the study (PIS_WS1_Feasibility), the research assistant will ask the resident to complete the Informed Consent Form for the feasibility study (ICF_WS1_Feasibility).

Considering that a considerable number of residents in many care homes will not be eligible for the study and also the upper limit of 20 participants per care home, this may practically mean that in some care homes we will approach all eligible residents for participation in the study. For large care homes where the number of eligible residents is much larger than the aforementioned figure, a sample of potentially eligible participants will be randomly selected by the research team and approached for participation in the study.

3.1.3 Informed Consent

For the recruitment of care homes, a research assistant who has completed their Good Clinical Practice (GCP) will go through the relevant PIS for care homes (PIS_WS1_CareHomes) with the manager of the potentially eligible care home, and discuss any questions or concerns that the manager may have. If the care home manager requires more information from the research assistant, they will be shown the study protocol and any relevant study documentation. The care home manager will then be asked whether they are happy to consent to their care home taking part in the research study. No specific consent form is required for the care homes in order to participate in the study, as the protocol and study documents are legally binding documents.

For the recruitment of care home residents, the aforementioned screening process describes also the stages of the informed consent process. A research assistant will go through the PIS_WS1_Eligibility with the potentially eligible resident in terms of undertaking the 6-CIT cognitive screening test and the brief dental examination to determine eligibility, and explain any issues that the potential participant may be unclear about. The potentially eligible resident will then be asked whether they are happy to consent for the eligibility tests. Written consent will be obtained via the ICF_WS1_Eligibility and stored securely in accordance with Data Protection procedures.

Following this, a research assistant will go through the PIS_WS1_Feasibility with eligible residents and follow the same process to explain any issues they may be unclear about. Then, and allowing for fourty-eight hours as per standard practice between PIS and ICF, the eligible resident will be asked whether they are happy to consent to participate in the feasibility study. Written consent will be obtained via the ICF_WS1_Feasibility (undertaken either by the research assistant or the dental examiner) and stored securely in accordance with data protection procedures.

3.1.4 Study Design Overview

Eligible care homes will be randomised (via NWORTH CTU) based on a 1:1 ratio (approximately equal number of intervention and control care homes). Research assistants at each site will inform the NWORTH CTU when there are two eligible care homes as they will be randomised in pairs. Randomisation will take place separately for each setting (London, Northern Ireland) and will be at care home level; therefore, once care homes have been entered into the system, an independent NWORTH member of staff will allocate the homes using a dynamic adaptive randomisation algorithm [22].

The intervention group will receive a complex intervention that fits within the MRC framework [23, 24] and is based on the recommendations of the NICE guideline on “Oral health for adults in care homes” (NG48) [17].

This complex intervention will include:

1) Administration by trained care home staff of the Oral Health Assessment Tool [25]: a brief and practical assessment of the resident’s oral health needs that is reviewed and updated over time.

Administration will take place immediately prior to the initial dental assessment at baseline and at the 12 month follow-up visit.

2) A “support worker assisted” daily tooth-brushing regime with toothpaste containing 1,500ppm fluoride (which will be provided by the research team). This aspect of the intervention will be added to resident’s drug charts to assess fidelity of the intervention implementation.

3) A care home staff training package (containing a training video and hard copy training manuals and laminated reference guides, as well as online training through a dedicated website) to facilitate appropriate knowledge and skills in oral health promotion.

Intervention materials (‘Oral Health Assessment Tool’, ‘Personal Oral Care Plan’, ‘Tips and tricks’ and ‘Weekly Oral Hygiene Record’) have been developed from a co-design process that worked with residents and care-home staff to understand how the NG48 guidelines could be best implemented in practice. This process is described in detail in WS2. The aforementioned intervention materials are supported by a care-home staff training video to create a package of NG48-informed measures to promote knowledge and skills in oral health promotion, amongst care-home staff. To further facilitate training and treatment fidelity, a dedicated web platform will be made available. Homes will be required to undertake formal training prior to the intervention, which will be overseen by the care home manager and the research team and will be added to the log of mandatory training.

The care homes and participants will not be able to be blinded, due to the nature of the intervention. However, the clinical dental examiners that will record the baseline and 12-months follow-up clinical outcome measures and the study statistician will be. The study statistician will become unblinded after primary analysis has been completed.

Participants on the control arm will receive routine practice. The results from a PHE survey, the PSP (led by CO-PI (PRB)) and preliminary data from an on-going study in Scotland led by CO-I (AS), suggest that this practice is likely to be heterogeneous and include intermittent tooth brushing with toothpaste by the residents [13,14], usually relying on the care home staff for their oral hygiene. This has been confirmed by the study’s PPI group and a review of existing literature on oral health practices in care homes [26], as well as from preliminary qualitative research findings from a recent project carried out in care homes in North London by the Chief Investigator (CI) (GT) and CO-I (AH) (funded by the Oral and Dental Research Trust). WS2 (outlined below) will enable the research team to gather information about current practice in care homes assigned to the control arm.

3.1.5 Data Collection

All study participants (intervention and control arms) will undergo an oral examination to collect clinical data. Participants will also provide self-report information on person-centred measures via an interviewer-administered questionnaire and a symptom checklist. The following assessments will take place at the care home for each selected resident:

• Clinical outcomes (assessed at baseline and 12 months) will include the number of teeth with coronal and root caries lesions, the proportion of teeth with visible plaque and the proportion of teeth that bleed on probing (BoP). The dental examination will be carried out by trained dental examiners, commissioned by the research team from the South Eastern Trust, in Northern Ireland, and the Whittington Health Dental Services, in London.

• A brief and practical assessment of the residents’ oral health needs. This will be assessed using the oral health assessment tool (OHAT) [25]. The dental examiner will undertake this assessment at baseline and 12 months and give these to the research assistant.

• Oral symptoms and domiciliary dental care: This refers to the number of reported episodes of dental pain, sepsis, discomfort and domiciliary visits. Care support staff using a checklist diary log will collect this information weekly. Research assistants will also collect this information at baseline, 6 months and 12 months.

• Health-related quality of life: This will be assessed through the EuroQol five dimensions questionnaire (EQ-5D5L) [27]. This questionnaire will be administered by a research assistant to all participants at baseline, 6 and 12 months.

• Oral health-related quality of life: This will be assessed through the Oral Impacts on Daily Performances (OIDP) [28]. This questionnaire will be administered by a research assistant to all participants at baseline, 6 and 12 months.

In addition, data will be collected at care home level (from the managers) for all participating care homes, through a relevant form. Information will be collected at baseline and at 12-month follow-up and refers to the funding and organisational features of the care home, the number and overall demographic and health characteristics of residents, the number and training of the staff, the provision of oral health programmes, and the arrangements for health care of the residents.

Furthermore, we will collect data to facilitate the assessment of the fidelity of the intervention. This refers only to the care homes in the intervention arm of the study and will include information on completion rates (fully, partially or not completed) for the following: 1) OHAT administered by trained care staff to participants; 2) Personal Care Plan for participants; 3) Weekly Oral Hygiene Record of participants; 4) Care Staff Completed Training. The research assistant will collect this information from the care-home managers.

3.1.6 Primary and Secondary Outcomes

The outcome measures that will be recorded in this study are as follows:

1. Clinical outcomes (assessed by dental examiners at baseline and 12 months) will include the number of teeth with coronal and root caries lesions, the proportion of teeth with visible plaque and the proportion of teeth that bleed on probing (BoP).
2. Oral symptoms and domiciliary dental care: This refers to the number of reported episodes of dental pain, sepsis, discomfort and domiciliary visits (weekly by care-home staff and at baseline, 6- and 12-months by researchers).
3. Health-related quality of life using EuroQol's five dimensions – EQ-5D5L [27] (collected at baseline, 6- and 12-months).
4. Oral health-related quality of life using the OIDP [28] (collected at baseline, 6- and 12-months).
5. Oral health needs assessed with the OHAT [25] (collected by dental examiners at baseline and 12-months).

Data will be collected using paper Case Report Forms (CRFs), which will be considered as source data, and then transcribed onto a web-based CRF that will not include the participant's name or other information that could identify them. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method). All electronic databases will use a participant identification number rather than the participant's name. Hard copies of data sheets linking the participant identification number to the person's contact details will be kept securely in a locked filing cabinet in a locked office and will only be accessible to a small number of people who are involved in the study. A more detailed Data Management Plan that complies with the NWORTH's Standard Operating Procedures (SoPs) addresses details about the data flow and storage, system validation, data cleaning, freezing and locking, sharing and archiving.

3.1.7 Sample Size

Overall, the feasibility study will be conducted in up to 24 care homes (approximately equally divided

between intervention and control). The aim is to recruit a minimum of five and a maximum of twenty participants per care home, resulting in an estimated recruited sample of 120 residents, equally divided between the two settings (London and Northern Ireland). This sample will allow us to establish the feasibility, rates of recruitment and retention, and any delivery issues with the proposed intervention and the research methods. Based on NIHR guidance [29], a sample of 120 participants will allow for an estimated attrition rate of 20% to within a 95% confidence interval of +/- 7%.

3.1.8 Statistical Analysis

As this is a feasibility study, statistical analysis will be restricted to generating summary statistics and confidence intervals. The sensitivity and distribution of the outcome measures proposed for the definitive study will be explored. Recruitment and retention outcomes with associated estimates of precision will be summarised. Acceptability of the interventions and outcome measures, clinical indices (including episodes of pain and hospital admissions) and subjective outcomes by study arm will also be summarised and 95% confidence intervals calculated for the difference in means or proportions as appropriate. All statistical analysis will be undertaken on an intention to treat basis and take into account the clustering of participants within care homes. All statistical analyses will be undertaken at NWORTH Clinical Trial Unit, led by CO-I (ZH). A full statistical analysis plan will be written and agreed by the trial team prior to the completion of data collection. This will be made available for comment by the independent committees.

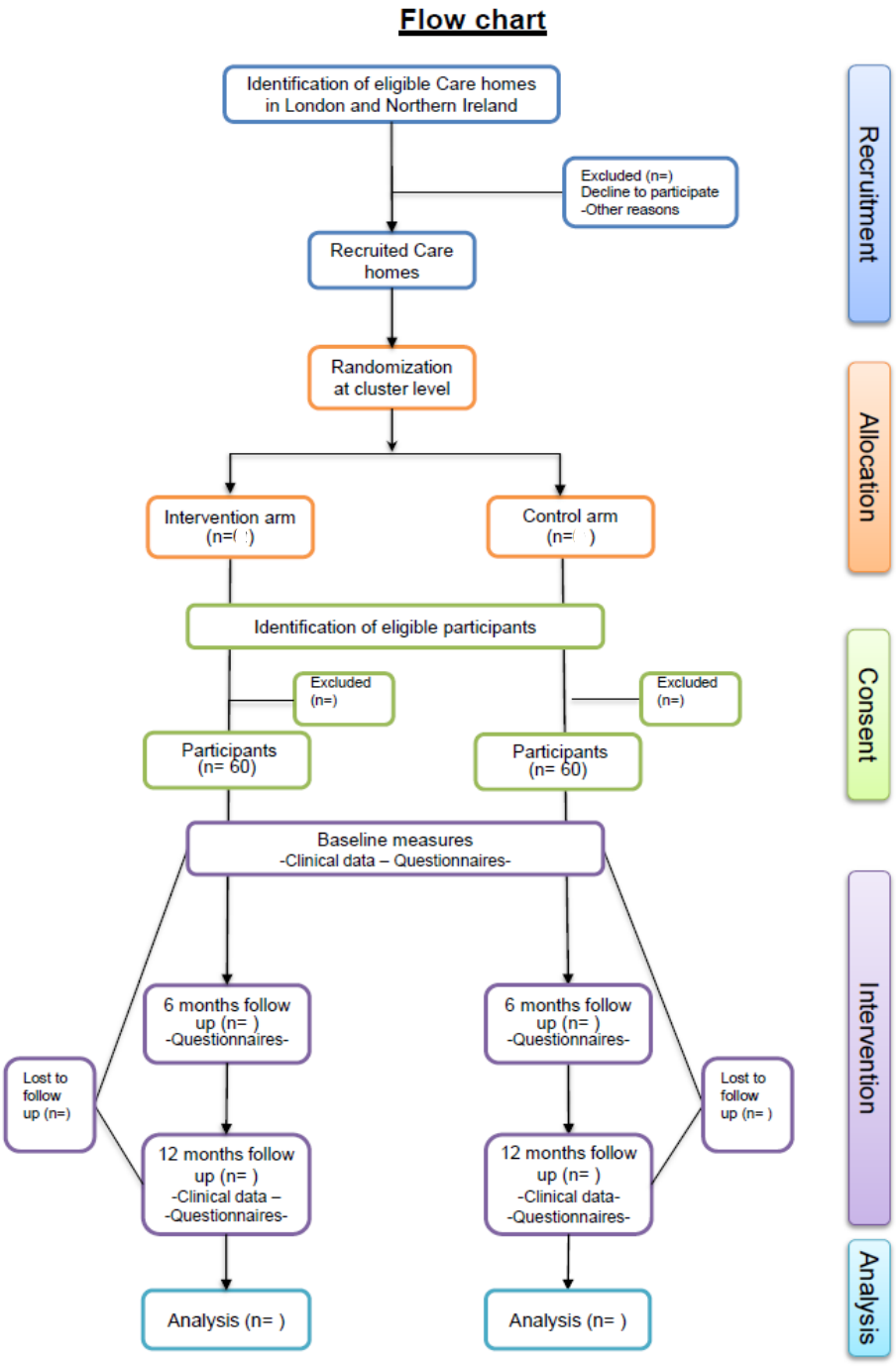

Figure 1: Flowchart of Recruitment, Allocation, Consent, Intervention and Analysis

3.2 Work Stream 2 – Refinement of a Complex Oral Health Intervention for Care Home Residents, and Process Evaluation of the Feasibility Study

WS2 addresses objectives no.1 and no.3 and will consist of three phases: Phase 1 (P1) will focus on the refinement of a complex oral health intervention so that it is relevant for care home residents, while P2 will focus on the process evaluation of the feasibility study and P3 on the embedment in standard practice. P1 of WS2 will run in the beginning of the study, before the main feasibility study (WS1), while P2 and P3 of WS2 will run in parallel with WS1.

3.2.1 Phase 1 – Refinement of a Complex Oral Health Intervention for Care Home Residents

We will use a co-design process to refine the intervention with care home residents and staff. This will take the form of three activities: (1) context familiarisation for two design researchers, (2) an iterative series of two co-design workshops with residents and staff at two care home locations with different oral health practices (3) some intervening studio design work before and after each of the co-design workshops.

Context Familiarisation (done during study set up)

During this phase, two design researchers will attend three different care homes based in Sheffield. They will spend approximately two hours at each care home. During this time, they will use observations, walking ethnographic interviews and an informal workshop with staff and residents to understand their current routines and habits and their responses to the intervention as currently defined.

Co-design Workshops

Following a similar structure to the Experience Based Co-design (EBCD) model, we will run a series of co-design workshops repeated at two care homes with varying degree of oral health practices; one that has in place ‘good’ oral health practices and another that does not. We will recruit both residents and staff to attend each workshop. These workshops will use creative design methods [30] to elicit experiences, knowledge, ideas and tangible refinements. The purpose is to harness contextual and experiential knowledge and the intervention use in context in practise and to consider content modification and the form in which the intervention should be delivered. For example, video, animation, leaflet or perhaps a waterproof, glossy guide-book could be considered. The first workshop will explore current experiences, routines and habits before introducing the intervention and exploring how and why it could be inappropriate in its current form. The second workshop will develop modifications and refinements to the intervention that will be ‘tried out’ during the workshop.

Over the course of these workshops across the two different locations, consideration will be given to the degree of tailoring required at different scales of use. For example, whether a single generic refinement will suit all care homes or whether an element of ‘personalisation’ is required depending on the provider, the care home, and resident or staff member. Expert judgement will be applied by the project team to balance the need for (and degree of) personalisation embodied within the refined intervention, against the benefits of uniformity for evaluation purposes in this feasibility study. This is in line with the Damschroder et al Consolidated Framework for Implementation [31], which presents an intervention core that is common to all contexts, and an adaptable periphery that enables context variations to be catered to.

Studio Design work

The studio design work will take place before each of the co-design workshops, preparing resources and prototype models for the participants. After the last co-design workshop the design researchers will generate a final ‘package’ that can be distributed to the care homes, that may include video and

animation materials, leaflets, process guide-books, reminders and memory joggers, posters etc. as a fully developed implementation package.

3.2.1.1 Participants

A sample of care home staff (managers, carers and other staff) and residents will be chosen via convenience sampling from four recruited care homes, contacted via the 'Enabling Research in Care Homes' (ENRICH) network. Recruitment will occur across the age range of residents and ensure a culturally and ethnically diverse sample, as far as possible.

3.2.1.2 Recruitment

The same recruitment methods outlined in **section 3.1.2** will be utilised.

Anyone interested in participating will be given a relevant PIS and ICF; these are PIS_WS2-P1_InterventionRefinement and ICF_WS2-P1_InterventionRefinement respectively. The researcher will clearly emphasize that this is a research study and is purely voluntary. The researcher will attend the care home at least 48 hours after discussing the study and will contact potential participants in terms of their willingness to consent and take part.

3.2.1.3 Informed Consent

A researcher who has completed their GCP and Informed Consent training will go through the PIS_WS2-P1_InterventionRefinement with the potential participant and discuss the study and explain any issues that the participant may be unclear about. The participant will subsequently (at least 48 hours later) be asked whether they are happy to consent. If they are, they will be asked to complete and sign the ICF_WS2-P1_InterventionRefinement form.

3.2.1.4 Study Design Overview

Participants will be asked to take part in two workshops, each lasting approximately 60 minutes. All workshops will be conducted prior to WS1 (feasibility study).

3.2.1.5 Data Collection and Analysis

A researcher trained in qualitative data collection methods will lead the discussion in the workshops. Davidson's toolkit [19] will be used to guide the discussions and the following questions considered: What stages need adaptation and what stages can be adapted for this population? Do any stages require prioritization for adaptation? What are the important elements? Any contextual elements? How heterogeneous is the population? Any shifting patterns or trends in behaviours? Are there competing priorities that would lessen engagement?

The workshop discussions will be recorded and transcribed verbatim. Audio recordings will be destroyed after verbatim transcripts have been prepared. Thematic analysis will be undertaken [32] and a quality checklist will guide analysis and writing [33].

3.2.2 Phase 2 – Process Evaluation

P2 of WS2 will run alongside WS1 to undertake a process evaluation of the feasibility study.

3.2.2.1 Participants

See **section 3.1.1** and **section 3.2.1.1.**

3.2.2.2 Recruitment

The same recruitment methods outlined in **section 3.1.2** will be utilised.

Care home staff (managers, carers and other staff) and residents interested in participating will be given a relevant PIS and ICF (PIS_WS2-P2&3_ProcessEvaluation and ICF_WS2-P2&3_ProcessEvaluation respectively). These PIS and ICF are applicable to both Phase 2 and Phase 3 of WS2. The researcher will clearly emphasize that this is a research study and is purely voluntary and is not something that they should feel obliged to undertake. The researcher will attend the care home at least 48 hours after discussing the study and will contact potential participants in terms of their willingness to consent and take part.

3.2.2.3 Informed Consent

See **section 3.2.1.3.**

3.2.2.4 Study Design Overview

Semi-structured interviews with care home staff (managers, carers and other staff) to assess the intervention's feasibility (issues relating to recruitment, retention and fidelity), and with residents to explore the intervention's acceptability will be undertaken. Care home staff and residents that refuse participation will also be interviewed to explore their reasoning. The interviews will last between 30 and 60 minutes and will be digitally recorded. Participants will be provided with the option to have the interview conducted in-person at the care home or over the telephone.

The process evaluation will run alongside the feasibility study (WS1).

A PPI group and stakeholder groups will be consulted to determine the most appropriate outcome measure for the definitive trial.

3.2.2.5 Data Collection and Analysis

The interviews will be conducted in accordance with a protocol consisting of semi-structured open-ended questions. The protocol will be developed in collaboration with the PPI group.

Researchers trained in qualitative data collection methods will undertake the interviews. Interviews will be digitally recorded and transcribed verbatim. Audio recordings will be destroyed after verbatim transcripts have been prepared. Thematic analysis will be undertaken [32] and a quality checklist will guide analysis and writing [33].

3.2.3 Phase 3 – Embedment in Standard Practice

P3 of WS2 will explore how the intervention could be embedded in standard practice guided by Normalisation Process Theory [34] and Pfadenhauer et al.'s framework to maximise pathway to impact [21].

3.2.3.1 Participants

See **section 3.1.1** and **section 3.2.1.1.**

3.2.3.2 Recruitment

The same recruitment methods outlined in **section 3.1.2** will be utilised.

Anyone interested in participating will be given the relevant PIS and ICF (PIS_WS2-P2&3_ProcessEvaluation and ICF_WS2-P2&3_ProcessEvaluation). The researcher will clearly

emphasize that this is a research study and is purely voluntary and is not something that they should feel obliged to undertake. The researcher will attend the care home at least 48 hours after discussing the study and will contact potential participants in terms of their willingness to consent and take part.

3.2.3.3 Informed Consent

See **section 3.2.1.3.**

3.2.3.4 Study Design Overview

Participants will be asked to take part in one semi-structured interview lasting between 30 and 60 minutes. Participants will be provided with the option to have the interview conducted in-person at the care home or over the telephone.

3.2.3.5 Data Collection and Analysis

In P3 of WS2, we will explore how the intervention could be embedded in standard practice guided by the Normalisation Process Theory [34] and Pfadenhauer et al.'s framework to maximise pathway to impact [21]. The different domains of Pfadenhauer et al. framework (Table 1) will be used to explore the factors that are important for implementation. As such, implementation will be considered from the start and will ensure that the definitive trial is planned with these factors in mind.

Table 1: Domains and Questions for Reflection from Pfadenhauer et al. [21]

Main	Questions for Reflection
Intervention characteristics	Which intervention characteristics interact with the setting, the context and the implementation? How do these intervention characteristics interact with the setting, the context and the implementation?
Context	How do these aspects of the context interact with the intervention? Which aspects of the context interact with the implementation of the intervention? How do they interact with implementation?
Implementation theory	Which theoretical underpinning guides the implementation? How does this theory interact with the setting and the context? How does this theory interact with the intervention?
Implementation process	Which stages of the implementation process are passed through during implementation? How does the implementation process interact with the setting and the context? How does it interact with the intervention?
Implementation strategy	Which implementation strategies are employed during implementation? How do these implementation strategies interact with the setting and the context? How do they interact with the intervention?
Implementation agents	Which implementation agents are involved in the implementation effort? How do these implementation agents interact with the setting and context? How do they interact with the intervention?
Implementation outcomes	Which implementation outcomes are reported with the setting and the context? How do these implementation outcomes interact with the intervention outcomes?
Setting	Which aspects of the setting interact with the intervention? How does the setting interact with the intervention? How does it interact with the context? How does it interact with implementation?

The interviews will be conducted in accordance with a protocol consisting of semi-structured open-ended questions. The interview schedule will be developed in collaboration with the PPI group.

A researcher trained in qualitative data collection methods will undertake all interviews. Interviews will be digitally recorded and transcribed verbatim. Audio recordings will be destroyed after verbatim

transcripts have been prepared. Thematic analysis will be undertaken [32] and a quality checklist will guide analysis and writing [33].

3.3 Work Stream 3 – Cost Consequence Model

The aim of WS3 is to identify key outcomes relevant to different stakeholders and the potential to reduce these to a core set of indicators. It will also explore issues associated with the valid, reliable and efficient collection and reporting of core indicators. A cost consequence model to inform a future larger scale definitive trial will be produced. Therefore, WS3 will address objective no.4.

3.3.1 Participants

Stakeholders will include care home residents, family members, care home staff, and policy makers and relevant organisations.

3.3.2 Recruitment

Care home staff (managers, carers and other staff) and residents from the included care homes will be recruited using the same recruitment methods outlined in **section 3.2.2**.

Family members of the care home residents included in the study will be asked to participate. The researcher will leave the relevant PIS and ICF (PIS_WS3_CoreOutcomeSet and ICF_WS3_CoreOutcomeSet, respectively) and pre-paid envelopes with the care home residents or care home staff, to give to the family members. Participants who are interested can then contact the researcher to discuss the study in more detail, or if consent is given, the researcher will contact them.

Policy makers and key stakeholders, such as the Health and Social Care Board in Northern Ireland, NHS Clinical Commissioning Groups, the Care Quality Commission, the Regulation and Quality Improvement Authority (Registration and inspection Unit in Northern Ireland), PHE and third sector organisations on ageing, will be approached to arrange a meeting or telephone call to discuss the study and provide input.

Anyone interested in participating will be given a PIS_WS3_CoreOutcomeSet and ICF_WS3_CoreOutcomeSet. The researcher will clearly emphasize that this is a research study and is purely voluntary and is not something that they should feel obliged to undertake. All potential participants will be given at least 48 hours from discussing the study with the researcher to decide whether or not they wish to take part.

3.3.3 Informed Consent

A researcher who has completed their GCP and Informed Consent training will go through the PIS_WS3_CoreOutcomeSet and ICF_WS3_CoreOutcomeSet with the potential participant and explore any issues that the participant may be unclear about. The participant will then be asked whether they are happy to consent. This process can be completed over the phone or in person, depending on the preference of the participant. If over the phone, the participant will be asked to send the completed and signed ICF_WS3_CoreOutcomeSet back to the researcher in a pre-paid envelope before the arranged interview.

3.3.4 Study Design Overview

Stakeholders mentioned above will be asked to take part in one semi-structured interview lasting between 15 and 20 minutes. The interviews will be conducted over the phone or in person and will be digitally recorded.

3.3.5 Data Collection and Analysis

The aim of the interview is to identify key outcomes including clinical, quality of life, resource use and measures of equity that are likely to inform decision making. The interviews will be conducted in accordance with a protocol consisting of semi-structured open-ended questions. Interviews will be undertaken until saturation of content is reached.

A researcher trained in qualitative data collection methods will undertake all interviews. Interviews will be digitally recorded and transcribed verbatim, with both audio recordings and transcripts anonymised. Audio recordings will be destroyed after verbatim transcripts have been prepared. Thematic analysis will be undertaken [32] and a quality checklist will guide analysis and writing [33].

WS3 will also use data collected as part of WS1 to examine the impact of resident attrition, staff turnover and inability to consent on the validity and reliability of the collected data, and consider the study perspective to best accommodate reporting of outcomes. It will explore opportunities to exploit routinely collected data and data reduction techniques to identify a set of core indicators as part of a cost consequence study. In addition, WS3 will examine the relationship between the broader context of the home such as staff/resident ratios and average resident dependency levels on various outcomes.

4. Data Protection

The study will be managed in accordance with GCP and GDPR. Data held at NWORTH will be subject to NWORTH's Standard Operating Procedures (SoPs), for all data management, statistical and regulatory matters. Data collection and storage in London and Northern Ireland will be subject to the SOPs from UCL and Queen's University Belfast respectively. Best practice will be employed throughout to ensure this project is managed to the highest possible standard. Appropriate supervision and training of project-specific staff and training in GCP will be ensured. Trial-specific training requirements will be addressed throughout the study period and regularly reviewed. NWORTH will supply appropriate templates to assist in developing the Trial Master File (TMF). The research will be sponsored by UCL and will be subject to their SoPs and routine internal audit through the University's standard research monitoring policies.

Patient confidentiality will be a priority. All data will be stored securely on password protected PCs/laptops and any paper records stored in locked drawers/filling cabinets in secure buildings. All participant personal information will be coded and anonymised as far as possible. Only personal identifiers that are essential will be kept and stored securely. Participants' names will not appear on any documentation associated with the study apart from the ICF and participant contact details, which will be kept in locked filing cabinets as described above. Participants will be allocated a unique study number, which will be used in any documentation associated with the study. All data will be collected, stored and disseminated in accordance with the General Data Protection Regulation 2018, and policies at the lead universities (University College London, Queen's University Belfast and Bangor University).

Only members of the research team will have access to the data. A master copy of all the data will be stored at the end of the study with the CI (GT) at University College London using UCL Data Safe Heaven. Electronic data (and all the related statistical elements) from WS1 will be stored at NWORTH Clinical Trials Unit, Bangor University in accordance with their SOPs. Any hard copies of data (e.g. paper copies of CRFs, consent forms) will be stored locally at each site (UCL and Queen's University Belfast) and in accordance with the SOPs of each respective site. The data from WS2 will also be stored at Bangor University and the data from WS3 will also be stored at Queens University Belfast.

5. Ethical Arrangements

The key ethical issues in this study relate to the process of gaining consent and the risk of coercing individuals to participate in the study. Consent into the study will follow guidance laid down within

the Mental Capacity Act 2005. The procedures for obtaining informed consent for the different stages of the study have been described in the relevant sections above.

Potential participants will be assumed as having capacity to consent for themselves unless formally assessed as lacking capacity. If the participant's lack of capacity is considered temporary; capacity will be reassessed prior to each contact with the researcher. Participants will be informed of the option to withdraw from the study at any time. If a participant communicates his/her objection to a research assessment or intervention, either verbally or non-verbally, the intervention will cease immediately. If any participants wish to re-join the study, they will do so freely, without any involvement from the study team. The safety and well-being of residents will be paramount at all times.

This protocol and the PISs and ICFs (submitted separately) and all relevant study materials have been reviewed and approved by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre team, as well as the sponsor and then submitted for a full ethical review to London – City and East (application submitted through the Integrated Research Application System) with respect to scientific content and compliance with applicable research and human subjects regulations.

The CI (GT) will make safety and progress reports to the Ethics Committee at least annually and within three months of study termination or completion. These reports will include the total number of participants enrolled as well as summaries of each DMEC (Data Monitoring and Ethics Committee) meeting and review of the study procedures.

6. Research Governance/Project Oversight

The study will adhere to NWORTH's Standard Operating Procedures, for all data management, statistical and regulatory matters. Best practice will be employed throughout to ensure this project is managed to the highest possible standard. Appropriate supervision and training of project-specific staff and training in GCP will be ensured. Trial-specific training requirements will be addressed throughout the study period and regularly reviewed. NWORTH will supply appropriate templates to assist in developing the Trial Master File (TMF). The research will be sponsored by UCL and will be subject to routine internal audit through the University's standard research monitoring policies.

The research team as a whole will meet every six months to check progress and decide on operational issues around the project, while an Advisory Committee consisting of key research team members will oversee the collaboration between the different partners. The core management team will consist of the CI (GT) and the CO-PIs (GMK and PRB).

The oversight to the project will be provided through the Study Steering Committee and the Data Monitoring and Ethics Committee. Both these Committees have been appointed. Their roles and responsibilities are determined by the relevant guidance provided by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, and they also comply with the respective requirements for independence.

The Study Steering Committee consists of a range of national and international experts on different aspects of the project and PPI representatives. Their expertise collectively covers the fields of gerodontology, dental public health, ageing, interdisciplinary care, nursing, health services research, dementia, clinical trials, medical statistics, epidemiology, operational research, care homes interventions, care homes regulation, and policy around ageing. The Study Steering Committee will have overall responsibility for overseeing the study, including aspects about the continuation or termination. It will ensure that the trial is conducted in accordance with the principles of GCP and the relevant regulations, and will provide advice on all aspects of the study. The Data Monitoring and Ethics Committee will monitor the data and ethics aspects of the study and provide advice on changes to the conduct of the study via recommendations to the Study Steering Committee. It

consists of three independent members that collectively have expertise on dental public health, statistics, health services research and ageing.

7. Safety Assessment

7.1 Definitions

Adverse event (AE): Any untoward medical occurrence in a trial participant which does not necessarily have a causal relationship with the intervention.

Serious AE (SAE): Any adverse event that a) Results in death; (b) Is life threatening; (c) Requires hospitalisation or prolongation of existing hospitalisation; (d) Results in persistent or significant disability or incapacity; or (e) Is otherwise considered medically significant by the investigator.

Related AE/SAEs: Any AE/SAEs defined as due to the administration of any research procedure. The relatedness of an event will be reviewed by the Chief Investigator or Principle Investigator at each site.

Expected AE: It is expected that there may be incidents of infections such as urinary tract infections and chest infections (treated without hospitalisation); pressure ulcers; oral candidiasis; falls; confusion; severe weight loss and dehydration.

Expected SAE: It is expected that there may be incidents requiring hospitalisation such as pneumonia, other respiratory conditions, fractures, cardiovascular related events and sepsis. Such events, which are deemed unrelated to the study, will not be reported to the ethics committee but will be recorded in the Investigator Site File (ISF) and the Trial Master File (TMF).

Unexpected SAE: Any SAE defined as a type of event not listed above as an expected occurrence.

Pre-existing conditions do not qualify as adverse events unless they worsen. The following will not be included as adverse events:

- Medical or surgical procedures, where the condition which leads to the procedure is the adverse event.
- Pre-existing disease or conditions present before the intervention that do not worsen.

7.2 Collecting, recording and reporting of adverse events

The adverse events reporting period for this study begins as soon as the participant consents to be in the study and one month after their final data collection ends. Adverse event data will be collected and recorded on the AE and SAE Case Report Form (CRF) by the Research Assistant on a monthly basis. Only details of any SAEs that are related to taking part in the study and are unexpected will be reported to the Research Ethics Committee (REC). The Research Assistant will inform the Chief Investigator/Principal Investigator at each site who will decide if the event should be reported to the REC as an SAE. Related and unexpected SAEs will be reported to the REC within 15 days of the Chief Investigator/Principal Investigator becoming aware of the event.

A copy of the AE and SAE CRF will be stored at the recruiting site in the ISF, and those signed by the Chief Investigator stored in TMF. The occurrence of adverse events during the trial will be monitored by the DMEC and Study Steering Committee (SSC).

8. Project Timetable and Milestones

The project timetable together with key milestones is as follows:

- Formal start date of the study: 01/12/2018;

- Setting up the study – initial arrangements: December 2018 – February 2019;
- Establish Study Steering Group and Data Monitoring and Ethics Committees: January – February 2019;
- UCL insurance and data protection, HRA and NHS Local Research Ethics Committee application and revision: April 2019 – March 2020;
- Content adaptation (WS2, P1): May - September 2019;
- Finalise data collection instruments: April – September 2019;
- Training package for care homes staff: July 2019 – February 2020;
- Recruitment of homes: November 2021 – May 2022;Recruitment of residents and baseline data collection on residents (WS1): February – May 2022;
- Initial Training care home staff: January – May 2022;
- 6-months follow-up data collection on residents (questionnaire): July - November 2022;
- Implementing Intervention: March 2022 – May 2023;
- Process Evaluation (WS2, P2): April 2022 – May 2023;
- 12-months follow up data collection on residents (clinical examination and questionnaire): February - May 2023;
- Embedding intervention in standard practice (WS2, P3): September 2022 – March 2023;
- Cost Consequence modelling (WS3): October 2022 – April 2023;
- Data Analysis (quantitative and qualitative): March – June 2023;
- Final Write up and Dissemination: May – July 2023;
- PPI involvement and Stakeholder groups: December 2018 – July 2023.

The covid-19 pandemic has had a substantive effect on the research on care homes, as any research and indeed access to care homes and contact with residents was not allowed in the interest of the safety of the residents. This has considerably affected the Gantt chart and timing of milestones.

9. Finance

This study is funded by the National Institute for Health Research (NIHR) Public Health Research Programme and will be managed in accordance with the relevant policies and procedures.

10. Definition of end of trial

The end of trial is defined as last participant, last visit.

11. Archiving

Archiving will be authorised by the Sponsor following submission of the end of the trial summary report. The Trial Master File (TMF) will be prepared for archive by the Chief Investigator and archived by the Sponsor according to Sponsor's archiving procedures. The Data Management Plan also covers provisions around data archiving.

12. Dissemination

The research group represents the majority of researchers in the UK with a specialist interest in gerodontology and dental public health who have a track record of publications in the area. A multifaceted approach will be used to promote the dissemination of the results of this research. The study protocol and also the key findings will be disseminated to the scientific community through conference presentations and peer-reviewed publications. Furthermore, informal dissemination networks will be made via the PPI and stakeholder groups and the developed relationships will be utilised. This will ensure dissemination of information directly to older people, carers and care home

managers. New and novel methods to support this dissemination will be developed with the PPI group and they will also create public-friendly summaries of the research. At a service level, formal links with dental commissioners, Consultants in Dental Public Health and gerodontologists in the UK will be established through the British Association for the Study of Community Dentistry network via RGW, PRB and GT (all Consultants in Dental Public Health) and the British Society of Gerodontology via RRW. Links to The European College of Gerodontology (ECG) and the International Association of Dental Research (IADR) Geriatric Oral Research Group will be utilised via GMK. The research team also has strong links with the Council of European Chief Dental Officers (CECDO). GT is Chair and GMK a member of the Platform for Better Oral Health in Europe (PBOHE), a joint initiative of the scientific oral health societies across Europe, with a mission to promote oral health and the cost-effective prevention of oral diseases and has links to the key stakeholders across Europe.

Furthermore, links with the Centre for Ageing and Dementia, the Centre for Policy on Ageing, the Age Sector Platform and with Age Cymru will complement and enrich the PPI group input and provide a robust channel for dissemination and knowledge transfer to both dependent older people and important policy-makers and stakeholders. We will further use our links with the PHE and with the Regulation and Quality Improvement Authority in Northern Ireland to further the pathways to impact of this project and promote engagement of all relevant stakeholders. Finally, GMK is a member of the Northern Ireland Council of the British Dental Association (BDA), which is very supportive of this work and will aid in dissemination of the research findings to its members.

13. Protocol Amendments

13.1. Current Protocol

Version 8 dated 5th May 2022

13.1.1 Amendments

Amendment 1.0

Section/page	Changes to text (from version) - approved
Page 2	Added a protocol authorisation box to allow for dates and signatures from the Chief Investigator and the Lead Statistician.
Section 2.1, pp. 5-6	Merged the content of objectives 2 and 4 into the revised objective 2, so that the different aspects of the feasibility part of the trial are considered in one objective. We have also removed the 6-CIT from the proportion of forms completed in objective 2, because it functions as a screening tool to determine eligibility for participation in the study and it is not one of the measures employed in the study.
Section 2.1, p. 6	Reviewed the wording of objective 3. The content of the objective has not been changed at all but the revised wording is clearer in terms the process evaluation remit of the study, while also considering that that work is guided by the Pfadenhauer et al.'s framework in terms of maximising pathways to impact.
Section 3.1.1, p.6	Slightly modified the text on the study population for Work Stream 1 in order to indicate that the suggested recruitment numbers of care homes and participants per care home serves to achieve the overall sample size of 120 participants.

Section 3.1.1, pp. 6-7	We further clarified the inclusion and exclusion criteria for the WS1. More specifically, we clarified the wording about the nature of the care homes (excluding that have only have a high-dependency unit or provide end-of-life care), as well as the wording about the age of the eligible residents (65 and over, as the previous wording of "over 65 years" may be interpreted to exclude 65-year-old residents). Furthermore, we have added that the eligible residents need to have a working level of oral English, as this is necessary for the data collection. And we are going to exclude participants that take part in another oral health intervention in order to avoid introducing bias in our study due to the potential effect of the other intervention. This is in line with the advice from the Study Steering Committee (SSC).
Section 3.1.2, pp. 7-8	In addition to the established minimum number of participants (n=5) to be recruited per care home, we have also added a maximum number (n=20). This provides more specificity to the protocol and allows practically for the inclusion in the study of large care homes without jeopardising the overall conduct of the study and timeframe, which would be the case if all eligible participants were to be recruited from very large homes. Such clarifications about minimum and maximum numbers recruited are in line with the discussions and relevant advice from the SSC.
Section 3.1.2, pp. 7-8	We have provided further details about the recruitment process for care homes and how this will be facilitated in the two sites. In addition, we have added more detail in terms of the practicalities of recruiting residents in the selected care homes.
Section 3.1.2, pp. 7-8	We have also introduced a clearer stepwise approach to the screening for eligible participants to the study. This has replaced the previous text by providing more detail of the different stages in the process and incorporated the text in the paragraph at the end of the inclusion/exclusion criteria, in order to avoid unnecessary repetition and present the whole process in the relevant place in the protocol (section on recruitment).
Sections 3.1.2 & 3.1.3, pp. 7-8	As a consequence of the suggested more detailed approach to recruitment, we have also added a further participant information sheet and informed consent form for potentially eligible participants so that they can consent to undergo the 6-CIT cognitive screening test and a brief dental examination; and then be consented to the study only if they are actually eligible (which is actually determined after all eligibility criteria are met). This has been explained in the revised text on recruitment and also informed consent sections.
Section 3.1.4, p. 8	Added more relevant detail in the process of randomisation and also provided a reference to substantiate the suggested approach.
Section 3.1.4, pp. 8-9	The protocol was updated in terms of the intervention materials and training package, in line with the co-design process to adapt the intervention to the care home environment (work undertaken as part of Work Stream 2).
Section 3.1.4, p.9	We also clarified the arrangements in terms of participants, examiners and statistician blinding.
Sections 3.1.5 & 3.1.6, pp. 9-10	We have specified that the Oral Health Assessment Tool will also be collected as part of the baseline and 12-month follow-up data collection by the clinical dental examiners, and have mentioned the data collected at care home level. And we have also provided a list of all the outcome measures that are going to be collected in the study on the relevant section. Furthermore, we have specified the data collected to assess completion rates of the intervention, so that to facilitate the assessment of its fidelity.
Section 3.1.6, p.10	More information has been provided about the capturing of data in Care Report Forms and an outline of the more detailed data management plan that has been put in place and complies with the NWORTH Standard Operating Procedures.

Sections 3.1.2, 3.1.3, 3.2.1.2, 3.2.1.3, 3.2.2.2, 3.2.2.3, 3.3.2 & 3.2.3	We have provided more specificity in terms of the different Participant Information Sheets (PISs) and Informed Consent Forms (ICFs) that are used in this study. This took place throughout the revised text and in the description of the relevant processes for the different workstreams.
Section 4, p. 18	We have revised the text on Data Protection by adding more specificity in terms of the respective roles of NWORTH, UCL, and Queen's University Belfast, so that it also considers were data are collected and stored and guarantees compliance with the Standard Operating Procedures in the different institutions.
Section 7, p. 20	Much more clarity and detail has been provided in terms of safety assessment, which now includes definitions and also procedures for collecting and reporting serious adverse events.
Section 8, pp. 20-21	There is a clear mentioning about the current situation in terms of the covid-19 pandemic and its effect on research on care homes, which will result in a further revision of the Gantt chart and study timelines once the overall picture is clearer.
Sections 9, 10 & 11, p. 21	We have added brief sections on finance, definition of the end of trial, and archiving.

Amendment 2.0

Section/page	**Changes to text (from version 6)**
Page 2	End date changed to 31st May 2022
Section 8, p.21	Information about recruitment of care homes and residents being paused due to the impact of covid-19, and about the timeline being updated as soon as access restrictions are lifted and permission for research to commence granted.
Page 22	Table - updated to show amendment 1.0 was approved
Footnote	Updated to reflect new protocol version (version 7: 16/04/2021)

Amendment 3.0

Section/page	**Changes to text (from version 7)**
Page 2	End date changed to 31st July 2022
Sections 3.1.1, p6; section 3.1.2, pg 7; and section 3.1.7, pg 11	We have changed the number of care homes to recruit from 12 up to 24.
Section 8, pg20-21	We have updated the project timeline and milestone section to reflect the current Gant Chart (version 5: 25/02/2022.
Figure 1	We have updated figure 1 to reflect the changes made to the number of care homes we could potentially recruit to meet 120 sample size
Section 13.1, pg 22	Updated to reflect new protocol version (version 8: 05/05/2022)

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