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PLANNED END DATE: 30th June 2024

Name	Role	Signature	Date
Paul Brocklehurst	Chief Investigator		
Rachel Evans	Trial Statistician		

Table of Contents

1.0 BACKGROUND:

Poor oral health, including dental caries and periodontal disease, is a very common problem for older adults residing in care-homes and the issue is increasingly becoming a significant public health problem.[1,2] 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.[3] The oral health of care-home residents is much worse than their community living peers. With increasing dependency, the ability for self-care deteriorates, poly-pharmacy leads to dry mouth and diets become rich in sugars.[6] All these factors significantly increase residents' disease burden and the risk of future problems. Oral conditions impact on their quality of life, self-esteem, general health and diet, exacerbating underlying medical conditions.[4,5,6,7] Income-related inequality in oral health of older adults is also a major issue.[8,9]

Despite this high level of need, dental service provision in residential care is poor, with little emphasis on prevention.[10,11] Access to domiciliary services is difficult and unscheduled care for dental problems (including hospital admissions) is common, complex to deliver and expensive.[12,13] The World Health Organisation (WHO) argue that the design of long-term care systems that are fit for ageing populations should take priority and the Royal College of Surgeons of England (RCS), Public Health England (PHE) and the National Institute of Clinical Excellence (NICE NG48) have all called for more high quality research.[14,15] The recent Care Quality Commission (CQC) have also highlighted the paucity of dental care in care-homes in their report published in June 2019 (https://www.bbc.co.uk/news/health-48711379).[16] As highlighted in their report "*although we saw some examples of good, joined-up practice between care homes and dentists, this was uncommon. People using services and their professional and family carers often found it difficult to access routine NHS dental care […] all too often, treatment would only be sought when people were in pain, but issues with accessing emergency NHS dental care meant care homes would call a GP or NHS 111, or even take the person to A&E – putting added burden on services that are already under pressure*".

There is increasing evidence that Dental Care Professionals (DCPs) offer an alternative to using dentists to meet the future challenges in dental public health.[17,18] DCPs are a broad range of professionals, which include Dental Therapists (DTs) and Dental Nurses (DNs). The Chief Investigator (PRB) has demonstrated that DTs can identify and screen for dental caries and periodontal disease and are safe as front-line health care workers.[19,20,21] The feasibility, productivity and effectiveness of using DTs has been tested in primary care (NIHR/CS/010/004; HS&DR 11/1025/04; HS&DR 16/01/79), but little has been undertaken in a care-home environment. Our ongoing systematic review (twelve studies with 1,530

residents) demonstrated the paucity of the literature and concludes "larger studies that are appropriately designed and adequately powered are required before evidence-based recommendations can be made about the care for dependent older people".

Emerging evidence suggests that the use of DCPs (DTs and DNs) within residential homes has the potential to improve preventive advice, the provision of care and access to services.[22]

Following an analysis of Welsh dental care-home survey data in 2010, Monaghan & Morgan concluded “a large proportion of need in care-homes could be wholly provided by hygienists or therapists” and an “efficiency gain of direct access arises from individuals who do not need to see a dentist for any aspects of their care”.[23] It is also argued that DTs can lead examinations in care-home settings.[24] However, robust empirical evidence from definitive trials about how best to successfully implement and sustain DCP interventions within care-home environments is currently lacking.

2.0 TRIAL AIM, OBJECTIVES AND DESIGN

2.1 Trial Aim:

The aim of this study is to undertake a cluster-randomised controlled trial to determine whether Dental Care Professionals (DCPs) could reduce plaque levels (improve the oral cleanliness) of dentate older adults (65 years and over) residing in care-homes over a six-month period, when compared to ‘treatment as usual’ (commonly a reactive and *ad hoc* service provided by dentists). In addition, we aim to determine whether this effect is sustainable over a further six-month follow-up period.

2.2 Trial Objectives:

The objectives of the study are to:

1. Undertake a cluster-randomised controlled trial across Wales, Northern Ireland and England to determine whether role-substitution using DCPs could reduce plaque levels (improve the oral cleanliness) of dentate older adults residing in care-homes over a six-month period, when compared to ‘treatment as usual’;
2. Follow residents for a further six-months to determine whether this effect is sustainable;
3. Use semi-structured interviews to undertake a process evaluation of the trial to determine acceptability, treatment fidelity and pathways-to-impact with the following stakeholders:
    a. Managers and staff to assess the intervention’s feasibility and sustainability;
    b. Residents, relatives and informal carers to explore the intervention’s acceptability;

   c. Managers and residents that refused participation to explore their narrative; and
   d. Commissioners of care renew care-pathways and pathways-to-impact;
4. Gather data to identify barriers and elicit detail of strategies that promote successful implementation and rollout of similar interventions across care settings; and
5. Undertake a parallel cost-effectiveness analysis from an NHS perspective and examine potential long-term costs and benefits of the intervention.

2.3 Research Questions:

The following are our research questions:

1. Can the use of DCPs reduce plaque levels (improve the oral cleanliness) of dentate older adults (65 years and over) residing in care-homes over a six-month period, when compared to 'treatment as usual' with dentists?
2. Is this effect sustainable over a further six-month follow-up?
3. What is the acceptability of the intervention and what are the factors that facilitate sustained implementation across similar care settings?

2.4 Trial design including expected duration of trial

A cluster-randomised controlled trial across Wales, Northern Ireland and England. Three work-streams (WSs) are proposed.

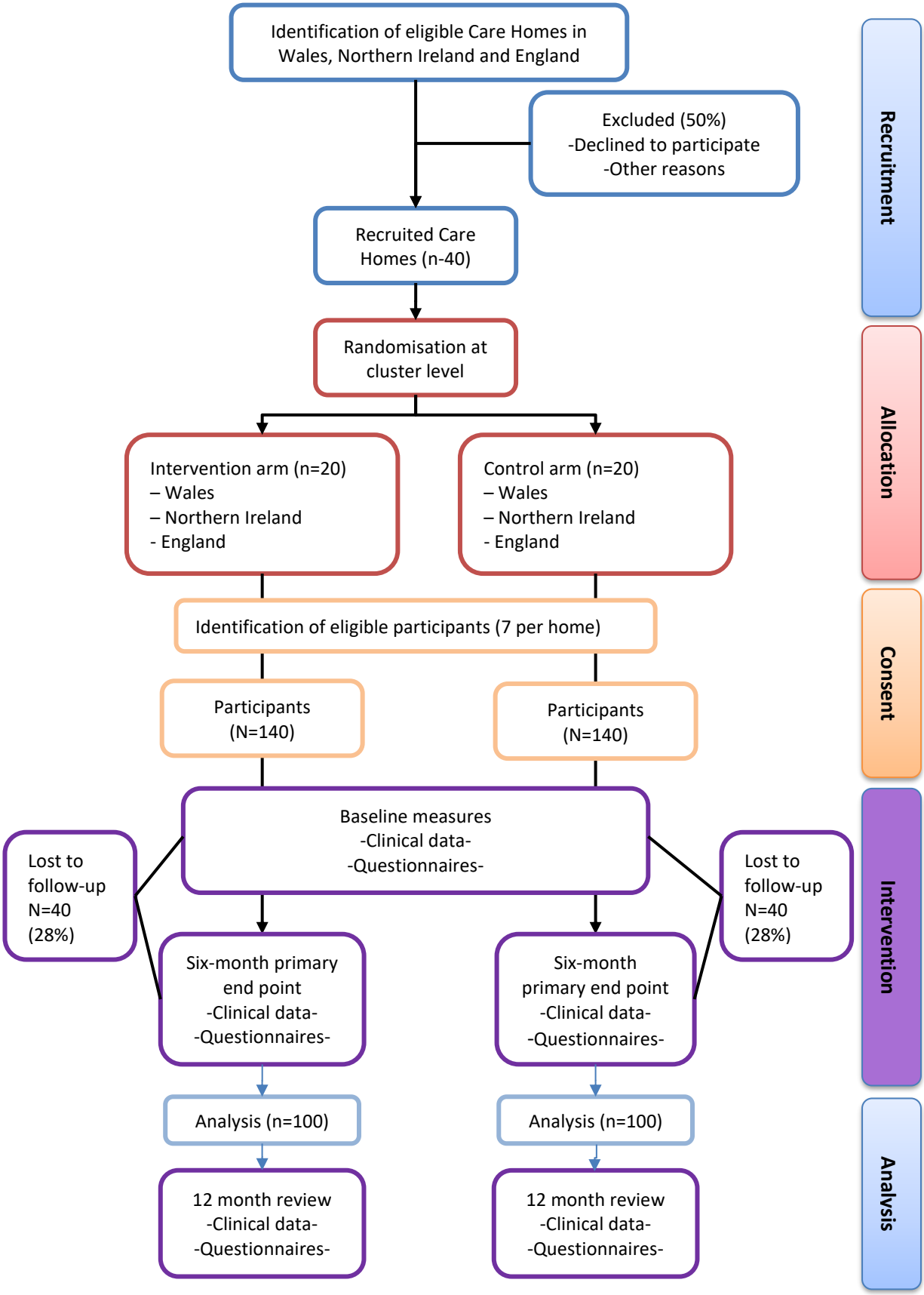
2.5 Project / research timetable:

The total time scheduled for the project is 42 months. This is detailed in the table below:

Milestones	**Start date**	**End date**	**Duration (months)**
Regulatory approvals and study set-up	1st October 2020	30th June 2021	8
Trial period	1st January 2021	30th June 2024	42
Trial documentation and MACRO set-up	1st January 2021	30th June 2021	6
Recruitment of care-homes, selection and training	1st July 2021	30th June 2022	12
Recruitment and randomisation of residents	1st September 2021	31st August 2022	12

Internal pilot	1st September 2021	30th November 2021	3
Assessment of stop-go criteria	1st December 2021	31st January 2022	2
Follow-up period	1st September 2021	31st August 2023	48
Follow-up T1	1st March 2022	28th February 2023	12
Follow-up T2	1st September 2022	31st August 2023	12
Analysis of data	1st September 2023	31st March 2024	6
Closing down of the study	1st September 2023	30th November 2023	3
Dissemination	1st March 2024	30th June 2024	3

2.6 Trial flowchart



3.0 TRIAL PROCEDURE

3.1 Workstream one:

WS1 will be a two-arm cluster-randomised controlled trial, with a three-month internal pilot. In the intervention arm, DTs will first assess and then treat eligible dentate residents, where necessary. All treatment will be conducted within the DT's Scope of Practice, which includes clinical prevention, debridement and the placement of fillings. Residents will be referred onto dentists when necessary (but this is likely to be limited to extractions – see detail in *Intervention* below). DNs will also form part of the programme and will visit the care-homes to promulgate advice to improve the day-to-day prevention offered to residents by formal and informal carers. The DTs will visit care-homes in their locality every six-months and the DNs will visit every month for the first three-months and then three-monthly afterwards (see below). The intervention has been developed from the on-going Gwên am Byth programme (https://gov.wales/sites/default/files/publications/2019-03/improving-oral-health-for-older-people-living-in-care-homes-in-wales.pdf) and will be contrasted with current practice (which is likely to be heterogeneous). The study will be conducted in 40 care-homes (with expected 50% recruitment rate, 80 homes will be approached). Care-homes that are participating in TOPIC (NIHR PHR 17/03/11) or Gwên am Byth in Wales will be excluded. They will then be randomised (via NWORTH CTU) based on a 1:1 ratio (20 intervention and 20 control), with 7 residents recruited in each home resulting in an estimated recruited sample of 280 (to include 28% attrition – based on our systematic review). Stratification of care-homes will be based on the following factors care home site (England, Northern Ireland, Wales) and care-home size (based on number of available beds within home: small 1-10 beds; medium 11-49 beds; large 50+) We will seek to balance these factors *a priori* using NWORTH's dynamic adaptive algorithm (http://nworth-ctu.bangor.ac.uk/randomisation/index.php.en) and will adjust for these factors *post-hoc* as part of our analysis. It is not possible to blind the care homes or the individual residents in this study, but the trial statistician will remain blind throughout the duration of the study, until the blinded analysis detailed in the statistical analysis plan has been conducted and reported to the study team.

3.1.2 Primary Outcome Measure:

Our Primary Outcome Measure (POM) for this study will be the Silness & Loë plaque index (https://www.mah.se/CAPP/Methods-and-Indices/Oral-Hygiene-Indices/Silness-Loe-Index/), which was also confirmed as suitable from discussions with clinicians from the on-going Gwên am Byth programme. Secondary outcome measures will be bleeding on probing, pain, oral health related quality of life (OHRQoL), health related quality of life (HRQoL), episodes of unscheduled care and new coronal and root caries lesions (unlikely over the six-month

period). These align with the POMs used in the included studies in our on-going systematic review. We will also record the number of onward referrals to dentists, when the treatment needed extends beyond the DTs' Scope of Practice (see below).

Our sample size calculation (see below) is based and powered on changes to our POM at six-months. This takes account of the 'time-to-effect' of the intervention on our chosen POM and the pragmatic consideration of the length of stay of eligible residents (where we have been as inclusive as possible). However, we will undertake a follow-up at twelve-months to determine whether the effect seen at six-months can be sustained. This aligns with our broadened eligibility criteria and a recent study where only 55% of residents lived beyond the first year (half of all residents died by 462 days).[25]

The Silness-Löe Plaque Index is a 0 to 3 ordinal score (representing the degree of plaque present), which is recorded across index teeth and presented as a mean of these ordinal scores (https://www.mah.se/CAPP/Methods-and-Indices/Oral-Hygiene-Indices/Silness-Loe-Index/). The prevailing model in the dental literature is to measure the change in this mean score and this approach is accepted by Cochrane. However, this model is difficult to infer clinical significance at a population level. To this end, we will seek to determine the proportion of individuals in each arm that have demonstrated a mean reduction in plaque scores. This enables the team to measure the change in the mean Silness-Löe Plaque Index at the individual level, whilst providing a meaningful primary outcome measure at a population level (see *Sample Size* below).

3.1.3 Internal pilot study:

A nested internal pilot will be conducted across all three geographical areas over three months using stop/go criteria, assessing the accumulated data using ACCEPT criteria:[26]

1. Recruitment rate of eligible participants (Green >/=50%+; Amber 40-49%; Red <39%);
2. Number who remain engaged with the study and that we expect to follow-up at six-months (Green >/=72%+; Amber 61-71%; Red <60%);
3. Fidelity rate from the participating clinicians (Green >/=80%; Amber 70-80%; Red <69%);
4. Data completion rate for the POM (Green >/=80%; Amber 70-80%; Red <69%);
5. Confirmation that cost data is available and that appropriate cost information can be collected from the setting to inform the health economic evaluation;
6. Confirmation of the social acceptability of the intervention for residents, formal carers and care-home managers; and
7. No Adverse Events (see Adverse Events below) that are considered by the Data Monitoring Committee to highlight an unacceptable risk to enrolled participants.

3.1.4 Intervention:

DTs will visit care-homes in their locality every six-months and the DNs will visit every month for the first three-months and then three-monthly afterwards. This approach builds on the existing Gwên am Byth programme (which hasn't been empirically evaluated). In this manner, DTs employed in the CDS will proactively oversee the clinical management of eligible dentate residents, whilst DNs will promulgate advice to improve the day-to-day prevention offered to residents based on Delivering Better Oral Health:[27]

- Professional application of fluoride (2.2% NaF varnish) every three-months*
- Prescription of 5,000 ppm fluoride toothpaste, as appropriate (should active coronal or root caries be detected at baseline)*
- Oral hygiene advice; and
- Recommendation of the Eatwell Guide.

* covered by a Patient Group Direction

The DTs will provide any simple operative treatment for individual residents, within their Scope of Practice (referring onto dentists within the CDS when necessary).[28] Should gingivitis or periodontitis be detected, they will offer suitable periodontal management, in accordance with their Scope of Practice.[41] Should dental caries or loose 'fillings' be detected, they will offer appropriate treatment (e.g. replace the 'fillings') in accordance with their Scope of Practice.[41] As highlighted above, Monaghan & Morgan (2015) found that these management strategies would address the majority of cases that are likely to be seen in residents based in care-homes.[23] Extractions will need to be referred to dentists and here, DTs will act to sign-post residents to the CDS. Other clinical cases which may require onwards referral are fractured dentures, crowns and bridges, but these are less likely to warrant further intervention, given the focus on palliative management in this context.[29]

The visits from the DNs will form an important function in terms of championing oral health amongst care-home managers and staff. This element of the complex intervention is just as important as the six-monthly clinical management of dental need by the DTs. As highlighted by Brocklehurst *et al*., "there is growing support for the use of change agents in implementation processes".[30] Human agency where clinical or non-clinical staff act as change agents to facilitate the enactment of complex interventions is increasingly seen to be key.[31,32,33] To facilitate this process, participating DNs will be trained by the All-Wales Faculty of Dental Care Professionals (www.awfdcp.ac.uk) (PRB Director). This will include a dedicated web platform for care-home staff, based on the findings from TOPIC (NIHR PHR 17/03/11) and STOP (NIHR RfPB 16922). This will be composed of training videos and an

animation, which have shown to be effective in trials involving care-home residents.[34] Hard-copy training manuals will also be provided to care-homes and their use will be evaluated in the parallel process evaluation in WS2.

The details of the intervention for each resident will be recorded in a Case Report Form (CRF; using the resident's ID to ensure anonymity) and filed in a folder kept in the resident's room (see also 3.1.12). The local study team will be responsible for reviewing the delivery of the intervention so that it meets the criteria of the trial i.e. a visit by the DT at least once every six-months and by the DN once a month in the first quarter and then three-monthly afterwards. These processes and the requirements for each role will be included in a set of training slides that will be developed for the study. These will be used at the start of the study and also form a training manual for the DTs and DNs (a copy will also be provided for the care-home manager). Deviations from this process will be reported by the NWORTH local study team to the Trial Steering Committee (TSC).

3.1.5 Control treatment:

The control will be routine practice. The results from a Public Health England survey, the Priority Setting Partnership (led by PRB) and the systematic review, suggest that this practice is likely to be heterogeneous and ad hoc, including intermittent domiciliary care and infrequent tooth-brushing with toothpaste by unsupervised residents.

3.1.6 Sampling:

Recruitment will be a two-stage process. The first stage will be the recruitment of the care-homes. As highlighted in the next section, the research team will work closely with Care Forum Wales, ENRICH-Cymru, the South Eastern Trust in Northern Ireland, Central and North West London NHS Foundation Trust, the Whittington Health Trust and ENRICH in London. We aim to keep the eligibility criteria as broad as possible:

3.1.7 Selection of Care homes

Inclusion criteria:

1. Minimum of ten residents 65 years and over;

Exclusion criteria:

2. Current participation in TOPIC, Gwên am Byth or other oral health programme; and
3. Care-homes that only specialise in end-of-life or palliative care.

3.1.8 Selection of Subjects

The second stage of recruitment is for dentate or partially dentate residents of the included homes. Recruitment will be restricted to a maximum of twelve months (to allow for difficulties there-in) and participants will be followed for six-months to test the effect of the intervention and then a further six-months to test the sustainability of the treatment effect. The following are the eligibility criteria:

Inclusion criteria:

1. 65 years and over;
2. Dentate or partially dentate (at least six natural teeth); and
3. Full-time resident in care facility.

Exclusion criteria:

4. Residents who are only receiving end-of-life or palliative care.

The care-home managers using the eligibility criteria above, will be responsible for initially screening the residents to determine who would meet the eligibility criteria**.**. All staff involved in the recruitment of participants will be trained on the eligibility criteria prior to site activation.

The local study team will then confirm eligibility and from the residents that have been chosen, select a random sample of eligible residents for the trial and will then provide a short presentation about the study to the potentially eligible residents. Any residents interested in participating will be given a Participant Information Sheet (PIS) and an Informed consent Form (ICF). The local study team will attend the care home at least 48 hours after discussing the study so that potential participants can ask questions about the study and express their interest in taking part. Before any trial specific procedures are performed, the participant will need to sign and date the ICF. As the project involves sites in Wales, to comply with the Welsh Language Act 1993, the PISs and ICFs will be translated into Welsh and offered bilingually.

On entry into the study, the local study team will complete a Six-item Cognitive Impairment Test (6-CIT) with each resident in order to assess their level of cognitive function. In order to be as inclusive as possible, all residents that are able to provide consent will be included in the study, but a record will be kept of their 6-CIT scores: 0-7 = normal cognitive function; 8-9 = mild cognitive impairment; >10 = severe cognitive impairment. The impact of this change to the eligibility criteria is reflected in the increase of our modelled attrition rate (28%). A sensitivity analysis will be undertaken at the analysis stage to determine its effect on the POM.

A log will be kept of residents who decide not to participate (explored in WS2) and the number of residents who were unable to provide consent.

3.1.9 Withdrawal

Care-homes and residents will be able to withdraw at any time during the study. Where possible, in agreement with participants, data from those withdrawn will be used in analysis unless consent for this is specifically withdrawn.

3.1.10 Sample size:

For the reasons outlined above, the primary outcome will be based on a binary outcome, with a successful case demonstrating a 50% reduction in their mean Silness-Löe Plaque Index over a six-month period i.e. we will be comparing across the two arms, the relative proportion of the residents whose Silness-Löe Plaque Index have been halved as a result of the intervention. This concurs with the two most relevant studies in our systematic review, which tested the implementation of an oral hygiene guideline in a comparable population.[35,36] Khanagar demonstrated a 50% reduction in the mean Silness-Löe Plaque Index (3.17 to 1.57) and the mean reduction amongst residents found by van der Putten was from 2.36 to 1.58. Assuming the proportion of the control group that will halve their mean Silness-Löe Plaque Index over six-months is 0.10 (given the halo effect of participating in a trial), a sample of 280 (20 care homes per arm with five completers per care home plus attrition at 28%) will provide 90% power to detect a 0.19 difference in proportions between the arms at a 5% significance level (i.e. 0.29 of intervention group will see a 50% reduction in their mean Silness-Löe Plaque Index). This incorporates an Intra-Class Correlation coefficient of 0.05. The measurements taken at twelve-months will determine whether this effect (our primary end-point being six-months), can be sustained for a further six-months.

It is likely that care-homes will be able to recruit a variable number of participants due to their relative size and differing populations. Therefore, a coefficient of variation has been included in the sample size to accommodate this. Taking the approach of Campbell & Walters (2014) and assuming that recruitment will vary between 5 and 15 participants within a home the sample proposed will accommodate this and still retain 90% power.[37]

3.1.11 Setting/context:

The trial will be conducted in 40 care-homes from across Wales, Northern Ireland and England (London, with the potential of expanding into Yorkshire). The research team have developed strong links with ENRICH-Cymru in Wales (https://www.swansea.ac.uk/enrich-cymru/) (e.g. VOICE) and they have agreed to support the study. They also have a formal link with NWORTH Clinical Trials Unit. We have also engaged with Care Forum Wales

(https://www.careforumwales.co.uk/), which represents over 450 care-homes (MW is a co-applicant), nursing homes and other independent health and social care providers across Wales. They support providing high-quality social care and dignity for all, sharing best practice and resources. In order to facilitate our understanding of the pathway-to-impact, representative from ENRICH-Cymru and Care Forum Wales are also on our proposed Trial Steering Committee.

The research team will also use the footprint of the CDS across Wales (e.g. co-applicant VJ is the Clinical Director in Aneurin Bevan NHS Trust), the CDS in the South Eastern Trust in Northern Ireland (co-applicant CL is the Clinical Director), along with the Central and North West London NHS Foundation Trust and the Whittington Health Trust and ENRICH in London (co-applicant GT has an Honorary Consultant contract with the former). CDSs are charged with the responsibility of providing NHS service provision for care-homes on a regional basis.

3.1.12 Coronavirus (Covid-19_ mitigation)

Due to the Coronavirus (COVID-19), remote contact will be privileged over face-to-face meetings (including trial visits), where possible, to ensure that both participants and staff are protected. Face-to-face trial visits that need to be performed will only be undertaken where care-homes have been COVID-free for at least 14 days. The care-home (on behalf of the staff and residents) and researchers will provide the answers to the following screening questions prior to the face-to-face visit to ensure risk is minimised:

- Have the care-home staff or residents or researchers been unwell recently (that could be attributable to COVID)?
- Have care-home staff or residents or researchers had a recent onset of a new continuous cough?
- Have care-home staff or residents or researchers had a high temperature? (temperatures may be checked and recorded).
- Have care-home staff or residents or researchers noticed a loss or change in normal sense of taste or smell?
- Have care-home staff or residents or researchers had recent contact (in the last 14 days) with anyone with COVID-19 symptoms or come into contact with someone who has been confirmed as COVID positive?*

*If yes, they must follow the local rules and national regulations on self-isolation

Visits will then be pre booked. During the visit researchers will wear a mask, ensure social distancing and handwashing/hand sanitisation are performed, in line with local rules and national regulations. Before conducting any trial visits at the care-home, the researchers will provide their details and a declaration of their own COVID status (no symptoms or contact with known COVID cases for 14 days). The provision of the details of the researchers will enable 'track and trace' to be performed, should this be necessary.

Due to the sensitive patient population, every precaution will be taken to minimise the risk of infection, with decontamination taking place prior to entering and leaving the resident and the care-home.

3.1.13 Data collection:

The CDS in all three locations will also be commissioned to collect epidemiological data to help evaluate the oral health intervention (teams are large enough to prevent contamination, but we have also had discussions with Bridgewater Community Healthcare NHS Foundation Trust, should this be deemed necessary by the Board). This is an approach that we have used in NIHR HS&DR 16/01/79 and TOPIC (NIHR PHR 17/3/11). Our POM will be the Silness & Loë Plaque Index: a four-point scale running from 0-no plaque to 3-Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

Our sample size calculation is based on changes to our POM at six-months. This takes account of the 'time-to-effect' of the intervention on our chosen POM and the pragmatic consideration of the length of stay of eligible residents (where we have been as inclusive as possible). However, we will undertake a follow-up at twelve-months to determine the sustainability of any effects seen at six-months.

Secondary outcome measures will be episodes of bleeding on probing, pain, oral health related quality of life (OHRQoL), health related quality of life (HRQoL) and episodes of unscheduled care. We will also record the number of onward referrals to dentists, when the treatment needed extends beyond the DTs' Scope of Practice. Data on the number of new caries lesions (coronal and root caries) will be collected, but this is unlikely to be seen over the six-month period.

Trained dental examiners from the CDS will collect the clinical data at baseline, six and twelve months (an approach used in NIHR HS&DR 16/01/79). This will be undertaken on six index teeth (according to Ramfjord) to reduce the burden on participating residents.[38] South Eastern Trust (http://www.setrust.hscni.net/), Whittington Health

(https://www.whittington.nhs.uk/default.asp?c=10989) and Bridgewater Community Healthcare (http://www.bridgewater.nhs.uk/communitydentalnetwork/) have all agreed to act in this capacity.

In addition to the clinical measures, person-centred outcomes will be collected: a) by care-home staff weekly in relation to oral symptoms (through the standard procedures in care-homes of a symptoms checklist diary log) and, b) by local study team employed for this study at three time points (baseline, six and twelve months) for OHRQoL and HRQoL. The EQ-5D5L is an established HRQoL outcome and also relevant for a cost-utility analysis in the trial.[39] We are aware that NICE are currently assessing the UK utility weights of EQ5D5L and we plan to use these weights for the analysis in SENIOR. For OHRQoL, the Oral Impacts on Daily Performances (OIDP) will assess the impacts of oral conditions on daily life.[40] This is a widely used OHRQoL outcome also applied in care-homes in the UK.[41] These person-centred measures will be collected on pre-printed CRFs for each resident using an ID code (based on both care-home and resident identifiers) to ensure anonymity. The pre-printed CRFs will be held in a folder in the resident's room and collected on a regular basis by the local study team. We will also collect data around the number of confirmed cases of COVID19 within the care homes at baseline, 6 months and 12 months to assess any impact this may have had on the home during the study. If in the event of the COVID pandemic preventing access to laptops and filing cabinets at work, the data collected will be stored in a locked filing cabinet at the local study team's home

The local study team at each site will be responsible for entering data into MACRO. The dates for the epidemiologists to visit the care-homes will be determined by the Chief Investigator and over-seen by the local study team at each site. The timings of these data collection points will be added to the Data Management Plan (with an Assessment Schedule table).

Training sessions for care support staff will be organised at the beginning of the trial, including Good Clinical Practice and General Data Protection Regulations. They will also be undertaken at regular time intervals (overseen by the local study team at each site), to ensure that support staff fully understand the research protocol, delegation log, and Standard Operating Procedures (SOPs) for the study. local study team will be trained in questionnaire administration and appropriate interviewing techniques. This is an approach we are adopting in TOPIC (NIHR PHR 17/3/11) and our previous studies have demonstrated the feasibility of collecting relevant clinical and questionnaire data in care-homes.[42]

Data will be collected and retained in accordance with the UK General Data Protection Regulations, alongside the data storage and data archiving policies at Bangor University, Queen's University Belfast and University College London. The information linking each

participant's study ID to their personal details will be kept securely. All other participant-related paper records will be anonymised and stored separately from their personal information.

3.1.14 Data analysis:

A full statistical analysis plan will be written and agreed before completion of data collection. The independent committees will have the opportunity to comment on this plan. If any deviations from the planned statistical analysis are required these will be fully documented and justified in the final analysis report.

Primary analysis will be considered at the six-month end point and will compare the plaque index levels between the two groups using a multi-level mixed effects model to accommodate the within care-home level clustering. Analysis will be conducted on an intention to treat basis and if required a per protocol analysis will be conducted as sensitivity analysis. Stratification variables will be incorporated into the model and other potential factors that could affect the results will be considered for inclusion in the models and determined a priori (e.g. characteristics of the care-home and the demographics of the participants). All treatment effect estimates will be presented with 95% confidence intervals. Analysis of secondary outcomes will follow the same analysis model as the primary analysis where possible. Binary outcomes will be analysed using multi-level logistic regression. Exploratory analysis will be conducted to establish the effect of cognitive impairment on the outcome.

The aim is to minimise the amount of missing data, supported by the limited additional visits required by the participants. However, there is an expectation that some missing data will occur; predictors of missingness will be investigated and will be considered for inclusion in the models. Multiple imputation will be employed to address missing outcomes where appropriate. Test modelling and missing data assumptions via sensitivity analyses will be undertaken.

3.2 Workstream two*:*

WS2 will run alongside WS1 to undertake a process evaluation of the trial. We will use semi-structured interviews with residents, staff, managers, DTs, DNs and informal carers to assess the intervention's acceptability. Managers and residents that refuse participation will also be interviewed, alongside informal carers, to explore their narrative. The sampling frame will account for geographic differences, care-home size, staffing ratios and proportion of residents with severe cognitive impairment. We will also interview Chief Dental Officers, dental commissioners, Directors of the CDS and 'high-street' dentists. This will identify the features/factors that are more likely to promote successful implementation and sustainability of the intervention.

Data collection will be guided by the three elements (Context, Evidence, Facilitation) of the PARIHS framework (Promoting Action on Research Implementation in Health Services).[43] A semi-structured interview schedule will be developed in collaboration with the PPI group. Audio-taped interviews will be conducted in person and via the telephone (as appropriate) and will last for 20-30 minutes with residents (to reduce burden) and between 30-60 minutes with 'non-resident' stakeholders. Data will be anonymised, fully transcribed, and analysed by the researchers under the supervision of co-applicants (see 'Data Collection' below). Thematic analysis will be undertaken and a quality checklist will guide analysis and writing.[44,45] To be consistent with TOPIC (NIHR PHR 17/3/11) and allow a direct comparison, we will also draw on the approach of Stirman *et al*.,[46] Davidson *et al*.[47] and in particular, Pfadenhauer *et al*. (see detail below).[48]

3.2.1 Data collection:

In WS2, we will undertake a process evaluation to explore the acceptability of the intervention. In addition, we will aim to capture data which focuses on the facilitators and barriers to the intervention and identify the features/factors that are more likely to promote successful implementation and long-term sustainability.[49] WS2 will run alongside WS1 and we will use semi-structured interviews with participating residents, formal and informal carers, care-home managers, DCPs and commissioners. We will also interview managers and residents that refuse to participate, to explore their narrative. We will explore how the intervention could be embedded in standard practice guided by the PARIHS framework and Pfadenhauer et al.'s framework to maximise pathway to impact.[52,50] The latter is the approach that we have adopted for TOPIC (NIHR PHR 17/3/11), where we have developed a logic model for the study. Although data from TOPIC will help us inform the process evaluation for this study, we will initially give emerging data primacy to ensure that new themes emerge (given that this study will focus on service provision). We will use the different domains of Pfadenhauer et al. framework (Table 1) to explore the factors that are important for implementation, so that the pathway-to-impact will be considered from the outset (see data analysis below).

Table 1: Domains and questions for reflection from Pfadenhauer *et al*.[52]

Domain	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?

Audio-taped interviews will be conducted in person and via the telephone (as appropriate) and will last between 30 minutes for residents (to reduce the cognitive burden) and 30-60 minutes for the remaining stakeholders. We will use PARIHS and Pfadenhauer's framework to understand potential pathways to impact and to determine how these could be adopted into routine practice.

3.2.2 Data analysis:

In WS2 data will be anonymised, fully transcribed, and analysed by the researchers under the supervision of co-applicants PRB and LW (LW and PRB have a particular interest in the use of human intermediaries to facilitate implementation and pathways-to-impact).[51,52,53] Thematic analysis will be undertaken and a quality checklist will guide analysis and writing.[48,49] WS2 will also draw on TOPIC (NIHR PHR 17/3/11), VOICE and qualitative research on barriers to implementing oral health interventions in care-homes in London.[28]

The process of data analysis for WS2 will follow an inductive approach, which will be guided by the overarching theoretical framework (PARIHS) and we will refer back to Stirman *et al.*, Davidson *et al*. and in particular, Pfadenhauer *et al*., to explore the factors that are important for implementation, so that the pathway-to-impact will be considered from the outset. The researchers will immerse themselves in the data by initially reading and re-reading the transcriptions. Initial codes will then be generated from transcripts selected at random by each of the researchers independently. The highlighted phrases will then be compared and once agreement has been reached the coding frame will be formed. Further transcripts will then be analysed until saturation is reached. This will be assessed [PRB & LW] when no new information was generated from the analyses. Overarching themes will be developed from the coded transcripts by organising them into clusters based on the similarity of their meaning by the researchers to facilitate triangulation. These will be checked against the coded extracts and the raw data to ensure that they formed a coherent pattern and were representative of what the participants were trying to convey. Specific examples will be selected to create clear definitions for the coding frame and representative quotes of each theme will be provided in the results.

As WS2 seeks to explore the factors that underlie the implementation of the intervention as fully as possible, we will look at factors that influence the Context, Evidence, Facilitation (PARIHS) of the intervention. We will pay particular attention to acceptability for care-homes and residents, treatment fidelity, contextual factors that shape the intervention; contextual factors that shape implementation; mechanisms that sustain or potentiate effects; and

unexpected pathways and consequences. This is an approach that is being used successfully in an on-going pilot trial led by co-applicant PRB (HS&DR 16/01/79) and a feasibility study (PHR 17/03/11). Areas of practice that the data collection will focus on will include day-to-day life for residents (personal hygiene, cleanliness and comfort; personal appearance; dining experience; care home environment and social participation); health and well-being of residents (prevention and oral hygiene practices; access to services; and diet and nutrition); staff and leadership in the home (care staff; nursing staff; care home managers) and the dental workforce (DCPs and dental commissioners). This will be informed by research already undertaken in a care-home environment (for example Goodman et al and Spilsbury).[54,55]

3.3. Workstream three*:*

WS3 will be a cost-effectiveness analysis from an NHS perspective and examine potential long-term costs and benefits.

3.3.1 Data collection:

WS3 will produce a cost-effectiveness model. Costs fall under a number of headings and will be gathered under these. Programme delivery costs (DN and DT) in terms of: (i) staff time; (ii) travel costs; (iii) consumables (such as toothpaste) and; (iv) production of training materials and websites, will be collected using a combination of staff diaries, surveys and programme records. Staff time will be monetised using estimates of salary costs from published sources; travel time using costs per mile travelled and consumables based on programme acquisition costs. Production of training materials and development of the website will be treated as a fixed cost and based on programme records. Other dental costs will be based on a survey of patients and review of patient records with respect to dental care beyond preventive activities provided by DN and DT or other dental practitioners. This will be monetised using the Statement of Dental Remuneration for Northern Ireland, which provides greater granularity in terms of the identification of fee for service.[56] Data will be collected at baseline, six-months and 12-months for the preceding six-months using surveys and patient records.

3.3.2 Data analysis:

Costs will be aggregated for the individual residents based on their consumption of resources under each heading and in total. Relevant costs will be differentiated between those required to ‘treat’ an individual and those required to set-up the study. Total treatment costs will be related to outcomes in a series of cost-effectiveness ratios, for oral cleanliness, pain, oral and general health-related quality of life. As analyses are confined to 6-months in the base-case, no discount rate will be applied. In order to quantify the uncertainty associated with the ICERs, a stochastic analysis will be undertaken, with the results presented as a series of cost-effectiveness acceptability curves (CEACs). The CEACs will show the probability of the

intervention being cost-effective compared to usual care for a range of maximum monetary values that decision-makers may be willing to pay for the outcome concerned.

Contextual data related to care-homes from WS2 (e.g. number of beds and staff-to-resident ratio) will be incorporated into the cost-effectiveness analyses in sensitivity analyses. These variables will be included as covariates in seemingly unrelated regression analyses from which incremental costs, effects and cost-effectiveness will be estimated. Additional sensitivity analyses will explore variations in unit costs and in the value set used to estimate generic health-related quality of life using a series of deterministic analyses where ICERs will be recalculated as well as within the contextual analyses.

The interviews with stakeholders from WS2 will be used to explore key outcomes, their understanding of these and the relative importance attached to them. Accessibility to data and the use of routinely collected administrative data to substitute for that collected as part of the study will be examined separately. The analysis of costs will be used to identify key drivers of cost and the potential to reduce data collection in future studies. This information will be examined collectively, discussed and used as the basis for recommendations on future data collection and whether and/or which outcomes focus further cost-effectiveness analyses.

Assessment Schedule

CRF	Measure	Screening	Baseline	6-months	12-months	Ongoing/throughout study	Data collected by
CE	Silness & Loë plaque index		X	X	X		Dental examiners from the CDS
CE	Bleeding on probing		X	X	X		Dental examiners from the CDS
CE	New caries lesions (coronal & root caries)		X	X	X		Dental examiners from the CDS
SCL	Symptoms checklist diary					*Weekly by C-H staff	Care-home staff
SCL	Episodes of pain					*Weekly by C-H staff	Care-home staff
SCL	Number of onward referrals to dentists					*Weekly by C-H staff	Care-home staff
SCL	Episodes of unscheduled care					*Weekly by C-H staff	Care-home staff
OIDP	Oral Impacts on Daily Performances		X	X	X		Local study team
EQ-5D-5L	QoL EQ5D5L		X	X	X		Local study team
CHQ	Care home data (randomisation stratification data included)		X	X	X		Local study team
DEM	Demographics		X				Local study team
	CONSORT data	X				X	NWORTH local study team
6CIT	Six-item Cognitive Impairment Test		X				Local study team
INTERVENTION	Intervention adherence					X	DN/DTs
SAE	Adverse events (including SAE)					X	Local study team
WDL	Withdrawal					X	Local study team

*weekly collection covers baseline, 6 months and 12 months data collection time points

4.0 PROJECT MANAGEMENT:

The study will be sponsored by Bangor University and the governance and management of the study will be undertaken by NWORTH. As a result, the study will adhere to NWORTH's SOPs, for all study and data management, statistical and regulatory matters. Trial-specific SOPs will be developed as required and will be addressed throughout the study period and regularly reviewed. We will establish a Trial Steering Committee (TSC), a Data Monitoring Committee (DMC) and a Trial Management Group (TMG). 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 Good Clinical Practice will be ensured. The TSC and DMC will meet every six-months. Both will consist of an independent chair and an independent statistician. The DMC will be able to advise on changes to the conduct of the study via recommendations to the TSC and will also receive regular safety reports from the TMG.

4.1 Trial Steering Committee

The project's TSC will oversee the running of the trial on behalf of the sponsor and funder and will have overall responsibility for the continuation or termination of the trial. It will ensure that the trial is conducted in accordance with the principles of Good Clinical Practice and the relevant regulations, and to provide advice on all aspects of the study.

4.2 Data Monitoring Committee

The project's DMC 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 Trial Steering Committee.

4.3 Trial Management Group

A TMG will oversee the day-to-day running of the study and be composed of research team members and will meeting frequently during set up and subsequently on an agreed periodic basis once the trial is open to recruitment. The TMG will monitor all aspects of the trial's conduct and progress and ensure the protocol is adhered to.

Trial-specific training requirements will be addressed throughout the study period and regularly reviewed. Working alongside NWORTH's Quality Assurance Officer, and under the guidance of the Bangor team, the local study team will co-ordinate oversight of monitoring, documentation and all aspects of quality management and regulatory issues. NWORTH's Senior Trials Manager will provide advice to the management team on all aspects of the running of the study. NWORTH will supply appropriate templates to assist in developing the Trial Master File (TMF).

5.0 DATA PROTECTION:

The study will be managed in accordance with General Data Protection Regulations, Good Clinical Practice and relevant NWORTH SOPs. Where data are stored locally at local sites, the study will adhere to the SOPs of the respective University. 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 at source. Participants will be allocated a unique study number, which will be used in any documentation associated with the study. Participants' names will not appear on any documentation associated with the study apart from the Consent Forms, which will be kept separate in locked filing cabinets within the resident's care home.

Only members of the research team will have access to the data. Any hard copies of data (e.g. paper copies of CRFs, consent forms) will be stored locally in the resident's folder (using an ID to preserve anonymity).

6.0 ETHICAL AND REGULATORY APPROVALS:

The trial protocol, associated documentation, and all substantial amendments thereof will be submitted for review by a Research Ethics Committee (REC). 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. Potential participants will be assumed as having capacity to consent for themselves unless formally assessed as lacking capacity, in which case the views of a Personal Consultee (usually a relative) will be sought. If no Personal Consultee can be identified, a Professional Consultee who is a) independent of the study, b) knows the participant well enough to consider their views, will be approached. If the participant's lack of capacity is considered temporary; capacity will be reassessed prior to each contact with the researcher. If a participant communicates his/her objection to a research assessment or intervention, either verbally or non-verbally, the intervention will cease immediately. Further attempts will be made at a later time; however, if the participant continues to object then he/she will be withdrawn from the study. The safety and well-being of residents will be paramount at all times. All study documentation, including information and consent forms, will be developed in partnership with ENRICH and relevant PPI representation.

7.0 ASSESSMENT OF SAFETY

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 Adverse Event (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 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.

SAEs will be recorded in a running log at each care-home. This will include death and hospitalisation due to any cause. Participants' Medical notes will be reviewed for any hospitalisation. Due to the nature of the study population, SAEs are unlikely to be rare. Care-home staff will keep a running log of SAEs and this will be entered into MACRO on a weekly basis (form part of the delegation log and training).

These will form the basis of a report, and details of any SAEs that are related to taking part in the study and are unexpected will be sent onto the Sponsor, the Research Ethics Committee, DMC and the TSC within the required timelines. Should any SAE be associated with the intervention, the local study team will notify the Chief Investigator immediately, who will actively investigate the event. Other adverse events, although unlikely in a health promotion intervention, will be noted in the same log as the SAEs and a monthly report will be compiled by the local study team.

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 the TMF. The occurrence of AEs during the trial will be monitored by the DMC and TSC.

8.0 DATA COLLECTION AND TRIAL MONITORING

8.1 Quality Assurance and Quality Control of Data

QA includes all the planned and systematic actions established to ensure the trial is performed and data generated, documented/recorded and reported in compliance with GCP and applicable regulatory requirements. QC includes the operational techniques and activities done within the QA system to verify that the requirements for quality of the trial-related activities are fulfilled. This trial has undergone a risk assessment, the outcome of which will assist in the development of a monitoring plan and the QC checks required. To this end:

- The TM/Coordinating Centre is to verify appropriate approvals are in place prior to initiation of the study and the relevant personnel have appropriate study-specific training and GCP training where applicable
- The Investigator will ensure that all members of the study team are qualified by training and experience to undertake any delegated duties, to be recorded on the ‘Delegation of Authority and Signature Log’. Signed, dated CVs of the trial team will be stored in the TMF.
- Oversight of the trial will be provided by the DMC and TSC.

8.2 Risk Assessment

A risk assessment has been conducted by a cross functional team to ensure all aspects of the trial are reviewed, including potential participants, organisational and study hazards, the likelihood of their occurrence and resulting impact should they occur. The outcome of the risk assessment has been used in the finalisation of this protocol and will be used in the development of the monitoring plan and statistical analysis plan.

8.3 Source Data

The CRF will be considered the source data and should be consistent and verifiable with the information recorded on the study database. Information regarding how the data is to be collected, stored, and transferred is included in the study-specific Data Management Plan.

8.4 Monitoring

A monitoring plan, based on the risk assessment, will be prepared prior to participant recruitment detailing the monitoring strategy for the trial. The plan will include procedures for day-to-day centralised monitoring, process for setting the 6 and 12 months follow up assessments conducted by DCPs, the requirements for source data verification, ISF audit, and for identification of protocol deviations and serious breaches of protocol and/or GCP.

8.5 Direct access to source data and documents

In order to perform their role effectively, monitors and persons involved in QA and inspection may need direct access to source data. Since this affects the participant's confidentiality, this fact is included on the Patient Information Sheet and Informed Consent Form.

8.6 Confidentiality

Individual participant medical information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited with the exceptions noted below:

- CRFs will be labelled with a unique trial identification number.
- Medical information may be given to the participant's medical team and all appropriate medical personnel responsible for the participant's welfare.

NWORTH will preserve the confidentiality of participants taking part in the study and the Sponsor is registered as a Data Controller with the Information Commissioners Office.

9.0 INDEMNITY

Cover for harm as a result of the design or conduct of the trial has been arranged with the study Sponsor.

10.0 FINANCIAL ASPECTS

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

11.0 DEFINITION OF END OF TRIAL

This is defined as the date of the last visit of the last participant.

12.0 ARCHIVING

The sponsor will authorise archiving following submission of the end of trial summary report. The TMF will be prepared for archive by the Chief investigator and archived by the Sponsor according to the Sponsor's archiving procedures. The Data Management Plan will also cover provisions around data archiving.

13.0 PROJECT / RESEARCH EXPERTISE:

PRB is Professor of Health Services Research at Bangor University. He is an experienced NHIR CI (NIHR/CS/010/004; HS&DR 11/1025/04; HS&DR 16/01/79), a former NIHR Clinician Scientist and is Director of NWORTH CTU (UKCRC #23). His research focuses on the efficacy, effectiveness and efficiency of role-substitution in oral service provision and has an interest in the provision of oral health care for older people. He will be the Chief Investigator and provide methodological oversight across the study.

GMcK is Consultant in Restorative Dentistry and a gerodontologist with experience of clinical trials in older adults. He is vice-president of the Geriatric Oral Research Group within the International Association for Dental Research and a past president of the European College of Gerodontology. He is PI on the Dunhill Medical Trust funded DECADE study: DEvelopment of a Core outcome set for orAl health services research involving DEpendent older adults. He is a co-author on the recent National Oral Health Policy for the Republic of Ireland:]https://health.gov.ie/blog/publications/smile-agus-slainte-national-oral-health-policy/. He will be Principal Investigator for the Northern Ireland centre.

GT is a Professor in Dental Public Health with experience in Oral Health Related Quality of Life in older people, social determinants, epidemiology and the relationship between oral and general health among older populations. He is PI on the NIHR PHR funded project (PHR 17/03/11) on Improving the Oral Health of Older People in Care-homes: a Feasibility Study (TOPIC). He will be Principal Investigator for the London centre.

ZH is the Principal Trial Statistician at NWORTH CTU and will lead on the methods and statistical analysis used in WS1. NWORTH CTU has particular expertise in complex interventions within older population settings.

IC is Professor and Honorary Consultant in Dental Public Health and provided the clinical expertise to the team commissioned by NICE to develop the evidence base for NG48. He will provide trial expertise to the study.

AK is the National Dental Public lead for Dental Services Innovation and Quality in Wales. He is team lead and a consultant in Dental Public Health within Public Health Wales. He is currently leading the General Dental Services Reform Programme in Wales, enabling the

research team to link this research with on-going NHS reform. He will provide subject expertise to the study.

MD is a Consultant in Dental Public Health and is responsible for commissioning all primary and secondary care dental services in Northern Ireland. He was also a member of the NICE committee that produced NG48. He will provide subject expertise to the study.

CL is the clinical director for the CDS in the South Eastern NHS Trust, including provision of dental services to more than 1,000 residential care-home residents. She will provide subject expertise to the study.

KM is the DCP Lead for Health Education and Improvement Wales, which is the commissioner of workforce training in Wales (https://heiw.nhs.wales/). She will provide subject expertise to the study.

LW is a Reader at Bangor University with a particular interest in implementation and the use of human intermediaries. She will lead on the process evaluation, with PRB and SRB.

SRB is a Chartered Health Psychologist with a wealth of experience of using theoretical models and understanding quality of life, as applied to dentistry and oral health (would also lead any expansion of the study into Yorkshire). She will contribute to the process evaluation.

CS is Consultant Gerontologist with experience in recruiting frail, older adults with comorbidities such as cerebrovascular disease and cognitive problems. He has completed an NIHR funded mixed method study evaluating an oral hygiene intervention for stroke unit care. He will provide subject expertise to the study.

CON is Professor of Health Economics with experience in the analysis of cost and care quality in care homes. He has completed an NIHR trial examining the cost-effectiveness of prevention measures in oral health (NIC-PIP). He will lead the health economic analysis for the study.

FS is a research-orientated DCP, who has experience of working with the Gwên am Byth programme and is currently undertaking a PhD looking at the implementation of an oral-health intervention in The Humber. She is also on the working-group for the Chief Dental Officer of England re DCP-prescribing, to enable DCPs to prescribe fluoride and local analgesia. She will provide subject expertise to the study.

LM and KS are two PPI members based in Wales. LM is the Vice Chair of Regional Gwent Citizen Panel and Chair of Action for Elders (https://www.actionforelders.org.uk/faqs/lorraine-morgan-chair). She also has a Ministerial advisory role in ageing in the Welsh Government. KS is a leading member of PARC-Bangor, a PPI initiative at NWORTH ensuring PPI is embedded in trials led by the Unit (http://nworth-ctu.bangor.ac.uk/parc-bangor.php.en).

VJ is Chair of the British Society of Gerodontology (https://www.britishgerontology.org/) and Clinical Director of the CDS at Aneurin Bevan University Health Board. She is an advocate of role-substitution in care-homes and is part of the Gwên am Byth programme. She will provide subject expertise to the study.

14.0 DISSEMINATION:

The Chief Investigator and all co-applicants will prepare and agree a publication policy, which will be reviewed by the TMG, to agree on authorship of future papers and other outputs from the study

Multiple routes will be taken to the dissemination of the study.

Academia: Existing links to the European College of Gerodontology (ECG) and the International Association of Dental Research (IADR) Geriatric Oral Research Group (GORG) will be made via GMcK who is vice-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 Elect 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 on the IADR Council representing the Behavioural Epidemiologic and Health Services Research group. We will publish the results of the trial in Gerodontology and the Journal of Dental Research. We will disseminate our results at the ECG, the International Association of Dental Research and the British Association for the Study of Community Dentistry (the latter with our PPI group).

Changes to practice: MD and CL have responsibility for commissioning primary care services in Northern Ireland and community services respectively. This gives the research team the potential to directly influence the commissioning of new services based on the results of the study. GMcK is also on the Council of the British Dental Association, the body that represents all practising dentists in the Province. PRB and AK will use the results of the study to influence the on-going NHS dental contract reform process in Wales (evaluation being undertaken by PRB). This gives the team direct access to ‘high-street’ dentists, DCPs and dental commissioners for dissemination. The results will also be relevant for Local Authorities in England and aligns with the recent guidance from PHE. The team will also hold a participatory workshop at the end of the study, bringing together key policy-makers (see below) and participating care-homes and representatives of commissioning bodies and practicing dentists and DCPs.

Dental Care Professionals: The results of the study will feed directly into an educational programme, supported by infrastructure funding from the Chief Dental Officer, which aims to promote the greater use of DCPs in Welsh service provision. The All-Wales Faculty of Dental Care Professionals (www.awfdcp.ac.uk) was developed by PRB as part of 'The Oral Health and Dental Services Response to A Healthier Wales' and links to the 'Prudent Healthcare' agenda. The Faculty is developing within-role and across-role skills-escalators for DCPs and building a programme of mini-Massive Online Open Courses to support a new DN roles (linking to non-dental health professionals). The key element of this role will be to work in care-homes and so the results from this study will inform this process directly. KM is the DCP Lead for Health Education and Improvement Wales, which is the commissioner of workforce training in Wales (https://heiw.nhs.wales/). This will ensure that the results can directly influence policy decisions about the future workforce.

Changes to policy: PRB, AK, MD, GMcK and GT have strong links to national and international policy-makers (including the Chief Dental Officers). PRB will be undertaking a new role from January 2020, as one of the Deputy Chief Dental Officers in Wales (0.4FTE). This gives a direct line to policy-makers for dissemination. In Northern Ireland, GMcK has been appointed as one of the policy leads for a national gerodontology project following an 'Oral Health Matters' event at Stormont in October. This event drew together policy-makers, the Chief Dental Officer, the British Dental Association and Assembly Ministers. 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 and GT are key figures in a number of International and European organisations: ECG, IADR's GORG, CECDO and PBOHE. PRB and AK work for the Chief Dental Officer in Wales. GMcK is a co-author on the recent National Oral Health Policy for the Republic of Ireland: https://health.gov.ie/blog/publications/smile-agus-slainte-national-oral-health-policy/. The results of this study will be a key driver in the development of a policy to improve oral health in residential care and encourage 'high-street' dentists to use DCPs and become more community facing (a key policy objective of the www.awfdcp.ac.uk highlighted above). 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/). See above re Health Education and Improvement Wales (https://heiw.nhs.wales/).

Regulators: Further collaborative links have been formed with the Regulation and Quality Improvement Authority (RQIA) (https://www.rqia.org.uk/). 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. We will also invite the RQIA, CQC and Care Inspectorate Wales to the participatory workshop highlighted above.

Patients: 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/research-centres/CentreforPublicHealth/Research/PPIGroup/) and PARC-Bangor (http://nworth-ctu.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. Patient-facing materials will be developed (and also produced in audio-format).

In disseminating our results, we will adopt the following principles in our '*communication plan*' based on www.health.org.uk/research-kit:

1. To create a clear and concise argument, we will structure our communication plan around the following core argument:
    a. Dental needs amongst dependent older people are changing rapidly;

   b. This means that we have to change how we care for older people in residential care;
   c. Examining new means of delivering care efficiently is key;
2. To provide snapshots of our research, we will use patient stories and graphics (see infographic costed in) hosted on a website based at Bangor and Queens (in conjunction with DECADE and VOICE);
3. We will tailor our communications plan to reflect the knowledge, interests and concerns of the different stakeholders. These will be patients; academics; clinicians, care-home staff, care-home managers, dental commissioners and Chief Dental Officers (see below);
4. We would also aim to maximise rich media and new technology, developing an animated infographic for the end of the study (used in HS&DR 14/19/12). This will be hosted on Bangor, Queen's and UCL's websites to spark curiosity and make our key results more visually engaging for all our stakeholders;
5. We'd also aim to use Prezi presentations at academic and clinical conferences (where permitted) to move away from a static, linear presentation of the results;
6. We'd also aim to develop PechaKucha style presentations (https://www.pechakucha.org) to provide fast-paced, image-based rich media presentations for care-home managers and dental commissioners;
7. We will adopt good e-learning principles (https://www.shiftelearning.com/home) to develop resources for care-home managers and staff:
   a. A problem-solving paradigm;
   b. Metaphors to make content unexpected;
   c. Visuals are easier to digest;
   d. Question to invite active participation;
   e. Emotionally-charged stimuli to capture people's attention;
   f. Storytelling to facilitate learning;
   g. Contrast and controversy;
   h. Bite-sized pieces of information; and
   i. Lists to organise thoughts into bite-sized chunks.

Our PPI representatives will also attend the British Association for the Study of Community Dentistry.

15.0 PROTOCOL AMENDMENTS

15.1 Current version

Final Version 2 9/12/2020

15.2 Amendments

Final Version 1 to 2

Pg/section	Changes to text
2.3, 3.1.7	Clarification of age as 65 years and over
2.6	Flowchart corrected – two intervention groups instead of intervention and control group
3.1	Stratification clarified Prescription of fluoride clarified
	Trial Manager (TM) amended to local study team throughout protocol
3.1.8	Clarification of exclusion criteria Process of how eligible residents are selected
3.1.10	Attrition rate clarified Typographical error corrected
3.1.13	Clarification of where collected data stored in the event of the COVID pandemic preventing access to work laptops and filing cabinets
4.3	Clarification that working alongside NWORTH's Quality Assurance Officer and under guidance of the Bangor team, the local study team will co-ordinate oversight of monitoring documentation and all aspects of quality management and regulatory issues
5.0	Consent form storage clarified
7.2	SAE reports provided to DMC

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