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# Using other members of the dental team to provide oral care for residents in care homes

**Submission date**
29/10/2020

**Registration date**
03/12/2021

**Last Edited**
18/03/2025

**Recruitment status**
No longer recruiting

**Overall study status**
Ongoing

**Condition category**
Oral Health

[_] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Poor oral health for older adults residing in care homes is a significant public health problem. Unlike previous generations, about half of all care home residents now have some of their own natural teeth, but their oral health is much worse than their community living peers. These can give rise to significant avoidable health and social care costs. Despite this, dental service provision in care homes is poor and extremely variable.
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 older adults (over 65 years of age) residing in care homes over a 6-month period, when compared to 'treatment as usual' (commonly a reactive and ad hoc service provided by dentists). In addition, the researchers aim to determine whether this effect is sustainable over a further 6-month follow-up period.

Who can participate?
Residents over the age of 65 years; who are dentate or partially dentate (at least six natural teeth); and a full-time resident in the care facility

What does the study involve?
Care homes will be randomly divided into two groups: intervention and control.
The intervention consists of an oral health assessment of residents. Dental therapists will visit the care home every 6 months and undertake any treatment the participating residents require. Dental nurses will visit the care home monthly for the first three months then 3-monthly afterwards to provide advice on how to improve the oral health of the participating residents, apply fluoride to teeth as required. They may also provide advice on the Eatwell guide.
The control will be routine practice.
Trained dentists will collect clinical information at the start of the study. Other data will be collected via questionnaires administered by trial managers. After 12 months, the health of the residents' mouths will be assessed again, and the questionnaires administered again and findings will be compared to those at the start of the study. Residents, managers and staff will be interviewed to assess the acceptability of the proposed intervention.

What are the possible benefits and risks of participating?
The study will help the researchers to understand whether using different members of the dental team can improve oral health. If the results are positive, this will help us to plan future services. Other than the time commitment taking part in the study, the researchers do not anticipate there being any risks.

Where is the study run from?
Bangor University (UK)

When is the study starting and how long is it expected to run for?
August 2018 to September 2025

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) (UK)

Who is the main contact?
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# Additional identifiers

## EudraCT/CTIS number
Nil known

## IRAS number

297182

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

IRAS 297182, CPMS 49709

# Study information

## Scientific Title

uSing rolE-substitutioN In care-homes to improve oRal health

## Acronym

SENIOR

## Study objectives

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 (over 65 years of age) residing in care-homes over a 6-month period, when compared to 'treatment as usual' (commonly a reactive and ad hoc service provided by dentists). In addition, the researchers aim to determine whether this effect is sustainable over a further 6-month follow-up period.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 05/05/2021, Wales Research Ethics Committee 5 Bangor (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 785738; Wales.REC5@wales.nhs.uk), REC ref: 21/WA/0116

## Study design

Cluster-randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Cluster randomised trial

## Study setting(s)

Other

## Study type(s)

Prevention

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Oral health in care-home residents

## Interventions
Three workstreams (WSs) are proposed. WS1 will be a two-arm cluster-randomised controlled trial, with a 3-month internal pilot. Recruitment will be a two-stage process. The first stage will be the recruitment of the care homes. The second stage of recruitment is for dentate or partially dentate residents of the included homes.

This is a cluster randomised trial and will be conducted in 40 care homes in England, Northern Ireland and Wales. They will be randomised (via NWORTH CTU) based on a 1:1 ratio (20 intervention and 20 control). Stratification of care homes will be based on the following factors care home site (England, Northern Ireland, Wales) and care-home size (based on the number of available beds within the home: small 1-10 beds; medium 11-49 beds; large 50+). The researchers 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 the analysis.

The intervention consists of:
1. Professional application of fluoride (2.2% NaF varnish) every 3 months
2. Prescription of 5,000 ppm fluoride toothpaste (should active coronal or root caries be detected at baseline)
3. Oral hygiene advice
4. Recommendation of the Eatwell Guide

On entry into the study, residents will complete the Six-item Cognitive Impairment Test (6-CIT) 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. 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.

WS2 will run alongside WS 1 to undertake a process evaluation of the trial. The researchers will use semi-structured interviews with residents, staff, managers, D-Ts, DNs and informal carers to assess the intervention's acceptability. Managers and residents that refuse participation will also be interviewed, 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. They will also interview Chief Dental Officers, dental commissioners, Directors of the CDS and high street dentists.
WS3 will be a cost-effectiveness analysis from an NHS perspective and examine potential long-term costs and benefits.

## Intervention Type
Behavioural

## Primary outcome measure
Plaque coverage measured using the Silness & Loë plaque index measured at baseline, 6 and 12 months

## Secondary outcome measures

1. Oral health measured using bleeding on probing at baseline, 6 and 12 months
2. Pain measured by asking the participating resident if they have experienced any episodes of sensitive teeth, episodes of toothache or abscess or swelling in the mouth (no = healthy, yes = adverse event – mild, moderate or severe) at baseline, 6 and 12 months
3. Oral health-related quality of life using the OIDP at baseline, 6 and 12 months
4. Health-related quality of life using EuroQol's five dimensions (EQ-5D5L) at baseline, 6 and 12 months
5. Episodes of unscheduled care reported weekly by care home staff and at baseline, 6 and 12 months by researchers
6. New coronal and root caries lesions reported weekly by care home staff and at baseline, 6 and 12 months by researchers

## Overall study start date
05/08/2018

## Completion date
30/09/2025

# Eligibility

## Key inclusion criteria
Care homes:
1. Care homes are expected to have a minimum of ten residents over the age of 65 years

Residents:
1. Over the age of 65 years
2. Dentate or partially dentate (at least six natural teeth)
3. Full-time resident in a care facility

## Participant type(s)
Other

## Age group
Senior

## Lower age limit
65 Years

## Sex
Both

## Target number of participants
Planned Sample Size: 280; UK Sample Size: 280

## Total final enrolment
327

## Key exclusion criteria

Care home:
1. High-dependency units
2. Current participation in TOPIC, Gwên am Byth or other oral health programme
3. Care-homes that specialize in end-of-life or palliative care

Residents:
1. Residents who are receiving end-of-life or palliative care

### Date of first enrolment
01/09/2021

### Date of final enrolment
11/10/2024

# Locations

### Countries of recruitment
United Kingdom

### Study participating centre
### To be confirmed
United Kingdom
-

# Sponsor information

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Bangor University

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### Sponsor type
University/education

### Website
http://www.bangor,ac,uk/

## ROR

https://ror.org/006jb1a24

# Funder(s)

## Funder type
Government

## Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

# Results and Publications

## Publication and dissemination plan
The researchers are in the process of writing up a protocol paper. They will publish the results of the trial in Gerodontology and the Journal of Dental Research. They will also disseminate the results at the ECG, the International Association of Dental Research and the British Association for the Study of Community Dentistry (the latter with the PPI group). The results of the study will also be used to influence the ongoing NHS dental contract reform process in Wales. The results will also be relevant for Local Authorities in England and align 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 and participating care-homes and representatives of commissioning bodies and practicing dentists and DCPs. 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. The researchers will also invite the RQIA, CQC and Care Inspectorate Wales to the participatory workshop

The results of the study will also 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 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 role (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. This will ensure that the results can directly influence policy decisions about the future workforce.

The research team have strong links 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 the dissemination of information directly to dependent older people and their carers/relatives and care-home managers/staff. The PPI co-applicants will also ensure a strong patient-facing dissemination strategy. Patient-facing materials will be developed (and also produced in an audio format).

## Intention to publish date
31/12/2025

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Anonymised data will be stored according to Bangor regulations (Bangor server). See https://www.bangor.ac.uk/planning/InfSecGuid.php.en

## IPD sharing plan summary
Stored in non-publicly available repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
| --- | --- | --- | --- | --- | --- |
| Protocol article | protocol version 3 | 18/03/2021 | 18/08/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |