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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

Recruitment status
No longer recruiting

Registration date
03/12/2021

Overall study status
Completed

Last Edited
18/03/2025

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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
297182

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
Plaque coverage measured using the Silness & Loë plaque index measured at baseline, 6 and 12 months

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

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

Organisation
Bangor University

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

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

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes