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Improving the oral health of older people in care homes

Submission date
17/02/2020

Recruitment status
No longer recruiting

Registration date
17/04/2020

Overall study status
Completed

Last Edited
03/07/2025

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The ageing population is increasing in number. Currently, half of all residents enter care homes with some of their own natural teeth and this proportion is likely to increase. Preventing dental disease for care homes residents is important for their function and quality of life. Good oral health affects the ability to eat and communicate, appearance and self-esteem through, for example, the willingness to smile. It also reduces the need to provide treatment in care homes, which is often difficult and costly. A study exploring the priorities for older people as their needs change and they move into supported accommodation, found that preventing oral disease was considered paramount. A national survey, however, found that current prevention practices and services in care homes are poor. There are also large gaps in the scientific literature about how best to prevent oral disease among care home residents. NICE guidelines on the maintenance of oral health in care homes have been published, but it is not known how feasible and effective these recommendations are in practice. As a result, a feasibility study is necessary to inform the design of a larger definitive trial. This study aims to assess the feasibility of an intervention to improve the oral health of older people (defined as those who are 65 or older) in care homes, based on the NICE guideline.

Who can participate?
Residents aged over 65 in participating care homes who have their own natural teeth

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, daily “support worker assisted” tooth brushing with fluoride toothpaste, and a staff training package on how to improve oral health. Trained dentists will collect clinical information at the start of the study. Other data will be collected via questionnaires administered by researchers. 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?
This research will contribute towards helping public health programs improve oral health for a

large number of care home patients. Care homes will be provided with an educational package to help train staff. The intervention will raise awareness of oral health and improve assisted self-care. The intervention in its entirety, including the educational package, is expected to be sustainable and suitable for implementation in care homes across the UK. The researchers do not anticipate any major issues associated with this study and the potential risks for research participants are considered to be very low. Inconvenience and time commitment taking part in the study will be the largest burden for participants.

Where is the study run from?
1. South Eastern Health & Social Care (UK)
2. Whittington Health NHS Trust (UK)
3. Central and North West London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2018 to November 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
1. Prof. Georgios Tsakos
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3. Prof. Paul Brocklehurst
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Study website
https://www.ucl.ac.uk/epidemiology-health-care/research/epidemiology-and-public-health/research/dental-public-health/research/topic-oral-health

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
254421

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42666, IRAS 254421

Study information

Scientific Title
Improving the oral healTh of Older People In Care homes: a feasibility study (TOPIC)

Acronym
TOPIC

Study objectives
This study aims to assess the feasibility of an intervention to improve the oral health of older people (aged 65 years or older) in care homes, based on the NICE guideline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/02/2020, London – City & East REC (Health Research Authority, Bristol HRA Centre, Level 3 Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8033, +44 (0) 7413516923; nrescommittee.london-cityandeast@nhs.net), REC ref: 19/LO/1107

Study design
Randomised; Both; Design type: Prevention, Complex Intervention, Other, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Care home, 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

Interventions

Care homes will be randomly divided into two groups: intervention and control. The intervention consists of:
1. An oral health assessment of residents
2. Daily “support worker assisted” tooth brushing with 1,500 fluoride toothpaste
3. A staff training package on how to improve oral health

Three workstreams (WS) are proposed. WS1 will assess the feasibility of undertaking the intervention. Eligible residents who have their own natural teeth will be recruited. Baseline assessments will be conducted, using trained dentists to collect clinical information. Questionnaires will be used to collect other data (e.g. sociodemographic, quality of life). Recruitment, retention and the acceptability of the intervention for residents, staff and managers will be determined. After 12 months, the assessments will be repeated and findings will be compared to those at baseline.

WS2 will interview residents, managers and staff to understand the proposed intervention’s acceptability.

WS3 will explore issues relating to an economic evaluation that presents costs and different outcomes in order to help decision-making. It will identify the outcomes considered important to different stakeholders and determine the possibility of reducing these to a core set of indicators.

Intervention Type
Behavioural

Primary outcome measure
TOPIC is a feasibility study and will primarily focus on the following feasibility-related outcomes:
1. Proportion of care homes that agree to participate in the study
2. Proportion of residents in the participating care that are eligible and able to consent
3. Proportion of eligible residents that agree to participate in the study
4. Proportion of participating residents in the intervention arm that receive the intervention per the protocol
5. Proportion of care homes and residents that remain in the study at 12 months follow-up
6. Proportion of completed measures used in the study (at least 75% completion rate required): i) oral health assessments; ii) quality of life questionnaires; iii) clinical measurement records; iv) oral symptoms checklist diaries

Secondary outcome measures
1. Clinical outcomes, including the number of teeth with coronal and root caries lesions, the proportion of teeth with visible plaque and the proportion of teeth that bleed on probing (BoP), assessed by dental examiners at baseline and 12 months
2. Oral symptoms and domiciliary dental care: number of reported episodes of dental pain, sepsis, discomfort and domiciliary visits, reported weekly by care home staff and at baseline, 6 and 12 months by researchers
3. Health-related quality of life using EuroQol’s five dimensions (EQ-5D5L) at baseline, 6 and 12 months
4. Oral health-related quality of life using the OIDP at baseline, 6 and 12 months)
5. Oral health needs assessed with the OHAT by dental examiners at baseline and 12 months

Overall study start date
01/12/2018

Completion date
08/11/2023

Eligibility

Key inclusion criteria
Care home providers in London and Northern Ireland will be recruited using the following eligibility criteria:
1. Care homes will require to have a minimum of 20 residents (as approximately half are expected to be edentate)

Residents in the recruited care homes will be screened to determine whether they meet the eligibility criteria:
1. Over the age of 65 years
2. Dentate or partially dentate
3. Full-time resident in care facility

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
119

Key exclusion criteria
The exclusion criteria for the care homes will be:
1. Have high-dependency units and end-of-life care

The exclusion criteria for the residents will be:
1. Residents who are receiving end-of-life or palliative care
2. Residents with severe cognitive impairment (6-CIT score of 10 or higher)

A trained dental examiner will screen the participants for eligibility using a screening questionnaire covering the above criteria. Participants will also be asked the Six-item Cognitive Impairment Test (6-CIT) in order to assess their level of cognitive function. Residents with normal cognitive function (6-CIT score of 0-7) and those with mild cognitive impairment (6-CIT score of 8-9) will be included in the study, while those with severe cognitive impairment (6-CIT score of 10 or higher) will be excluded. As cognitive function tends to fluctuate in this population, we will attempt the 6-CIT screening test at different days and times on residents identified with severe cognitive impairment in order to identify potential time periods that would facilitate higher inclusion of participants in the study.

Date of first enrolment
01/07/2020

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Study participating centre
South Eastern Health & Social Care
Top Floor
Thompson House Hospital
19/21 Magheralave Road
Belfast
United Kingdom
BT28 3BP

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Central and North West London NHS Foundation Trust
Stephenson House
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/03/11

Results and Publications

Publication and dissemination plan
The study protocol will be submitted to a peer-reviewed international journal in 2020.

The researchers already have two abstracts accepted in international conferences with TOPIC related content. The study protocol was presented in a poster presentation at the European College of Gerontology Congress in 2019, while an abstract that covered the content adaptation phase of the work was accepted for an oral presentation at the International Association of Dental Research General Session in 2020.

The researchers plan to submit a paper with the study protocol to an international peer-reviewed journal in 2020, and plan to publish the main study findings separately in 2022.

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request. A data request form will need to be completed and permission granted from the CI (Prof. Georgios Tsakos; g.tsakos@ucl.ac.uk) to share any data. Data will be stored for 5 years and will be anonymised and stripped of personal identifiers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/07/2021	05/07/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	A Theoretically Informed Process Evaluation in Parallel to a Feasibility Study of a Complex Oral Health Intervention Using NICE Guidelines in a Care Home Setting	15/01/2025	20/01/2025	Yes	No
Other publications	Intervention development	14/03/2022	28/03/2025	Yes	No
Results article		10/06/2025	11/06/2025	Yes	No
Results article		02/07/2025	03/07/2025	Yes	No