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Improving the oral health of older adults using milk supplemented with fluoride and probiotics

Submission date
04/10/2022

Recruitment status
No longer recruiting

Registration date
29/11/2022

Overall study status
Completed

Last Edited
29/11/2024

Condition category
Oral Health

[X] 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
Dental caries continues to be a significant health problem among older people globally. This growing problem will consequently have significant financial repercussions for societies. There is, therefore, an urgent need to find feasible and cost-effective population-based oral health preventive measures for older people.
Although the role of fluoride in preventing carious lesions has been well established, implementation of effective individual- or community-based fluoride preventive measures has not occurred. Whilst effective professionally-applied interventions to prevent dental caries in older adults exist, there are significant barriers to their provision, particularly for care home residents.
Whilst supplemented milk with fluoride and/or probiotics would address many of the concerns, the efficacy of any programme will depend on the practicalities around provision as well as the feasibility, acceptability and cost-effectiveness of the programme to key stakeholders. Our research will explore supplemented milk as a community-based oral health intervention to reduce oral health inequalities among groups of older adults at high risk of poor oral health. To our knowledge, no study has previously investigated the feasibility and acceptability of the provision and implementation of supplemented milk for older adults living in care homes.
The provision of milk supplemented with fluoride and/or probiotics could offer a potentially cost-effective method for caries prevention in older adults, particularly those living in care homes. However, to the best of our knowledge, there is only one study in adults focusing on the role of supplemented milk in the prevention and management of dental/root caries. Although there are no pertinent criteria on how much evidence is needed for a clinical recommendation, it has been suggested that clinical recommendations should be based on at least two independent studies or one very large well-performed multicentre study.
Our project, which includes partners from the UK, Sweden and Denmark, will expand the current extremely limited knowledge on the use of probiotic supplements as an adjunct to a standard fluoride programme on caries prevention and management in older adults. More importantly, our proposed pilot study will generate valuable and much-needed data for a larger multicentre study. Our findings ultimately could guide public health policy- and decision-making for populations.

Who can participate?
Senior full-time care home residents

What does the study involve?
The trial aims to recruit at least 240 care home residents who will be assigned randomly to one of the following study arms:
1. Group 1: non-supplemented milk (the placebo or dummy)
2. Group 2: milk supplemented with fluoride (5.0 mg fluoride/l)
3. Group 3: milk supplemented with probiotics (Lactobacillus)
4. Group 4: milk supplemented with fluoride and probiotics

All subjects will be asked to drink a glass of plain/supplemented milk once daily, five days a week, for six months. Fluoridated milk or probiotics, or placebo (referred to as the Study product) will be administered by the resident's routine caregiver during medicinal/meal rounds. A dentist who does not know which group each participant is in will perform baseline and follow-up dental examinations.

What are the possible benefits and risks of participating?
There are no direct benefits for participants taking part in the study.

There are no known side effects associated with the use of fluoridated milk or probiotics the basic two study products, used alone and as a combination as part of the study intervention.
1. The fluoridated milk provided to the study participants is the same dosage and frequency distributed to primary school children daily as part of the government scheme to reduce oral health inequalities among groups of young children at high risk of poor oral health in geographical areas with the highest disease burden (e.g. Blackpool Council)
2. According to the manufacturer's information, the safety information sheet states that the probiotic strain LB21 used in this study has no reported consumer illness or injury and is a harmless product to use in humans (ELDER_Probiotic supplement (Manufacturer document_Safety Sheet) Though rare cases of secondary infection have been reported in immunosuppressed patients, and since the trial excludes residents with any immune-compromised condition, therefore no adverse events are expected based on the current data. Additionally, LB21 is well tolerated in younger children and therefore is reported to be provided as a food supplement to children aged 1-5 years to prevent the development of dental caries.
3. There is a trivial risk that a participant may experience gastrointestinal discomfort, for the first few days after taking them but this should subside quickly. All participants will be fully informed of all that is involved prior to being asked to consent and will be free to stop at any time. Although to our knowledge no such side effects have been reported for LB21 in the literature.

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

When is the study starting and how long is it expected to run for?
May 2022 to February 2025

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. Eklund Foundation (Sweden)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316798

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 316798, CPMS 53328

Study information

Scientific Title
Improving the oral health of older adults using milk supplemented with fluoride and probiotics: An interventional feasibility study and pilot randomised controlled trial

Acronym
ELDER

Study objectives
1. Milk is an efficient, acceptable, and feasible vehicle to deliver fluoride and probiotics on a community basis.
2. Milk supplemented with fluoride and probiotics is more effective than milk supplemented with either fluoride or probiotics in improving the oral health of older adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval 25/11/2022, East of England – Cambridge East Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)207 104 8102; cambridgeeast.rec@hra.nhs.uk), ref: 22/EE/0258

Study design
Multicentre open-label parallel-group four-arm prospective cluster-randomized placebo-controlled pilot trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Improve oral health of older adults living in care homes

Interventions
Current intervention as of 18/08/2023:
Trial intervention:
The trial aims to recruit at least 240 Care Home Residents. A cluster randomised trial is required, as an individually randomised trial would be subject to the threat of contamination (unintentional drop-out and drop-in across treatment arms due to mixing up milk) and managing four different kinds of milk within a single care home would be infeasible.

The consented care homes will be assigned randomly to one of the study arms:
1. Group 1: non-supplemented milk (placebo)
2. Group 2: milk supplemented with fluoride (5.0 mg flouride/l)
3. Group 3: milk supplemented with probiotics (Lactobacillus)
4. Group 4: milk supplemented with fluoride and probiotics.

All subjects will be asked to drink a glass of plain/supplemented milk once daily, five days a week, for six months. Fluoridated milk or probiotics, or placebo (referred to as the Study product) will be administered by the resident's routine caregiver during medicinal/meal rounds. The study product will be sourced from the manufacturer and transported to the study site. Fluoridated milk will be distributed in a small carton, and the probiotics will be provided as a powder in sealed sachets. The preferred route of administration is as follows:
1. The carton containing fluoridated milk is to be emptied into a tall glass and then consumed
2. The probiotic powder is to be dispensed in a spoon, then added to a prepared glass of skimmed milk/fluoridated milk, mixed well and then consumed

Each care home will be provided with the manufacturer's dossier detailing the composition of the probiotic form and fluoridated milk. After allocation, probiotic sachets will be distributed to the care home at the beginning of the trial, whereas milk (both skimmed & fluoridated) will be distributed to the trial sites weekly. Participants admitted to the hospital would not be expected to continue taking the study product during their hospital stay.

Randomisation:
The unit of randomisation is the care home (cluster). The care homes will be randomised based on a 1:1 ratio to each available intervention arm or control arm. Trial staff at each trial site will inform the coordinating centre when there are four eligible care homes as they will be randomised in a set of four or six if two sister care homes belonging to the same chain are

recruited. As the unit of randomisation is a care home, and the number of participants in each care home is expected to vary, blocking will be used to ensure a close balance of the number of participants (and not necessarily care homes) assigned to each arm. The allocation for a particular trial site will only be revealed after gaining informed consent (i.e., both at the care home level and the individual participant level) and baseline data collection. This approach reduces the threat of post-randomisation selection bias in cluster trials, as individual participants consent to be randomised to one of the four arms rather than being told which arm they have been allocated to if consent is only sought at the level of the care home.

Blinding and concealment:
As the ELDER trial is an open-label study, the participants, care home staff, and trial team (including the trial statistician and RNs conducting all assessments) will not be blinded to intervention assignment due to the nature of the trial procedure. However, the dentist performing the baseline and follow-up dental examination will be blinded to intervention and outcome assignment. Release of allocation only following enrolment, resident consent, baseline data collection, and dynamic randomisation of care homes using minimisation will ensure allocation concealment.

Previous intervention:
Trial intervention:
The trial aims to recruit at least 240 Care Home Residents. A cluster randomised trial is required, as an individually randomised trial would be subject to the threat of contamination (unintentional drop-out and drop-in across treatment arms due to mixing up milk) and managing four different kinds of milk within a single care home would be infeasible.

The consented care homes will be assigned randomly to one of the study arms:
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3. Group 3: milk supplemented with probiotics (Lactobacillus)
4. Group 4: milk supplemented with fluoride and probiotics.

All subjects will be asked to drink a glass of plain/supplemented milk once daily, five days a week, for nine months. Fluoridated milk or probiotics, or placebo (referred to as the Study product) will be administered by the resident's routine caregiver during medicinal/meal rounds. The study product will be sourced from the manufacturer and transported to the study site. Fluoridated milk will be distributed in a small carton, and the probiotics will be provided as a powder in sealed sachets. The preferred route of administration is as follows:
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Intervention Type
Supplement

Primary outcome measure
Current primary outcome measure as of 18/08/2023:
1. Acceptability of the supplemented milk measured by assessing the number of participants agreeing to take part and going to complete the study at baseline and at 6 months
2. Compliance with the intervention programme measured through a semi-structured questionnaire collected every month for the nine-month period of intervention
3. Potential clinical dental results of the intervention:
3.1 Root caries measured using the Petersson and Baysan grading score at baseline and 6 months
3.2 Gingival inflammation measured using the gingival index scoring system at baseline and 6 months
4. Bacterial and fungal counts in saliva and supragingival plaque estimated using non-selective blood agar and sabouraud dextrose medium with an aid of a stereo-microscope at baseline and 6 months

Previous primary outcome measure:
1. Acceptability of the supplemented milk measured by assessing the number of participants agreeing to take part and going to complete the study at baseline and at 9 months
2. Compliance with the intervention programme measured through a semi-structured questionnaire collected every month for the nine-month period of intervention
3. Potential clinical dental results of the intervention:
3.1 Root caries measured using the Petersson and Baysan grading score at baseline and 9 months
3.2 Gingival inflammation measured using the gingival index scoring system at baseline and 9 months
4. Bacterial and fungal counts in saliva and supragingival plaque estimated using non-selective blood agar and sabouraud dextrose medium with an aid of a stereo-microscope at baseline and 9 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
16/05/2022

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Full-time residents in a care home
2. Aged 65 years old and over
3. Have no acute or immunocompromised medical condition
4. Are able to give informed consent for participation
5. Have tolerance for dairy products

Participant type(s)
Healthy volunteer

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
Total Sample Size: 240 participants; 60 participants in each cluster of four groups.

Total final enrolment
88

Key exclusion criteria
1. Receiving planned respite (temporary care home resident) or end-of-life or palliative care
2. Aged 64 years old and under
3. Lack the mental capacity to provide informed consent
4. Have any immunocompromised medical condition
5. Are currently taking/being prescribed regular probiotics
6. Have severe lactose intolerance
7. Do not have a working level of oral English

Date of first enrolment
09/03/2023

Date of final enrolment
09/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Teesside University
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Sponsor information

Organisation
Teesside University

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Sponsor type
University/education

Website
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ROR
https://ror.org/03z28gk75

Funder(s)

Funder type
Government

Funder Name

Eklund Foundation

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study results will be consolidated to be reported first to the trial collaborators, including the funding organisation and the CRN North East North Cumbria network group. To maintain the quality of reporting, the study will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The trial team will aim to disseminate the findings in a way it reaches both academic and non-academic audiences, and therefore, the dissemination output will be tailored accordingly. Findings will be disseminated to the scientific community through publication in academic journals and conference presentations. Oral/poster presentations at Funder/Sponsor hosted events, regional council and professional stakeholder conferences and care home forums, and community meetings will be targeted to promote study findings and visibility. The trial team will use their early engagement links with ENRICH network to identify a wider frame of non-academic national audiences across the UK. The findings will be made available to care home staff and residents as newsletter updates and public-friendly summaries presented as infographics which will be featured on the service provider’s media page and websites and displayed on their bulletin boards. Enabling the help from the academic members in the trial team and with their links sought media coverage in newspapers, local radio outlets and social media.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.4	20/09/2022	20/10/2022	No	Yes
Protocol file			20/10/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.6	30/05/2023	18/08/2023	No	No