ISRCTN63296676 https://doi.org/10.1186/ISRCTN63296676

MAPPS: Mouth care to prevent pneumonia in older people study

Submission date	Recruitment status	[_] Prospectively registered
15/12/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/01/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2024	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Hospital acquired pneumonia (HAP) is the commonest healthcare associated infection in Europe. Up to 70% of patients with HAP may die. HAP occurs because certain bacteria start to live in the mouth when patients become unwell and travel to the lungs. Patients with HAP stay on average an extra 12 days in hospital which is unpleasant for patients and costly for the NHS.

Research suggests frequent mouth care might prevent pneumonia whilst in hospital. However the evidence is not strong enough to make changes to clinical care. A large trial is therefore needed, but some initial work is required to guide successful design and delivery.

This is a feasibility study, aiming to investigate the training, delivery and fidelity of the intervention, with particular emphasis on patients with delirium/dementia, and investigate collection of outcomes for a larger study.

Who can participate?

Four wards (3 trusts) that admit patients with hip fractures (and some medical patients) will participate.

What does the study involve?

The sites will be randomised to start the mouth care intervention every three months apart. Patients will receive three times a day tooth/tongue/denture brushing with an antiseptic mouthwash and recorded by trained healthcare assistants. Interviews will be held with staff and patients to record experiences of delivering and receiving mouth care.

What are the possible benefits and risks of participating?

Benefits:

More frequent mouth care will improve oral health and may be easier to eat, talk and socialise. It may be that it also will reduce risk of getting a pneumonia in hospital, reduced hospital stay and impact quality of life however, this will need to be proven. Sometimes mouth care is not consistently provided in hospitals, especially those who cannot do mouth care by themselves, so taking part in this study may mean they are more likely to access regular mouth care.

Risks:

The mouth wash (chlorhexidine – the same thing in the mouthwash Corsodyl) can cause tooth staining in some people. Staining can be minimised by avoiding tea or coffee in the hour after using chlorhexidine. If staining occurs, brushing with toothpaste an hour after using chlorhexidine can remove it. If staining persists then it can be removed by scale and polish by the patient's routine dentist.

Where is the study run from?
South Tees Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2021 to September 2023

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

Who is the main contact?
Dr Lucksy Cottam, lucksy.kottam@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
291778

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS50653, NIHR201110, IRAS 291778

Study information

Scientific Title
Mouth cAre to Prevent Pneumonia in older people Study (MAPPS): a feasibility study

Acronym
MAPPS

Study objectives
It is feasible to deliver three times daily mouthcare (with an antiseptic mouthwash (Chlorhexidine 0.2%) and application of lip moisturiser) to hospital inpatients for up to 4 weeks consistently with existing staffing, provision of an education pack, a mouthcare pack, and premade documentation set

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/11/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0242

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Mouth care to prevent pneumonia in older people

Interventions
Patient: Three times daily tooth brushing with an antiseptic mouthwash (Chlorhexidine 0.2%) and application of lip moisturiser for a maximum 4 weeks. Patients will be encouraged to complete this independently however there will be trained healthcare assistants to help deliver the intervention for those requiring assistance due to lack of capacity or any other issues. Healthcare assistants will also offer and prompt patients to complete the mouth care intervention at the specified time points.
Staff: Attending mouth care education and training as provided by the study team.

Documentation - completing the daily mouth care and infection record.
Intervention delivery - assisting the patients and prompting patients to complete the intervention.
Mouth care champions will be identified at the start of the study for each participating site. The mouth care champion will usually be a healthcare assistant, ideally with an interest in mouth care. The mouth care champion will be asked to conduct weekly huddles with participating nursing staff to discuss and resolve problems, promote the intervention, and to act as a bridge to the study team to feedback concerns and ideas.
Mouth care champions will feed back comments to the study team via electronic systems. Research nurses will log any significant comments from the staff delivering the intervention via the study log.

Intervention Type
Behavioural

Primary outcome measure
Proportion of mouth care episodes delivered out of eligible episodes, information will be collected daily via the daily mouth care record during their stay on the participating ward. This will be the proportion of mouth care episodes that were delivered (i.e. not coded as missed or forgotten). Participants could be in the intervention for up to 28 days, with 3 eligible mouth care episodes each day, unless they are discharged or withdrawn sooner.

Secondary outcome measures
1. Mouth care delivery
1.1 Proportion of delivered mouth care episodes out of eligible mouth care episodes in patients needing consultee consent, reported monthly per unit
- Information will be collected daily via the daily mouth care record during their stay on the participating ward. This will be the proportion of mouth care episodes that were delivered (i.e. not coded as missed or forgotten). Participants could be in the intervention for up to 28 days, with 3 eligible mouth care episodes each day, unless they are discharged or withdrawn sooner. For this patient population, we will also look at their consent type i.e. nominated or personal consultee agreement

1.2 Proportion of refused mouth care episodes out of eligible mouth care episodes, per unit per month
- Information will be collected daily via the daily mouth care record during their stay on the participating ward. This will be the proportion of mouth care episodes that were not delivered (i.e. coded as refused/declined). Participants could be in the intervention for up to 28 days, with 3 eligible mouth care episodes each day, unless they are discharged or withdrawn sooner.
1.3 Proportion of staff related non delivered mouth care episodes per unit per month
- Information will be collected daily via the daily mouth care record during their stay on the participating ward. This will be the proportion of mouth care episodes that were not delivered (i.e. coded as missed or forgotten). Participants could be in the intervention for up to 28 days, with 3 eligible mouth care episodes each day, unless they are discharged or withdrawn sooner.
1.4 Time to achieve maximal mouth care delivery in each unit (expressed in days)
- The number of days taken for all eligible mouth care episodes to be delivered (e.g. expected vs actually delivered).

2. Recruitment
2.1 Proportion of recruited patients out of eligible patients per unit monthly
- Comparison against the monthly screening logs and recruitment logs.
2.2 Proportion of patients recruited out of eligible patients needing consultee consent per unit, monthly
- Comparison against the monthly screening logs and recruitment logs. For this patient population, we will also look at their consent type i.e. nominated or personal consultee agreement.

3. Acceptability of intervention
3.1 Acceptability to patients/carers/staff assessed by themes from interviews and observations of mouth care
- Themes derived from the qualitative interviews, using a coding frame.

4. Data collection
4.1 Proportion of participants with complete data for cost effectiveness analysis
- Completeness of data, what is expected to be completed vs what has been completed.
4.2 Proportion of participants with complete records for antibiotic data (as proxy for episodes of HAP)
- Completeness of data, what is expected to be completed vs what has been completed, for those with episodes of HAP and required antibiotics.

Overall study start date
01/10/2021

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Mouth care intervention:
1. Aged over 18 years old
2. Admitted to unit in study (predominantly patients with hip fracture, but will include some

medical/orthopaedic patients)
3. Consent or assent to take part in the study
4. Anticipated hospital stay of >3 days

Qualitative interviews:
1. Ward staff
2. Senior nursing staff
3. Patients/carers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1470; UK Sample Size: 1470

Total final enrolment
248

Key exclusion criteria
Mouth care intervention:
1. Patients on the end of life care pathway
2. Within 10 days of a positive COVID swab

Date of first enrolment
01/11/2021

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Hexham General Hospital
Corbridge Road
Hexham
United Kingdom
NE46 1QJ

Study participating centre
Wansbeck Hospital
Woodhorn Lane
Ashington
United Kingdom
NE63 9JJ

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://southtees.nhs.uk/

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research (NIHR) (UK)

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
1. Publication in peer reviewed journals
2. Presenting our findings at Trauma Network meetings, British Geriatrics Society national meetings, surgical geriatrics (POPS) conference, Hospital Infection Society conference and at nursing conferences.
3. Sharing the videos and documentation on the Mouth Care Matters website, and the videos on YouTube.
4. Tweeting the link to these via established Mouth Care Matters, British Geriatrics Society, NIHR and personal accounts.
5. Sharing results with partner organisations via blogs and magazine articles. Example organisations include, but are not limited to: National Osteoporosis Society, Health Service Journal (for managers and policymakers), AGE UK, Alzheimer's UK, and regional NHS Trusts
6. Communication to known interested parties via email, with a link to the information

7. Asking participating nursing staff how best to share the information with the wider nursing community
8. Discussing the project and results with regional and national press (radio, TV, newspapers)

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Consultee (Prospective) version 1.1	16/11/2021	04/01/2022	No	Yes
Participant information sheet	Consultee (Retrospective) version 1.1	16/11/2021	04/01/2022	No	Yes
Participant information sheet	PIS (Prospective) version 1.1	16/11/2021	04/01/2022	No	Yes
Participant information sheet	PIS (Retrospective) version 1.1	16/11/2021	04/01/2022	No	Yes
Participant information sheet	Qualitative interview version 1.1	16/11/2021	04/01/2022	No	Yes
Protocol file	version 1.0	07/09/2021	04/01/2022	No	No
HRA research summary			28/06/2023	No	No