MAPPS

Mouth cAre to Prevent Pneumonia in older people Study

PROTOCOL TITLE:

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

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ABBREVIATIONS

BNF = British National Formulary

C&C = Capacity and capability

CI = Chief Investigator

CONSORT = Consolidated standards of reporting trials

CRF = Case report form

CRP = C-Reactive Protein

CRT = Cluster randomised trials

CXR = Chest X-ray

GCP = Good Clinical Practice

GDPR = General Data Protection Regulation

HAP = Hospital-acquired pneumonia

HCRW = Health and Care Research Wales

HRA = Health Regulatory Authority

HRQoL = Health-related quality of life

HSDR = Health Service Deliver and Research

ISF = Investigator Site File

JCUH = James Cook University Hospital

MAPPS = Mouth cAre to Prevent Pneumonia in older people Study

MCA = Mental Capacity Act

NHFD = National Hip Fracture Database

NHS = National Health Service

NIHR = National Institute for Health Research

NPT = Normalisation practice theory

PAG = Patient advisory group

PI = Principal Investigator

PIS = Participant information sheet

PPE = Personal protective equipment

PPI = Patient and public involvement

PROMs = Patient reported outcome measures

RCT = Randomised controlled trial

REC = Research Ethics Committee

REDCap = Research electronic data capture

RFPB = Research for Patient Benefit

R&D = Research and Development

SAE = Serious adverse events

SOP = Standard operating procedures

TSC = Trial Steering Committee

TMG = Trial Management Group

WCC = White Cell Count

1. STUDY SUMMARY

Study Title	Mouth cAre to Prevent Pneumonia in older people Study (MAPPS): a feasibility study
Short Study Title	Mouth cAre to Prevent Pneumonia in older people Study (MAPPS)
Study Rationale	Hospital-acquired pneumonia (HAP) is the commonest healthcare associated infection in Europe. Up to 70% of patients with HAP may die, and there are currently no prevention strategies being used in hospitals to mitigate this. HAP is costly, to hospitals because of excess length of stay of 10-12 days, and to patients because of the time spent being ill, physical deconditioning, loss of independence and death. HAP is common, and occurs because certain bacteria appear in the mouth when patients become unwell, and these may travel from the mouth to the lungs via a process called aspiration. Frequent mouth care might prevent HAP by reducing the number of these organisms. The evidence is not yet strong enough to make changes to clinical care, and a large trial is needed to test the hypothesis. However some initial work is required to guide the successful design and delivery of a larger, definitive trial. This study will undertake that initial work, focussing on the recruitment of the high risk population (patients with delirium and dementia) and delivery of the intervention to this hard to reach group. We will make the information learned from this work easily available for other researchers internationally, in order to improve the delivery of similar trials elsewhere.
Population	Units/wards which admits patients with Hip fracture; Medical patients within these wards will also be included
Intervention	Patient: Three times daily tooth brushing with an antiseptic mouthwash (Chlorhexidine 0.2%) and application of lip moisturiser. Staff: Mouth care education, training, documentation and process intervention delivered as part of the study
Study Design	MAPPS is a multi-centre mixed methods feasibility study, which utilises a stepped-wedge, cluster randomised design. The study will test the feasibility of delivering a mouth care intervention designed to prevent HAP in a real world ward based setting, including a subset of participant and staff qualitative interviews.
Study Duration	18 months.
Study Centre(s)	Four wards which admit patients with hip fracture and medical patients will be the clusters.
Objectives	We aim to understand how to deliver consistently a mouth care intervention to older patients in a ward setting.

	The aim is to assess the fidelity of the intervention especially in patients with cognitive impairment (those at highest risk of HAP) before undertaking a more expensive, larger study. We will also investigate how best to collect the primary outcome for the future study (Antibiotic diagnosis of HAP) and secondary outcome (cost-effectiveness of the intervention).
Outcomes	**Primary outcome:** • Proportion of delivered mouth care episodes out of eligible mouth care episodes, reported monthly per unit **Secondary outcomes:** **Mouth care delivery** • Proportion of delivered mouth care episodes out of eligible mouth care episodes in patients needing consultee consent, reported monthly per unit • Proportion of refused mouth care episodes out of eligible mouth care episodes, per unit per month • Proportion of staff related non delivered mouth care episodes per unit per month • Time to achieve maximal mouth care delivery in each unit (expressed in days) **Recruitment** • Proportion of recruited patients out of eligible patients per unit monthly • Proportion of patients recruited out of eligible patients needing consultee consent per unit, monthly **Acceptability** • Acceptability to patients/carers/staff assessed by themes from interviews and observations of mouth care **Data collection** • Proportion of participants with complete data for cost effectiveness analysis • Proportion of participants with complete records for antibiotic data (as proxy for episodes of HAP) At the end of this trial, we will assess specific targets for recruitment, data collection and being able to complete the mouth care intervention to inform whether a larger trial is feasible.
Sample Size	A sample size of four clusters has been calculated as being necessary for the

	feasibility. The future trial is to be a cluster randomised trial, and as such the randomisation units are clusters rather than participants.
Inclusion Criteria	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
Exclusion Criteria	1. Patients on the end of life care pathway 2. Within 10 days of a positive COVID swab
Analysis of Results	Quantitative data analysis Qualitative data analysis Economic analysis

2. FEASIBILITY SCHEDULE

Table 1: *Project timeline*

	0	1-3	4-6	7-9	10-12	13-15	16-18
Site 1		(150) 56	(150) 112	(150) 112	(150) 112	(150) 112	
Site 2			(150) 56	(150) 112	(150) 112	(150) 112	
Site 3				(150) 56	(150) 112	(150) 112	
Site 4					(120) 45	(120) 90	
Video		Filming					
Interviews		Focus groups					
HAP data							
Health Ec data							
Analysis							

(Total eligible) estimate recruited, based on 75% recruitment after training/transition period

Monthly data collection of mouth care delivered on single day, per unit pre-intervention

Training and transition to intervention

Intervention

3. BACKGROUND

Hospital acquired pneumonia (HAP) is the commonest healthcare acquired infection, and accounts for 26% of all healthcare associated infections in Europe (1). It is a leading cause of death in hospitalised patients, with a mortality of up to 29% (2). Broad-spectrum antibiotics, used to treat HAP, contribute to the threat of antimicrobial resistance, and consequently have implications for safe healthcare in the near future (3). Patients stay in hospital an average additional 12 days because of HAP (4, 5), and a single day in hospital is estimated to cost £333 locally.

Approximately 1.5% of all hospital in-patients develop HAP (6); on a national scale, the potential individual, economic and system gains from reducing HAP are substantial. The incidence of other healthcare associated infections has been reduced by care units (7). A significant evidence base exists around prevention of ventilator associated pneumonia (8), but two-thirds of patients who develop HAP have never been ventilated (7), and HAP remains an under researched condition.

When people become unwell, particular bacteria (typically Enterobactericeae, Staphylococcus aureus and Pseudomonas aeruginosa) become dominant within the microbiome at multiple body sites and pose the risk of secondary infection (9). HAP occurs predominantly due to aspiration of these organisms from the mouth to the lungs (10). Patients are six times more likely to develop HAP if the mouth is persistently colonised by one of these bacteria (11). These bacteria are not usually native to the healthy mouth (12).

Regular mouth care has therefore been proposed as a strategy to prevent HAP (13). A number of small, low quality studies have suggested that the strategy may be effective, but failed to provide sufficient detail around the intervention, preventing replication (14, 15). Using a quality improvement approach, four times daily mouth care was delivered across a whole US hospital over a 12 month period, and costs avoided were estimated at $1.72 million, with 500 bed days avoided (16). However, there were a number of quality issues with this study including lack of control group, heterogeneity of the intervention delivered, no reporting of fidelity, and using a coding-based definition for HAP. In addition, the products used were more expensive than would be feasible in an NHS setting. Nevertheless the approach used was later translated into a toolkit, and used in other healthcare settings in North America, which reported similar results (17, 18).

The main barriers to introducing mouth care interventions include lack of knowledge, training, time and available products, and unfavourable attitudes towards mouth care (19, 20). Mouth Care Matters is a Health Education England initiative to help improve oral health of adults in hospital to address this issue. However, uptake of the training and delivery of mouth care remains patchy nationally, and there is a cost implication for Trusts in terms of products and time to train staff. In addition, Mouth Care Matters aims to improve oral hygiene, but not specifically to reduce HAP, and the addition of an antiseptic mouthwash appears to be important in the efficacy of the intervention (21).

Even with training, there is evidence locally that practice has not changed substantially. Mouth Care Matters training has been delivered to staff on at least one of the proposed wards, but oral hygiene still remains suboptimal. This observation is supported by comments from our Patient and Public Involvement (PPI) group:

'*As far as I was concerned it [oral care] was non-existent*'

'Washing facilities very good [when I was] just in hospital…. Got towel, soap, flannel….. [but] teeth? No'

'They didn't clean my teeth the whole time [I was in]'

Therefore while mouth care may be perceived as an intervention that would be easy to adopt, additional actions are likely to be needed to enable widespread adoption (22).

A randomised controlled trial (RCT) is required to provide a definitive answer as to whether a mouth care intervention reduces HAP. This evidence, coupled with robust health economic data, will provide a strong case for stakeholders to invest resources in mouth care training and implementation, both nationally and internationally.

Several key barriers exist to running a robust and successful RCT that can answer the above question. These include how to quickly and effectively deploy mouth care intervention training to environments with high staff turnover, how to ensure that logistic aspects of mouth care occur consistently (such as product ordering and restocking), and importantly how to deliver a mouth care intervention to patients with dementia or delirium, who may be fearful of, or resistant to, such care. The intervention needs to be simple, easy to adopt, and consistent across all patients. This means it should need to be designed to be acceptable to patients with dementia and delirium, and then delivered to those without these conditions, rather than the other way around. Another key issue is fidelity of the intervention, and documentation thereof. Omissions in either of these (i.e. intervention delivered but not documented, and vice versa) would pose significant risks to the analysis of trial results.

Understanding what constitutes 'usual care' is important, to understand what the intervention delivers over and above this. Most patients will not receive antiseptic mouthwash, but while we have evidence that mouth care is generally poor in hospitals, there is little evidence to show how much mouth care is performed, as it is currently under documented in many hospitals.

In addition to the above, identifying patients with HAP is problematic in non-ventilated patients due to the lack of a gold standard diagnostic investigation. A consistent approach which creates minimal additional work is required, and it is unclear whether hospitals which are digitally immature could take part in such a trial (i.e. those without electronic records/prescribing).

Prior feasibility work is therefore needed to inform the design of such a trial.

4. STUDY DESIGN

4.1 Design and calculation of sample size

The design of this trial has been informed by the Consolidated Standards of Reporting Trials (CONSORT) extension for feasibility trials (23). The future trial is intended to be a cluster randomised trial, so that design has been used for this feasibility study.

A stepped wedge cluster randomised study design was chosen for this study because it is ideal when trialling an intervention which is likely to benefit most participants, or when it would be difficult to implement at individual level e.g. a service delivery intervention. Every person within the 'cluster', which in our case is a hospital ward, is potentially eligible to take part. The stepped wedge part refers to the timing, where each unit is able to adopt the intervention in sequence, such that by the end of the trial, each unit is undertaking the intervention. This can reduce the potential for bleedover, where units not undertaking the intervention perceive it to be valuable and start doing it anyway. In this study we will investigate the implementation of a mouth care intervention and the feasibility of collecting primary outcome in four clusters, where the clusters are hospital wards receiving patients with hip fracture.

The order of participation of sites will start with the lead site, but subsequently the order of starting will be randomised.

A sample size of four clusters has been calculated as being necessary for the feasibility CRT, using the methodology suggested by Hussey and Hughes (24). The intra-cluster variation is likely to be high, given different models of care and different case mixes between wards, and therefore the stepped wedge rather than parallel cluster model has been chosen, to maximise power.

4.2 Setting

Four wards in North East hospitals were chosen due to their having an average length of stay >7 days, which admit patients with hip fracture, over a 15 month recruitment period.

5. OBJECTIVES AND OUTCOME MEASURES

5.1 Objectives:

1. To understand what mouth care is given on participating wards prior to study start (i.e. 'usual care') using observation/audit.
2. To produce mouth care documentation in partnership with the nursing staff who will be using this.
3. To understand patients, nurse and carer perspectives of delivering and receiving mouth care, in order to optimise the process, including in patients with delirium and dementia.
4. To produce educational videos to train other staff in delivering the mouth care intervention, delivering the intervention in a dementia-friendly way, and ordering products.
5. To determine the feasibility and fidelity of delivering three times daily mouth care in a hospital ward of older patients using existing NHS resource.
6. To determine maximal mouth care delivery per site given the current resource, and to understand the time needed to achieve maximal mouth care per unit, in order to inform the timing of the steps in a stepped-wedge trial.
7. To determine recruitment rates in order to inform number of study sites needed for the subsequent trial

5.2 Outcome measures:

5.2.1 Primary outcome:

- Proportion of delivered mouth care episodes out of eligible mouth care episodes, reported monthly per unit

5.2.2 Secondary outcomes:

Mouth care delivery

- Proportion of delivered mouth care episodes out of eligible mouth care episodes in patients needing consultee consent, reported monthly per unit
- Proportion of refused mouth care episodes out of eligible mouth care episodes, per unit per month
- Proportion of staff related non delivered mouth care episodes per unit per month
- Time to achieve maximal mouth care delivery in each unit (expressed in days)

Recruitment

- Proportion of recruited patients out of eligible patients per unit monthly
- Proportion of patients recruited out of eligible patients needing consultee consent per unit, monthly

Acceptability of intervention

- Acceptability to patients/carers/staff assessed by themes from interviews and observations of mouth care

Data collection

- Proportion of participants with complete data for cost effectiveness analysis
- Proportion of participants with complete records for antibiotic data (as proxy for episodes of HAP)

Admission rates per month are expected to be approximately 50 per unit. If recruitment rate >75% per cluster (50% reduction during training/transition period) then we would anticipate progression without significant changes. If 50-75% recruitment per cluster then we would consider adding additional sites. If recruitment rates <50% per cluster then progression to a full trial would be unlikely to occur. Analysis of recruitment rate and perceived barriers, will be undertaken at recruitment rates <100%. As an example of total numbers, with a recruitment rate of 75% in each cluster, based on average monthly admission numbers and including the transition period, a total of 1311 participants (average 31.2 patients per cluster/unit per month) would be recruited over 15 months (see, Section 2. FEASIBILITY SCHEDULE, Table 1: Project timeline).

6. STUDY PARTICIPANTS

Any patient admitted to the study sites, with anticipated hospital stay of > 3 days.

6.1 Inclusion criteria

1. Aged over 18
2. Admitted to unit in study (wards predominantly with hip fracture patients, but can also include some medical/orthopaedic patients)
3. Consent or consultee approval to take part in the study
4. Anticipated hospital stay of > 3 days

6.2 Exclusion criteria

1. On the end of life care pathway
2. Within 10 days of a first positive COVID swab

6.3 Early discontinuation / withdrawal of participants

All participants have the right to withdraw participation in the study at any time. Options for withdrawal will be explained in the participant information sheet (PIS) and it will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal. The type of withdrawal and reason for withdrawal, if the participant is willing to provide one, will be recorded in the withdrawal Case Report Form (CRF). Participants can choose to withdraw from the mouth care intervention and or follow up questionnaires however still allow hospital data to be collected without fully withdrawing from the study. Study data collected up until the point of participant withdrawal will be used for analysis.

6.3.1 Patients who test positive for COVID-19

Patients who test positive for COVID-19 on admission may be moved to a different part of the hospital and will not be approached to be recruited into the study. Patients who initially test negative will be approached to join the study. If a participant subsequently tests positive, they will be moved to a different part of the hospital, and we will send on their mouth care products and instructions with them. With consent, we will continue to collect hospital data and follow-up from these patients but daily mouth care will not be recorded if the patient moves to another ward.

6.3.2 Discharged patients and transfers to other healthcare settings

When patients are discharged they will be given their oral health pack to take with them to continue undertaking oral care after discharge, up to a maximum of 4 weeks. They or their carers will be advised to switch to using fluoride toothpaste at this point. If patients are transferred to other wards for continuing therapy, these packs will be transferred along with the patients, but continuing daily data collection will not be undertaken in those wards. These patients will also be advised to continue undertaking mouth care up to a maximum of 4 weeks and thereafter advised to use fluoride toothpaste. We will explore the feasibility of collecting hospital record data as well as follow-up PROMs.

7. STUDY PROCESSES

7.1 Study set-up (months 1-3):

1. We will design documentation with nursing staff so that relevant information is captured, the documentation is easy to fill in and it reflects the experience of delivering mouth care. Fidelity of the intervention is crucial to the analysis of any subsequent trial, so particular care will be taken to design documentation that makes this information easy to submit and assess. We will also design posters and advertisement material for staff and patients, to be displayed on the ward.

2. We will develop short (5 minute) training videos at the lead site, informed by comments from the focus groups, demonstrating the intervention, the study documentation, and on overcoming care resistant behaviour in patients with dementia and delirium. We will undertake 1 day of baseline data collection of mouth care monthly before the intervention starts, using observation, and screening existing documentation. For the starting unit, this will take place 1 month before the intervention starts.

3. We will also develop a 30 second video suitable for patients with delirium or dementia, demonstrating a patient having mouth care performed. This can be shown to participants using an iPad prior to mouth care.

4. At the start of the intervention period, we will deliver a presentation about mouth care, based on Mouth care Matters toolkit, alongside a demonstration of how to deliver the study intervention, to nursing staff at the lead ward. Within the first 3 months of intervention at the lead site, we will convene a focus with staff involved with the intervention to discuss documentation, barriers, workability integration into routine work, and acceptability of the intervention. Any delivery issues that are identified during this will discussed with the TMG and make any appropriate changes to processes as required. We will also ask staff how best to share information and the training videos. We will document the information gathered, and use this information to refine implementation of the intervention using the NPT process to inform amendments.

7.2 Recruitment and intervention delivery (months 3-15)

7.2.1 Screening and eligibility assessment

Patients with hip fracture will be assessed for eligibility by the research nurse, hip fracture specialist nurse, nursing staff and/or members of the orthopaedic clinical team including trainees. This will be done at the admitting/operating site. This will usually be done on the day of admission. In sites operating a 'hub and spoke' model the bulk of the intervention will then be delivered at a distant community hospital site.

Medical patients will be screened for eligibility by the ward staff and research team looking after the patient as they arrive onto the participating site ward (note this may be 1-3 days after admission).

7.2.2 Obtaining informed consent: Patient consent

Wherever possible, written informed consent will be obtained from patients as soon as possible after being admitted to participating units, accepting that for some patients this might be after a surgery. Patients will be given a copy of the PIS and given sufficient time to consider their decision whether to participate in the study.

7.2.3 Obtaining informed consent: Personal consultee consent

Where a patient lacks the capacity to consent, a personal consultee approval (e.g. relative, friend) will be sought, where available. The personal consultee will be provided with study information, and given the opportunity to ask questions and discuss the study, after which their written or verbal agreement will be recorded. Where the urgent nature of the treatment limits access to time for an appropriate discussion with personal consultees, we will act in accordance with section 32, subsection 9b of the Mental Capacity Act (MCA) 2005, following a process approved by the relevant research ethics committee. A nominated consultee (Section 7.2.4) will be approached under such circumstances.

7.2.4 Obtaining informed consent: Nominated consultee consent

Where a patient lacks capacity to consent and a personal consultee is not contactable 12 hours following screening for eligibility, then a nominated consultee will be identified to advise the research team. The nominated consultee will usually be the patient's treating Trauma and Orthopaedic surgeon, but may also be another healthcare professional, such as an ortho-geriatrician. If that surgeon (or healthcare professional) is a member of the research team, another independent healthcare professional will be identified.

7.2.5 Obtaining informed consent: Retrospective patient or personal consultee consent

For participants initially unable to consent, but who subsequently regain capacity to consent during their ward stay, an appropriate member of the research team will provide study information and ample opportunity to ask questions and discuss the study with their family and carers. They will then be asked to provide written or verbal consent for continuation in the study. If the participant does

not wish to continue the study, they can choose to decline continued participation either partly (to the intervention and or follow up data collection) or fully including hospital data collections.

For participants unable to consent prior to surgery, and required a nominated consultee, but who do not subsequently regain capacity to consent, every effort will be made to contact a personal consultee to advise the research team about the patient's continued participation in the study and gain retrospective personal consultee consent. See appendix 1 for study flow chart; Appendix 2 for "Patients with capacity" and Appendix 3 for "Patients lacking capacity".

8. DESCRIPTION OF STUDY INTERVENTION, COMPARATORS AND STUDY PROCEDURES

8.1 Description of comparator

We will ask senior nursing staff to collect data on the frequency of mouth care per patient in their unit over a single day, once per month before the intervention starts, including at the lead site. Senior nursing staff will be asked to observe practice and complete standardised forms.

8.2 Mouth care intervention

In participating units, for each recruited patient we will ask nursing staff to complete an oral health assessment tool once just after recruitment. We will provide laminated posters which can be displayed above the participant's bed.

Each recruited participant will be given a mouth care pack at recruitment, consisting of a bag containing a bottle of alcohol free Chlorhexidine 0.2% , a 10ml tube of lip moisturiser and a small headed soft toothbrush, contained within a bag branded with the study logo. We will ask staff to store the bag on the bedside cabinet as a reminder. This pack can be taken with the patient on discharge or at transfer to other care settings.

After recruitment participants will be offered mouth care three times daily and we will ask staff to document each of these episodes on a simple daily recording sheet, provided as part of the study. Participants will be encouraged to take part in as much of their mouth care as possible, and staff will be trained in dementia-friendly techniques (e.g. hand over hand techniques) using the training videos described above. Healthcare assistants will assist the patient where necessary (ranging from verbal prompting to physical assistance) to undertake the mouth care intervention (see Table 2) three times per day, before/after meals. Patients with delirium and dementia may be shown a short video on iPad explaining what will happen. If the intervention is declined, a more limited intervention will be offered (e.g. lip moisturiser only), and the intervention will be offered again at the next round.

Mouth care will be recorded on a daily recording sheet either by staff or patient, documenting whether the intervention was delivered, any issues, and how much help was needed.

Table 2: *Mouth care intervention*

Dentition	Action
Teeth	• Put on the appropriate PPE • Provide the mouth care kit • Dip soft toothbrush in chlorhexidine mouthwash, squeeze once • Brush teeth, gums and tongue, 2 minutes using clock in bay • Apply lip moisturiser
Dentures	• Put on the appropriate PPE • Provide labelled denture pot • Remove dentures, safely transfer to pot and rinse in water under tap • Dip toothbrush in the chlorhexidine mouthwash and clean dentures. Dab off the excess. • Brush gums and tongue, and any natural teeth for 2 minutes using bay clock • Reinsert clean dentures into mouth • Apply lip moisturiser • Bedtime only: Advice to remove dentures into labelled denture pot with water.

8.2.1 Staff training

Staff will be trained in general oral hygiene care by the Mouth Care Matters team, with a specific section on the study intervention delivery.

These sessions will be delivered face to face if possible or socially distant training via online meetings or video/s.

Staff members will be signed off as competent to deliver the intervention by the study team or mouth care champions using a training log. Staff are not required to have GCP or on the study delegation log to provide the mouth care intervention or to fill in the mouth care assessment documentation from wards due to the nature of the study and the number of staff involved at each cluster

8.2.2 Staff involvement in mouth care delivery

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 and or with qualitative research team via weekly phone calls. Research nurses will log any significant

comments from the staff delivering the intervention via the study log. This will be fed back to the study team, which can then be shared with other sites if appropriate.

The Study Log, along with the training videos will be used to contribute to a final practical tool, at the end of the study, for other sites interested to deliver a similar intervention. The tool might take the form of videos or might also include written information, which can be uploaded to the Mouth Care Matters website.

8.2.3 Fidelity of the intervention

The fidelity of the intervention will be assessed using a number of methods, including the documentation of mouth care and feedback recorded on the study log from mouth care champions/other healthcare staff during weekly huddles. The qualitative research team will undertake observation exercises and also interview staff and patients about the delivery of the intervention. As a further quality measure, unannounced plaque scoring will be undertaken by a dental trainee, using modified Quigley Hein scores (25) on five patients per site who have received mouth care in the preceding 24 hours, after the first three months of transition.

8.3 Definition of end of study

The study will end when the final site has undertaken the final follow-up for the final patient and all data queries have been resolved. Analysis of data will then occur.

9. PUBLIC AND PATIENT INVOLVEMENT (PPI)

The study proposal has been developed with PPI at all stages since identifying the research question. We have engaged with patients, carers, clinicians, Nurses, Health care assistants and wider stakeholders at various levels to ensure the research proposal answers the key feasibility questions for this patient group, especially those with dementia and delirium.

We conducted a focus group meeting at the lead applicant's site with former patients who had received treatment for hip fractures, and their family members at the outline stage. A patient advisory group (PAG), consisting of up to eight members led by our PPI co-applicant will continue to be involved during the conduct of this study and supported by the study team member/s.

The PAG will meet at regular intervals throughout the setup phase, the study phase and the dissemination stages of the study, and will be supported by the core study team.

At the end of the study, the PAG will help develop a lay summary of trial results and assist in the public dissemination plans, as appropriate, based on the study findings.

We will keep a narrative log over the lifetime of the study detailing the interaction and involvement between our PPI members, and the study. Our PAG members will have access to guidance regarding getting involved in research from the NIHR PPI team in the North East and North Cumbria and INVOLVE. Project manager will support them throughout the study duration as PPI lead.

10. DATA COLLECTION

10.1 Quantitative data collection

10.1.1 Baseline assessments

The study will collect baseline data on all recruited participants prior to them starting the mouth care intervention. This will include oral health assessment data, EQ5D-5L and demographic data. The participant will be asked to complete two EQ5D-5L assessments, one based on how they were one week prior to hospital admission and a second based on how the participant is at the time the data is being collected.

10.1.2 Demographic, health economic and HAP data collection

During the study we will collect prospective data on all antibiotic prescriptions on all four wards via daily visits by a research nurse. Methods of retrieving antibiotic data across the different wards will be explored. Antibiotic data will be retrieved electronically where possible or prospectively via screening drug cards. For cases of HAP, indication not recorded and source unknown, antibiotic prescriptions may be correlated with clinical notes, and routinely collected clinical, biochemical and radiological data.

EQ-5D-5L data will be collected from all patients, by use of proxy where the patient is unable, at 90 days after discharge. The use of EQ-5D-5L patient reported outcome measures (PROMs) data to provide baseline values will also be investigated (10.1.1). Health care resource utilisation within secondary care will be estimated using the outcome measures listed in Table 3.

Table 3: *Data collection for quantitative analysis*

Type	**Variable**	**Source**	**Population**	**Point of data collection**
Recruitment	Number approached Number eligible Number consented Type of consent	Research Nurse/Clinician	All ward patients	At screening / consent
Patient covariates*	Age Sex Diagnosis 4AT Score Rockwood Clinical Frailty Scale	Clinical notes	All recruited participants	At study entry
Primary outcome	Proportion of delivered mouthcare episodes of eligible mouth care episodes, per unit, per month	Mouth care documentation	All recruited Participants	Monthly
Secondary outcomes	Proportion of: Patient refusal Staff related non delivery of intervention Time to maximal mouth care delivery	Mouth care documentation	All recruited participants	Monthly
Staff training	Proportion staff trained in mouth care per unit	Off duty log and research logs	All nurses and health care assistants per unit	Monthly
Efficacy of mouth care intervention	Modified Quigley Hein Plaque Scores	Prospective (by Study team)	A sample of Five patients per site during intervention phase having received minimum twice daily mouth care in preceding 24 hours	Random
Infection outcomes	Antibiotic prescriptions	Prospective (Research Nurse)	All recruited participants	Daily while on ward
HAP outcome data	HAP episodes Have they had a CXR? Y/N Was there a diagnosis of HAP? Obs- highest NEWS on day starting abx WCC/CRP on day starting abx	Clinical notes Webice Vitalpac (or equivalent in each site)	Subset of patients with HAP	Daily while on ward

	Oxygen level/sats on day starting abx			
Other outcome data	Length of stay- acute hospital Death in hospital Death within 30 days EQ-5D at 90 days	Hospital records, contact with participant or consultee	All recruited participants	Once
Discharges/transfers	Discharge Transfer destination Discharge date	Hospital records, contact with participant or consultee	All recruited participants	Once

10.2 Qualitative data collection

Researchers from the York Trials Unit will conduct a qualitative interview study with key stakeholders to address important issues in the delivery of the intervention. We would expect these interviews to be short and focused on the following feasibility issues:

- Ward staff (including senior nurses, nurses and health care assistants (n=16-20, at least 2 per site until saturation is reached) will be asked about experience of delivering and documenting (or managing/supervising) the oral care intervention, understanding of the intervention, adequacy of training, confidence in performing intervention, impact on workload, potential for sustainability and any safety concerns.
- Senior hospital nursing staff (n=4, at least 2 per trust), will be asked about sustainability and workload implications for staff.
- Patients/family members (n=16-20), including patients with dementia/delirium, will be asked about the acceptability of the components, the utility of the video and frequency of the intervention.

We will briefly observe each ward on up to three occasions to gain insight into how the oral intervention is delivered in practice. We will avoid imposing structure on our observations, rather writing detailed field notes immediately after the observation period. As 'outsiders', our intention is to question practices and assumptions that are taken for granted. Through observation, supplemented by informal conversations we will examine the:

- Nature of interactions (how the content of service delivery used and adapted to individual needs, in particular with those patients with dementia/delirium)
- Physical environment (where the oral care intervention delivery takes place; how the physical environment constrains/promotes the delivery of good quality care.

These observations will be used to refine the intervention and training iteratively, and to customise training videos accordingly.

11. SAFETY REPORTING

Safety reporting for each participant will begin from the first point of administration of the intervention (tooth brushing) and will end when the participant has reached their final main follow up time point, at 90 days. This is a low risk, pragmatic study where the trial interventions is basic personal hygiene for patients. In light of this, we do not anticipate many serious adverse events (SAEs) associated with the study intervention.

The study team does not endorse or recommend the use of pink foam swabs during the study and this information will be made clear during the training for staff. The pink foam end can be bitten off and cause choking. As a result pink foam swabs are banned in Wales, and not used in Mouth Care Matters toolkits.

11.1 Definition of Serious Adverse Events (SAE)

A serious adverse event is any untoward medical occurrence that:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

11.2 Reporting procedures for SAEs

A SAE occurring to a participant should be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator (CI) the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the Chief Investigator becoming aware of the event, using the HRA report of serious adverse event form (see HRA website). As the study treatment procedures investigated forms part of basic personal hygiene for participants, we will not be collecting unrelated SAEs.

When the local research team becomes aware of an SAE in a trial participant, the PI will review the SAE locally and make a decision about the causality (i.e. likelihood of the event to be related/attributed to the intervention). Further details on grades of causality can be found in the SAE reporting guidelines document available in the ISF. Following the assessment of causality the PI will assess any related events for expectedness. For any SAEs assessed as unexpected and potentially

related, the details of the event will be entered on an SAE reporting form on the database, and the local research team will notify the central trial team via email or telephone within 24 hours of the PI becoming aware of the event. Once the SAE form is received, causality and expectedness will be confirmed by the CI or delegate (Nominated Person). In the event that consensus is not reached between the PI and Nominated Person about assessment of causality and expectedness, this will be escalated to the CI for further discussion. However, if no consensus decision is reached about expectedness after further discussion within one working day, and the SAE is judged to be unexpected by any one of either the Principal Investigator (PI), Nominated Person or CI, the event will be classified as an unexpected event.

11.3 Foreseeable AEs & SAEs

All related AEs should be reported using the study AE reporting forms within 48 hours of the Investigator becoming aware of the event. As the study treatment procedures investigated forms part of basic personal hygiene for participants, we will not be collecting unrelated AEs or SAEs. An SAE form may be triggered following the initial AE form as applicable. This is a low risk study, and potential related adverse events would include:

Expected AEs include:

- Confrontational behaviour around mouth care and towards staff (participants with Dementia)
- Staining on teeth as a result of Chlorhexidine use (e.g. consuming tea straight after intervention)
- Gum bleeding
- Minor accidental injury to mouth while brushing
- Tooth loss
- Broken dentures or loss of dentures
- Spillage of mouthwash resulting in slips and falls
- COVID infection risk to staff and patients as similar to all inpatients

Unexpected AEs include:

- Aspiration of mouthwash
- Drinking mouthwash
- Allergic reaction to lip moisturiser

Training in delivering oral interventions to patients with delirium/dementia will be delivered by our speech and language team, who have a wealth of experience in this area. Confrontational behaviour is common in this population and the ward teams are generally experienced in dealing with patients with delirium or dementia, as it forms a part of 'normal business'. Not opening the mouth will be taken as lack of consent to proceed with the intervention.

Mouth care is not classed as an aerosol generating procedure and standard ward PPE, as per each sites individual hospital guidelines, will be worn. This could include, gloves, plastic apron, fluid repellent surgical face mask and visor (see, Section 14.1).

SAEs/AEs that are foreseeable, or expected, in the treatment of hip fractures/medical procedures do not need to be reported and only variables on the CRF and/or Patient Questionnaires will be collected including HAP episodes.

12. STATISTICS AND DATA ANALYSIS

Permission will be obtained to transfer anonymised data to York Trials Unit for analysis. A pre-specified Statistical Analysis Plan (SAP) will be developed and signed off prior to database lock and commencement of the analysis.

12.1 Statistical Analysis

12.1.1 Quantitative data analysis

We will measure and review the primary outcome monthly at each unit. Secondary outcomes relating to recruitment and mouth care episodes will also be collected and reviewed monthly. These will be analysed using simple descriptive statistical techniques, and may be displayed using control charts. Antibiotic use (data collected will include: antibiotic name, dose, frequency and length of course) will be presented with summary statistics. We will compare rates of antibiotic prescribing across trial wards to determine baseline variation and determine timing of antibiotic prescriptions using first day antibiotic prescribed.

For participants moved to community hospitals in Trusts where there is no electronic prescribing, a research nurse will phone the community hospital weekly to check for any prescribed antibiotics. Intra-cluster correlation estimates of outcomes derived from this trial will be compared with those from the SOCLE II trial (26) and used to inform the sample size estimation for a larger trial.

12.1.2 Qualitative data analysis

The formal data for analysis will consist of anonymised transcripts, field notes of observation and reflective notes made by researchers. The constant comparative method of analysis will be used with an iterative process of data collection and analysis. A coding frame will be developed by the qualitative team at York Trials Unit, informed by the core concepts of NPT and the data will be coded by the researchers. A software package (QSR NVivo 11) will be used to facilitate data management.

12.2 Economic analysis

The feasibility of undertaking an economic evaluation of the previously described mouth care intervention versus usual care will be explored in order to inform a future trial. The economic analysis aims to incorporate the impact of the intervention in terms of potential HAP prevention and the associated costs and outcomes of HAP, i.e. extended length of stay, antibiotic use, and impact on health-related quality of life and mortality. The health economics component of the feasibility study will include consideration of an appropriate evaluation framework, the appropriate instruments, and data collection methods for the cost and outcome data used for the economic analysis. As part of this, the feasibility of collecting economic data via medical records/databases, such as the NHFD and PROMs, will be assessed. An indication of costs associated with the intervention will be provided.

The feasibility of collecting health-related quality of life (HRQoL) data via the EQ-5D-5L (27) will be investigated. EQ-5D-5L data will be collected from all patients, and patients will be asked to describe their health before admission, at admission and 90 days after admission by phone, paper or email; for patients with hip fracture this will be the day before their hip fracture (NHFD 2018). EQ-5D-5L questionnaires will be compared between a subset of patients who developed HAP, and from age-sex matched controls who did not develop HAP. The EQ-5D-5L will be completed by a proxy where the patient is unable to complete the questionnaire themselves. The HRQoL for patients who develop HAP will thereby be compared to the HRQoL for patients who did not develop HAP, in order to estimate the utility decrement associated with HAP.

An NHS costing perspective will be taken for the analysis, with a focus on health care utilisation within secondary care; specifically length of hospital stay for patients who developed HAP versus those who did not develop HAP, obtained via the various hospital databases, including NHFD for participants recruited who have sustain a hip fracture The cost of antibiotics for HAP will also be estimated. Unit costs feeding into the analysis will be derived from established costing sources, such as NHS Reference Costs (28) and the British National Formulary (29).

In order to accurately capture the patient pathway in terms of health care resource use, the patterns of care for patients will be described at hospital level (primary care resource use is unlikely to be significant for this patient group as HAP mainly occurs while still hospitalised). This will help to determine whether additional resource utilisation within primary care would need to be collected for a potential future trial. The cost of the intervention will be estimated, including staff time to deliver the intervention, training costs and costs of the mouth wash etc. versus the cost of usual mouth care.

To inform missing data methods and improve completion rates for a full trial, the missing economic data will be explored as part of this feasibility study. A full economic evaluation will not be undertaken, due to looking at the feasibility here rather than conducting a full trial. However, findings regarding the health economic component of this study will be used to make refinements and improvements to the methods used for a health economic analysis of a future trial, which would involve a full economic evaluation being conducted.

12.3 Feasibility progression criteria objectives

The feasibility objectives of our study include determining recruitment rates, specifically those of participants with cognitive impairment, and of protocol adherence. The progression criteria for a subsequent full trial will be assessed at the end of the study.

Approximately 30-40% of patients with hip fracture complete a consent form 4 (patients lacking capacity), and therefore 40% has been used as estimate for total number of patients who need a consultee for consent. We will monitor the recruitment logs carefully on a monthly basis, and identify and try and resolve any problems early. Progression to a full future study will be based on overall recruitment figures.

Table 4: *Proposed progression criteria for a full future trial*

Progression criterion	**Subset**	**Red % (n)**	**Amber % (n)**	**Green**
Proportion of eligible patients recruited per unit per month (not including transition/training period)	All (n=2040, excluding transition period n=1470)	<50% (<735)	50-75% (735-1102)	>75% (n=>1102)
	Proportion of participants who need consultee for consent	<50%	50-75%	>75%
Proportion of delivered mouth care episodes expressed out of all eligible mouth care episodes (not including transition/training)	All	<50%	50-60%	>60%
	Proportion of participants who need consultee for consent	<50%	50-60%	>60%
Antibiotic data	All	<70%	70-79%	>79.1%

13. DATA MANAGEMENT

13.1 Source document

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, patient-reported outcome measures that are submitted directly to the sponsor and correspondence. CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number; name and hospital identifiers on daily mouth care documentation source documentation will be removed or redacted before storage.

13.2 Access to data

Direct access will be granted to authorised representatives from the Sponsor, study team, host institution and regulatory authorities for monitoring and/or audit of the study to ensure compliance with regulations.

13.3 Data recording and record keeping

Whenever possible, data will be collected in electronic format with direct entry onto the trial database, including the collection of documentary evidence of consent. Electronic data collection has the major advantage of building data logic and edit checks into forms, minimising missing data, data input errors and ensuring the completeness of consent forms. All data entered will be encrypted in transit between the participant's web browser and server. All identifiable information will be held on a server located in an access controlled server at the South Tees Hospitals NHS Foundation Trust. The data will be entered into a Good Clinical Practice (GCP) compliant data collection system and stored in a database on the secure server, accessible only to the research team based on their role within the study. The database and server are backed up to a secure location on a regular basis.

Participant name and key identifiers will be redacted form any source paper documentation such as the daily mouth care documentation collected prior to storage. Contact details for follow-up purposes will be collected and accessed separately from the outcome data obtained from/about the participants and managed within the rules of the clinical database system. In all other data, participants will be identified by a trial ID only. Direct access to source data/documents will be required for trial-related monitoring and/or audit by the Sponsor, NHS Trust or regulatory authorities as required. All electronic data will be retained for at least three years after publication of the trial. Contact details will be retained for 6 months after the last data collection. The data from consent forms (in most cases the consent will be given electronically) will be retained for one year after the last study data collection.

The study team and the recruiting hospital will have access to all participant data collected.

Study data will be collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at the South Tees Hospitals NHS Foundation Trust.

REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Wherever possible, trial data will be entered directly into the study database by site staff or participants. If requested, paper forms will be provided for data collection. Data captured during phone calls to participants and trial data completed on paper forms by local site staff will be entered into the trial database by suitably trained site /central study staff. Full details will be recorded in the Data Management Plan. The participants will be identified by a unique trial specific number in any data extract. Identifiable data will only be accessible by members of the study team with a demonstrated need (managed via access controls within the application) and only used to communicate with the participant (e.g. sending follow-up reminders for online form completion or data query resolution).

14. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulatory authorities and South Tees Hospitals NHS Foundation Trust (Sponsor) Standard Operating Procedures (SOPs).

14.1 Risk assessment COVID-19

Owing to the recent COVID-19 outbreak, we have also risk assessed the individual components of the study and suggested changes as below:

Mouth care has been risk assessed as not being an aerosol generating procedure, therefore personal protective equipment (PPE) is likely to include the use of fluid resistant surgical masks, face visor, gloves and standard apron, as per the current guidelines for that area within each hospital as per their standard practice. Training and communication can convert to via electronic means if needed. Qualitative work may move to a period during the intervention phase where COVID rates are low to allow face to face visiting.

14.2 Study monitoring

Quality control procedures will be undertaken during the recruitment and data collection phases of the study to ensure research is conducted, generated, recorded and reported in compliance with the protocol, GCP and ethics committee recommendations. Data management and study monitoring plans will follow sponsor SOPs.

14.3 Trial oversight

The trial will be conducted in accordance with the principles of GCP and guidelines, the Declaration of Helsinki, Sponsor organisation SOPs, relevant UK legislation and this Protocol.

14.4 Trial Management Group

The day-to-day management of the trial will be the responsibility of the Project Manager, supported by both CI and the Joint CI. This will be overseen by the Trial Management Group (TMG), who will meet 3 monthly to assess progress and review data collection from the previous three months. A PPI representative will be an integral member of the TMG. It will also be the responsibility of the Project Manager and CI to deliver training of the research and ward staff at each of the study centres. The TMG and other key collaborators will be closely involved in setting up data capture systems, design of databases and case report forms.

14.5 Oversight committee

The study oversight committee includes independent members, provides overall supervision of the trial on behalf of the funder. Its terms of reference will be agreed with NIHR and will be drawn up in a charter which will outline its roles and responsibilities. The oversight committee will include at least one PPI representative as an independent member. Meetings of the oversight committee will take place initially after 6 months from recruitment start and at least once every 6 months during the recruitment period.

An outline of the remit of the oversight committee is to:

- Monitor and supervise the progress of the trial towards its interim and overall objectives.
- Review at regular intervals relevant new information from other sources.
- Inform the funding body on the progress of the trial and any recommendations

As a separate Data and safety monitoring committee is not set up for the study, in addition to the overall study progress, the oversight committee will also review study conduct, issues relating to participant safety and, if required critical endpoints of the study.

14.6 Protocol deviations

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process) or from GCP or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file. As study intervention delivery is part of the feasibility and primary aim of the study, the data on any deviations, delivery issues or acceptability of participants will be collected routinely via daily mouth care documentation and is not considered a protocol deviation.

14.7 Serious breaches

A "serious breach" is a breach of the protocol or of the conditions or principles of GCP which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or
(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the CI, the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving Research Ethics Committee (REC) and the relevant NHS host organisation within seven calendar days.

15. ETHICAL AND REGULARTORY CONSIDERATIONS

15.1 Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

15.2 Guidelines for Good Clinical Practice (GCP)

The Investigator will ensure that this study is conducted in accordance with relevant regulations and in compliance with the principles of GCP.

15.3 Approvals

Health Regulatory Authority (HRA) and Health and Care Research Wales (HCRW) approval will be sought prior to the start. Following Sponsor approval, the protocol, informed consent form,

participant information sheet and other study materials will be submitted to an appropriate REC and HRA for written approval.

The CI will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Local R&D Capacity & Capability approvals will be sought prior to recruitment start at individual sites.

15.4 Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC, HRA (where required) host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties. The CI will submit progress reports to the funder at regular intervals, 6 monthly.

15.5 Participant confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic databases. All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

15.6 Risks and benefits

Benefits to patients:

- Increased frequency mouth care
- Increased oral intake
- Increased social interaction
- Potential decreased risk of pneumonia

Risks to patients:

- If chlorhexidine and toothpaste used together can cause dental discoloration (toothpaste not being used at time of study intervention). Standard dental cleaning can remove discolouration.

16. FINANCE AND INSURANCE

16.1 Funding

The project is funded by a National Institute for Health Research (NIHR) Research for Patient Benefit (RFPB) Grant

Participants will not undergo any hospital visits in addition to normal care, therefore no expenses will be payable.

Hospital R&D departments will receive payments to cover research specific activities as per contractual agreements.

16.2 Insurance

The sponsor is South Tees Hospitals NHS Foundation Trust.

16.3 Contractual arrangements

Appropriate contractual arrangements will be put in place with all participating sites/third parties; a contract will be drawn up between the Department of Health and the sponsor South Tees Hospitals NHS Foundation Trust.

17. DISSEMINATION OUTPUTS AND ANTICIPATED IMPACT

17.1 Outputs

The main output of this trial would be the progression to further funding to conduct the larger cluster trial. We will seek NIHR funding from either HTA or HSDR streams, and the trial will be designed after the conclusion of this study. Undertaking this study will establish the teams involved as national leaders in the field, and strengthen the relationships within the lead team, with a view to future funding applications and conduct of the larger trial. This study will deliver outputs that are directly applicable to patients and will inform future studies. We will make these available to other researchers and clinical teams, and these include:

1. Mouth care documentation, which can be used to assess fidelity of a mouth care intervention
2. A video for staff explaining why mouth care is important
3. A video to explain how practically to deliver mouth care to participants who are not able to do this for themselves, including dementia-friendly techniques.
4. A short (e.g. 30 second) video explaining mouth care for patients with dementia or delirium
6. The feasibility methodology and results will be reported in peer reviewed publications.
7. A video describing our experiences in the study and the results, including about the collection of HAP data and health economic data.

The dissemination of these outputs may include:

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)

17.2 Anticipated impact

This intervention has the potential to make a significant improvement to the clinical outcomes of older patients in hospital. Individual patients could benefit greatly from the prevention of HAP through reduced deaths and shorten length of stay in hospital. The wider healthcare gains from reducing HAP are also likely to be substantial, and important on an international scale, with potentially reduced healthcare costs and reduced antibiotic use. However, progressing straight to an efficacy trial without prior implementation work risks suboptimal trial design and suboptimal intervention delivery, increasing the chance that the definitive trial will not be successful. Poor understanding of fidelity of mouth care interventions, lack of criteria-driven primary outcome (HAP) data, and under recruitment of patients who cannot consent for themselves has prevented the design and delivery of high quality, repeatable trials of efficacy of mouth care in reducing episodes of HAP. This trial will prepare the groundwork that would allow us to design an effective, robust and well-informed, cluster randomised trial to investigate whether mouth care reduces the risk of HAP.

18. PUBLICATION POLICY

We will seek publication in journals with general/geriatric/respiratory medicine audience and previous track record of publishing similar work. All co-applicants and external collaborators named on this protocol will be named as authors on the main study publication. TMG will approve author list for any journal publications based on the author contributions as per ICMJE checklist.

19. INTELLECTUAL PROPERTY

Foreground IP and Research Data

The potential foreground IP outputs that we have identified are listed below:

1. Mouth care documentation, which can be used to assess fidelity of a mouth care intervention. This may be based on the Mouth Care Matters documentation, but is likely to need substantial changes to accurately assess fidelity.
2. A video for staff explaining why mouth care is important
3. A training video to explain how practically to deliver mouth care to participants who are not able to do this for themselves, including dementia-friendly techniques.
4. A short (e.g. 30 second) video explaining mouth care for patients with dementia or delirium
5. The feasibility methodology and results will be reported in peer reviewed publications.
6. A video describing our experiences in the study and the results, including about the collection of HAP data and health economic data.

The videos created in the study may be uploaded to the Mouth Care Matters website, and/or other websites in order to disseminate the knowledge generated during the study.

The Foreground IP and Research Data shall vest in the Contractor (South Tees Hospitals NHS Foundation Trust). The draft collaboration agreement template attached above includes the following text:

'"Results" shall mean all information, data, know-how, results, inventions, software and other Intellectual Property arising through conduct of the Project. In accordance with the Head Terms, all Results shall be owned by the Lead. The Lead may commercially exploit the Results in consultation with the other Parties. In such circumstances, the Lead will pay the other Parties a fair and reasonable royalty rate/revenue on the value of any products or processes commercially exploited by it which incorporate any Results taking into consideration the respective financial and technical contributions of the Parties to the development of the Results, the expenses incurred in securing intellectual property protection thereof and the costs of its commercial exploitation and the proportionate value of the Results in any such product or process.'

20. ARCHIVING

Documents and electronic systems will be archived as per protocol and the appropriate SOPs as prepared by South Tees Hospitals NHS Foundation Trust. Sites will be asked to store source documents for a period of 3 years from end of study. Personal data will be stored for 12 months from the end of the study.

21. KEY CONTACTS FOR STUDY TEAM

Role	Name	Email	Telephone
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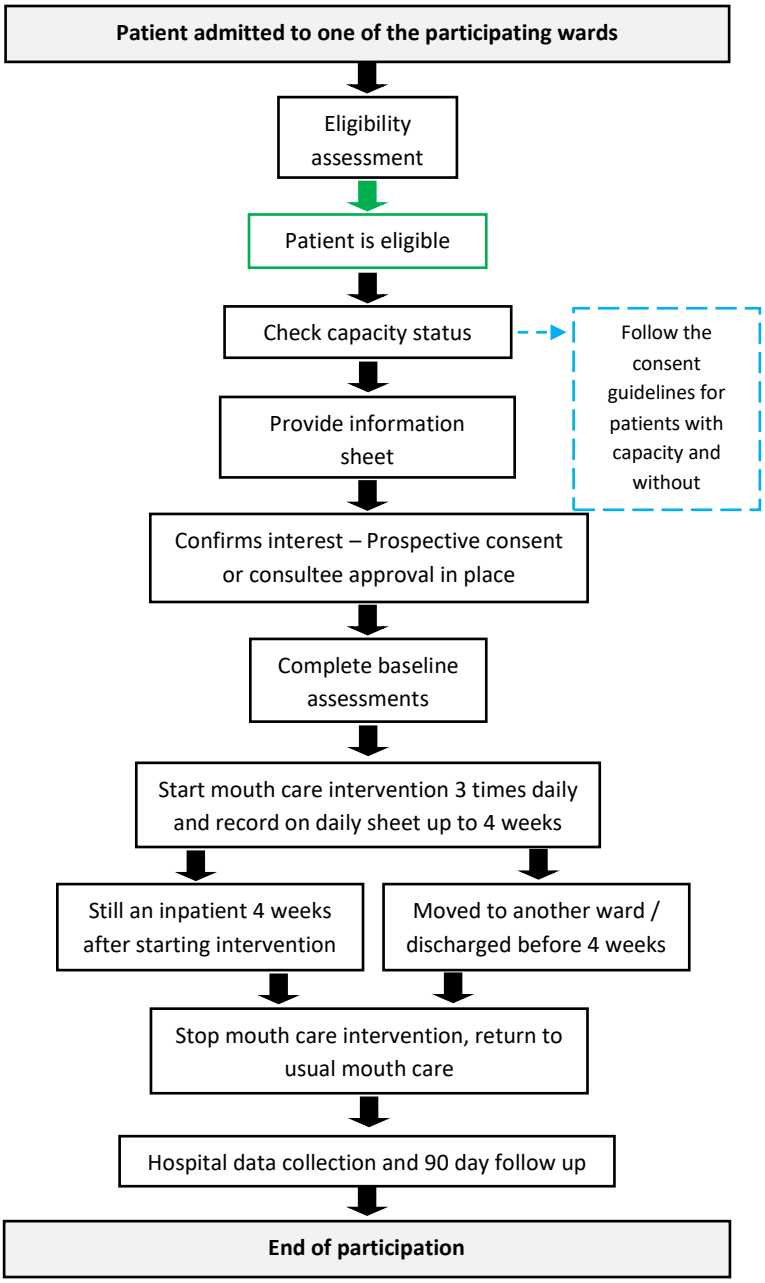
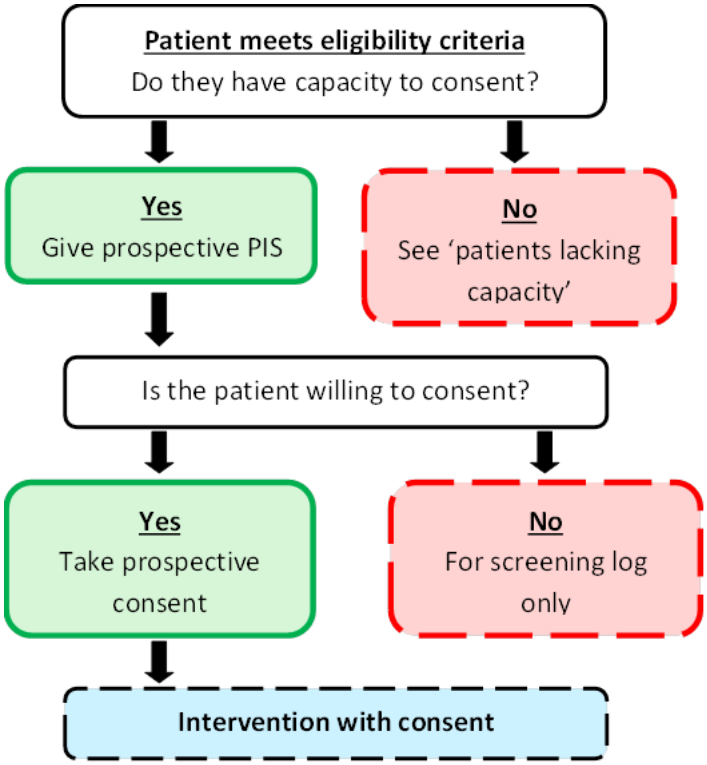
23. APPENDICES

Appendix 1: Study flow chart



Appendix 2: Consent Process for Patients with Capacity



Appendix 3: Consent process for Patients Lacking Capacity: