PARTICIPANT INFORMATION SHEET

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

Study Sponsor: South Tees Hospitals NHS Foundation Trust

Chief Investigator: Dr Vicky Ewan, Consultant in Older Person's Medicine, South Tees Hospitals NHS Foundation Trusts

PLEASE READ THIS INFORMATION CAREFULLY AND MAKE SURE THAT YOU UNDERSTAND IT.

We would like to invite you to take part in a research study. Your decision to join the study is entirely voluntary. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please read this sheet carefully. If at any time you have any questions, feel free to ask a member of our research team using the contact details provided at the end of this document or your treating consultant. Please feel free to talk to others about this study if you wish.

Why is the study being done?

It is very common for people to develop pneumonia after being admitted to hospital, this is called hospital acquired pneumonia (HAP). In this case, pneumonia most often occurs because of certain bacteria appearing in the mouth and throat. It can be quite serious and is fatal in some people. We are looking for ways to stop this happening.

Although there is evidence suggesting cleaning your teeth and mouth more frequently might prevent this pneumonia, there are gaps in what has been found. Sometimes the trials did not study enough patients at the highest risk of pneumonia, including patients who may struggle with their memories or sometimes have difficulty thinking, such as people with dementia or delirium.

Our study aims to recruit the a variety of patients, including those with dementia and delirium, and also to document carefully what mouth care is given to patients in our study so that we can confidently design a larger study to understand how best to prevent HAP.

Why have I been invited to take part?

You have been invited to take part in this study because you have been admitted to one of the four study sites and are expected to stay in hospital for 3 days or more.

Do I have to take part?

No. It is up to you to decide whether or not you wish to take part in this study – participation is entirely voluntary. If you decide not to take part, you do not have to give a reason and it will not affect the standard of clinical care you receive in any way.

You are still free to withdraw from the study at any time, without giving a reason. Again, this decision will not affect the standard of clinical care that you will receive.

If you lose capacity to make decisions around mouth care during the study, every effort will be made to contact a consultee (a suitable family member or member of staff) to advise on your continued participation. If we are unable to contact anyone, you will remain in the study, we will continue to offer mouth care (respecting your wishes if you choose to decline the mouth care when offered) and collect routine hospital information (including 90 day hospital follow-up information).

What would taking part involve?

You are being asked to take part in this study at South Tees Hospitals NHS Foundation Trust. If you choose to participate, you need to:

- read and understand this Participant Information Sheet (PIS)
- sign an Informed Consent Form

Following consent, we will collect baseline information from you and your medical records.

What will we do?

Mouth Care Intervention

Instead of brushing your teeth with toothpaste, you will be asked to brush your teeth, tongue and gums with an antiseptic mouthwash. Then you will be encouraged to use a lip moisturiser. If you have dentures, we ask to use antiseptic mouthwash to clean them. If you need help with any of this then staff will help you. We will provide a soft toothbrush, a bottle of mouthwash and a tube of lip moisturiser.

Once you are discharged from this ward you would go back to using your usual toothpaste. We will send your mouth care pack with you, and encourage you to continue using it, for up to 28 days. Even if you are still on the ward, after 28 days you should go back to using normal toothpaste.

If you choose to stop being part of our study, you will resume brushing your teeth twice per day using a toothbrush and toothpaste.

OPTIONAL INTERVIEWS:

We are also interested in finding out your view of what it's like to receive the mouth care.

If you are willing, a member of our research team might contact you or your family to talk through your experience of having mouth care, to see if it went well, or if there was anything

we could have done better. This will help us make things better for future patients when we design new studies.

This would be with a researcher from the University of York. They contact you using the contact details you have given us, will agree a time that is suitable for you. Before the interview, they would check you were happy to take part and ask you to sign a consent form. Due to COVID-19 restrictions, it is likely that these interviews will take place via the telephone or via a platform such as Zoom.

The interview would take approximately 30 minutes. The interviews will be recorded and stored securely so that we can keep an accurate record. Any comments would be anonymised.

We are also interested in understanding views from some staff members involved in your care (ward staff, senior nursing staff etc.). We will ask about their experience of delivering the mouth care at their hospitals.

After discharge

The research team will record your length of stay, whether you go home or somewhere else, and whether you have any further hospital readmissions for up to 90 days after your first admission. This will help us better understand if using the mouthwash three times a day is beneficial to patients and reduces NHS costs. We will also use the information to inform future studies.

After 90 days after your admission, the research team will ask you to complete a questionnaire about your quality of life which was also collected at the start of the study. This can be done over the phone with a member of the research team or sent to you via email (if you have an email address).

Please be aware that researchers may also visit the participating wards to observe ward staff delivering the mouth care intervention. Patients will not be observed in intimate care.

How many people will take part in this study?

We are anticipating approximately 1,470 patients to take part in the study, which will be across 4 hospital wards over 15 months.

OPTIONAL INTERVIEWS: We will include, 16-20 ward staff, 4 senior hospital nursing staff and 16-20 patients or family members for the interviews

How long will I be in the study?

You will take part in the intervention for up to 28 days (4 weeks). You go back to using toothpaste after 28 days. We will then ask you to complete a questionnaire at 90 days from the day you entered the study.

What are the potential benefits of taking part?

More frequent mouth care will improve your oral health and may be easier to eat, talk and socialise. It may be that it also will reduce your risk of getting a pneumonia in hospital, reduced hospital stay and impact your 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 you are more likely to access regular mouth care.

What are the potential disadvantages and risks of taking part?

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 your dentist.

Tooth brushing is a basic care need and a low risk intervention. However we have anticipated the below as possible risks, as with your routine oral care:

- 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
- Drinking/aspirating mouthwash
- Allergic reaction to lip moisturiser
- COVID infection as similar to all inpatients

What alternatives are available to potential participants?

Patients who do not take part in the study will receive the standard mouth care intervention as provided by the NHS, this being tooth brushing with toothpaste twice a day.

What happens if I don't want to be in the study?

Your participation in this study is entirely voluntary. It is OK to decide not to take part, and your care will not be affected by this decision.

Even if you initially decide to take part, you can withdraw later, and again this will have no impact on your future care. You can choose whether you would like to withdraw fully or from receiving the mouth care intervention, follow-up questions and/or the interview.

The information collected until you withdraw will be used anonymously. If you allow us to, we would like to continue to collect your hospital data up to 90 days, such as if you were

readmitted to hospital (see also, "**What are your choices about how your information is used?**").

Are there any costs and compensation?

You will not receive any compensation for taking part in this study. The hospital and your treating healthcare professional will not be receiving any additional payments or benefits for conducting this study.

What if something goes wrong?

If you have a serious medical problem during the course of this study, please inform a member of our team as soon as possible. We will follow-up with you until the problem has resolved, or until it has stabilised.

If you have any concerns or questions about any aspect of this study or any complaint about the way you have been dealt with during this study, in the first instance you should speak to a member of the research team, or the principal investigator or study co-ordinator whose details can be found at the end of this participant information sheet.

If you are unhappy with any aspects of the study you can also your local research team, see 'Further Information and Contact Details' at the end of this document.

If you remain unhappy, and wish to proceed with a complaint, you can contact the National Health Service's complaints mechanism by contacting the Patient Advice and Liaison Services (PALS).

Contact details:
Patient Advice and Liaison Service (PALS)
The James Cook University Hospital
Marton Road
Middlesbrough
TS4 3BW
Email: stees.pals@nhs.net
Freephone: 0800 0282451
Phone: 01642 854807/01642 282657

How will we use information about you?

We will need to use information from you and your medical records for this research study. This information will include:

- Your name and initials
- NHS number
- Contact details
- Date of birth

South Tees Hospitals NHS Foundation Trust, as sponsor, is the data controller and is responsible for looking after your information and using it properly. We will keep all

information about you safe and secure. We will remove any details that would identify you personally. The results of the study will be written in a way that no-one could identify you personally from the reports and publications. Any data collected will be anonymised and may be used to inform future research. See, "**How will my information be kept confidential?**".

If you wish to know the results of the study, you can contact a member of the research team. The study findings will also be available to view via the sponsor's website *https://www.southtees.nhs.uk/about/teaching/research/* and social media.

What are your choices about how your information is used?

- You can stop being a part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- At www.hra.nhs.uk/information-about-patients/
- By asking a member of the research team
- By contacting a member of the research team via email or telephone

How will my information be kept confidential?

Your privacy is important. All information collected during this study will be kept private and personal data will be handled in accordance with the GDPR and Data Protection Act (2018). Your medical records may also be inspected by regulatory authorities and the sponsor (South Tees Hospitals NHS Foundation Trust), local Research & Development department staff to check that the study is being carried out correctly.

Information collected for the study will be accessed for the purposes of analysing the results. However, your identity as a participant in this study will remain strictly confidential. Details such as your name, date of birth and address will not be disclosed outside the hospital without your consent. Researchers from the University of York will be able to securely access your contact details with consent, if you are taking part in the interviews.

By consenting to take part, you accept that the information from this study, including anonymised data and results of examinations and tests, will be collected and processed for the purposes of the study and for any additional scientific research in compliance with the Data Protection Act (2018). The study results will be published, in journals and other multimedia, but it will not be possible to identify you personally.

What if relevant new information becomes available?

You will be notified in a timely manner of any new information that develops over the course of this study that may affect your willingness to participate in this study.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests.

This study has been reviewed and was given a favourable opinion by the Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (ref: 21/YH/0242) and Health Research Authority approval (ref: 21/YH/0242).

Further information and contact details

If you want more information about this study, please contact any of the research team members below.

Contact Information

Research Nurse:
Marc Atkinson
Marc.atkinson1@nhs.net
01642 850850 ext. 55485

Principal Investigator:
Vicky Ewan (details below under Chief Investigator)

For further information, please contact:

Chief Investigator:
Vicky Ewan
Older Person's Medicine Consultant,
The James Cook University Hospital,
South Tees Hospitals NHS Foundation Trust,
Marton Road,
Middlesbrough,
TS4 3BW
Email: Victoria.ewan1@nhs.net
Phone: 01642850850 ext. 55417

Project Manager:
Dr Lucksy Kottam
Research & Development Department,
STRIVE,
Marton Road,
Middlesbrough,
TS4 3BW
Email: lucksy.kottam@nhs.net
Phone: 01642854814

University of York Researcher:
Dr Heather Leggett,
York Research Fellow,
University of York,
Heslington,
YO10 5DD
Phone: 01904326387
Email: heather.leggett@york.ac.uk

Thank you for reading this information sheet and considering your participation.