MAPPS
Mouth cAre to Prevent Pneumonia in older people Study

NHS
South Tees Hospitals
NHS Foundation Trust

PARTICIPANT INFORMATION SHEET
For patients, carers/family members and ward staff taking part in the Qualitative Interviews

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: Vicky Ewan, Older Person's Medicine Consultant, 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?

The MAPPS study will test the feasibility of delivering a mouth care intervention designed to prevent HAP in a real-world setting across 4 hospital sites. We are interested in interviewing key stakeholder groups (ward staff, senior nursing staff, patients and carers) to find out their

views and opinions about the MAPPS intervention and how this has been trialled in the hospital sites.

At the end of the study, we would also like to know how the feasibility study findings may be incorporated into routine nursing care, what resources are likely to be needed in the future and if any changes to the mouth care intervention would be required in view of the study's findings.

Do I have to take part?

No, taking part is entirely voluntary. You can change your mind at any point without giving a reason.

What would taking part involve?

You will be asked to take part in an interview with a researcher from the University of York. This may be in person, over the phone or using a communications app such as Microsoft Teams or Zoom. We will agree a time that is convenient for you. Before the interview, we will ask you to complete a consent form or we can obtain verbal consent. The interview will take approximately 30 minutes. The interviews will be recorded and stored securely so that we can keep an accurate record.

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 interview?

We will include, 16-20 ward staff, 4 senior hospital nursing staff and 16-20 patients or family members.

How long will I be in the study?

You will only be involved in the study for the length of the interview, approximately 30 minutes.

What are the potential benefits of taking part?

As a result of the interviews, we hope to better understand how the intervention can be delivered to older adults to reduce the development of pneumonia, resulting in shorter lengths of stay in hospital and greater outcomes following discharge.

There are also wider healthcare gains from reducing pneumonia including reducing healthcare costs and reducing antibiotic use. This is particularly important on an international scale.

What are the potential disadvantages and risks of taking part?

The interview will take up approximately 30 minutes of your time.

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

Your participation in this study is entirely voluntary. If you do not want to participate in this study or if you decide to withdraw at any point, your decision to do so will have no negative impact and you do not have to provide a reason.

The research team will be available if you have any questions regarding your participation in this study (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.

What if something goes wrong?

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 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 for this research study. This information will include:

- Your name and initials
- Contact details

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.
- 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). 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.

Who has reviewed this study?

This interview is being organised by clinicians and researchers from South Tees Hospital Trust and the University of York. This study is funded by the National Institute for Health Research (NIHR) Research for Patient Benefit NIHR201110.

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.