Participant Information sheet

Research study title: **Clinical detection of silent aspiration in acute stroke**

Research investigator: Julie Trimble, Highly Specialist Speech and Language Therapist, j.trimble@nhs.net

After a stroke, some people have difficulties with swallowing food and liquids. Sometimes, food or drink can 'go down the wrong way' and enter the lungs. This is called 'aspiration'. Some people cough when food or fluid enters their lungs but some don't. If someone doesn't cough, this is called 'silent aspiration'. Food and liquids going down the wrong way can sometimes cause aspiration pneumonia (a chest infection caused by food and liquids going into the lung).

Speech and language therapists assess people who have had a stroke to find out whether their swallowing has been affected and who is at most risk of aspiration.

This is an invitation to take part in a research study which compares two methods of assessment aimed at identifying patients who may be at risk of food or fluids entering their lungs without coughing in response.

Before you decide whether to participate, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If anything is not clear, or if you would like more information, please ask.

What is the study's purpose? The study aims to determine whether a larger study comparing two approaches for identifying patients at risk of silent aspiration (i.e. food or fluids entering their lung without a cough response) is possible. It also looks at whether patients find one of the tests acceptable. Findings may help to improve the care of future stroke patients with suspected silent aspiration and direct further research studies to improve the quality of care for stroke patients with swallowing difficulties.

Why have I been chosen? You have been approached because you have had a stroke and meet the criteria for being included in this study.

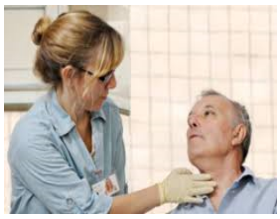
Who approved this study? This study has been approved by the Newcastle upon Tyne Hospitals NHS Foundation Trust.

How many people are taking part in this study? Approximately 30 people are expected to be involved in the study.

Who is responsible for the data collected in this study? All data will be collected by the research investigator, Julie Trimble, a Highly Specialist Speech and Language Therapist with over 10 years' experience of working with stroke patients with swallowing difficulties.

How long will it take? It is likely that it will take between 30-60 minutes for all parts of the assessment. There is likely to be a break of several hours and up to 24 hours in between each test.

What is involved in the study? You will be asked to take part in a test of your swallowing which will include:



Bedside swallowing test

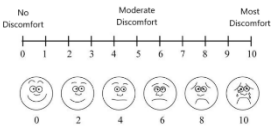
Examination of the muscles in your mouth and throat

and an observation of you having things to eat and drink

Breathing test

Inhaling a citric acid solution (a bit like lemon juice)

via a nebuliser mask



Rating scale

Rating how comfortable you found the nebuliser test

Camera test

Called a fibreoptic endoscopic evaluation of swallowing (FEES)

A small flexible endoscope containing a camera is inserted in your nose while you are given things to eat and drink

This test will be video recorded

Before the swallowing test, you will be asked to sign a consent form to confirm that you have agreed to be involved in the study.

How is this different to usual care? You would not normally be given the nebuliser test and would not always be offered a FEES. Otherwise the assessment is the same as the one you would usually have when you have been admitted with a stroke.

Do I have to take part? No, you do not have to take part. If you don't, you will still receive standard care (bedside swallowing test).

If I do take part, will I miss out on any assessment I would usually be offered? No, you will receive the same standard care but with the addition of the nebuliser test and the FEES.

How will my data be collected, used and shared? The research investigator will need to access your medical records to obtain relevant information for the purpose of the study. This is the same as the care you would usually receive. All the information that is collected about you during the course of the research will be kept strictly confidential. You will not be able to be identified or identifiable. Any data collected about you or others involved in your care during the assessment will be stored on a password protected computer in a form protected by passwords and other relevant security processes and technologies. Data collected

including the FEES video recording may be shared in an anonymised form to allow re-use by the research team and regulatory authorities. The research team includes one member of staff from Newcastle University. These anonymised data will not allow any individuals or their institutions to be identified or identifiable. Any paper documents will be kept in a secure place, stored for 5 years as per Trust policy and then destroyed.

What are the risks/disadvantages involved in this study? There are no known harmful side-effects of the nebuliser test. There is a chance that you may be uncomfortable with breathing the citric acid through the nebuliser. The test makes many people cough. This is a normal reaction.

When swallowing liquids and foods there is always the possibility that they may "go down the wrong way". If this happens and causes you to cough or feel uncomfortable, you will be given as much time as you need to recover.

The FEES may cause a small amount of discomfort or a tickly sensation when the scope is inserted in your nose. The tip of the scope will be coated with lubricating gel to help minimise any discomfort. Scope insertion may cause you to sneeze and on very rare occasions may result in nose-bleeding. You can ask for the test to be stopped if you are finding it too uncomfortable.

Participating in the research is not anticipated to cause you any disadvantages or discomfort and only includes very small differences from the standard swallow assessment received by all stroke patients on admission to hospital.

What are the benefits of taking part in this study? It is hoped that findings from this study will have a beneficial impact in helping to more accurately identify stroke patients who are at risk of silent aspiration in the future. The benefit to you will be that the FEES allows us to see whether liquids or foods are going down the wrong way and whether any particular textures are easier or safer for you to swallow.

Results will be discussed with you after the assessment and will help to inform you regarding whether you are safe to eat and drink and, if you are safe, what textures are most appropriate for you. If you then eat and drink the textures you have been recommended, there may be a reduced risk of food and liquids going down the wrong way and therefore a reduced risk of you developing aspiration pneumonia.

What are my rights as a participant? Taking part in this study is voluntary. It is up to you to decide whether or not to take part. You can still withdraw at any time. You do not have to give a reason. If you decide to take part, you are still free to stop at any time without giving reasons. No questions will be asked if you stop and there will be no penalty for withdrawing

Do I need to pay to be involved in the study? No, you do not have to pay for any part of the study.

Will I receive any payment or monetary benefits? You will receive no payment for your participation. The data will not be used by any member of the project team for commercial purposes. Therefore, you should not expect any royalties or payments from the research project in the future.

Will there be any follow-up after the study? No follow-up is required. If you have communication or swallowing difficulties, you will continue to receive advice and support from Speech and Language Therapy but not specifically in relation to this study.

What if something goes wrong? If you are injured as a direct result of your participation in this study, the study will be discontinued and you will receive medical attention from staff on the ward. The research investigator will determine whether your injury is related to your participation in this study. Please contact one of the research team members listed on this form should you wish to discuss this further. If you experience an injury or have questions about any discomforts that you experience while participating in this study medical staff will be present to assist you.

Who is funding this study? This study has been funded by Research Capability Funding provided by the National Institute for Health Research and Bridging Stroke Across Newcastle and Gateshead charity and has been registered with the Newcastle upon Tyne NHS Foundation Trust.

Will I be updated about the results of this study? If you would like feedback about the results of the study, please let the Research Investigator know the best way to contact you (see contact details below). You will be sent a written summary of the results when all the data has been analysed or we can speak to you over the phone if this is easier for you.

Who should I contact if I have any questions or concerns about this study? If you have any further questions or concerns about this study, the procedures involved or how it is being conducted, please contact:

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