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**University of Nottingham, School of Medicine**

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Consultee Information Sheet

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**Does swallow therapy with feedback in the early stages after stroke improve swallowing?**

Your relative (it could also be a friend or someone you care for, but for brevity this document will use the term ‘relative’) is being invited to take part in a research study. Before you decide whether you agree to their participation it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

**Who can act as a consultee?**

Where people cannot take the decision to consent to be involved in a research project then a consultee must be appointed. A consultee can either be ‘personal’ or ‘nominated’. A personal consultee is someone unconnected with the research who knows the potential research participant in a personal capacity and is able to advise on the person’s wishes or feelings. This can be a friend, family member or court appointee. A ‘nominated’ consultee’ is someone unconnected with the research, appointed by the researcher, to advise the researcher about the person’s wishes and feeling in relation to the project. This can be another health-care worker but they must not have any connection with the study. Before a nominated consultee is appointed, the researcher will take all reasonable steps to identify a personal consultee.

**What is the role of the consultee?**

The consultee advises the researcher on what the participant’s wishes and feelings would be if they were able to consent for themselves, and on whether they should take part. The consultee does not give consent, only advice. The responsibility to decide whether the participant should be entered into the research lies ultimately with the researcher. Consultees will be provided with information about the research project and will be given the opportunity to discuss it and their role as consultee. All consultees must be able to understand their role and be willing to undertake it.

**What is the research?**

Swallowing therapy has shown to help patients improve their swallowing after a stroke. We would like to find out whether swallowing therapy with visual feedback helps improve patient’s swallowing more than usual therapy and if having this therapy twice daily is more effective than once a day. We would also like to know whether swallow therapy with feedback can feasibly be delivered by hospital teams in the early stages after stroke. Please note that this research will not delay your relative’s discharge from hospital.

**Why has your relative been invited?**

Your relative has been invited because they have difficulties swallowing as a result of a new stroke. We are looking for 120 people in total.

**Does my relative have to take part?**

We would like you to think very carefully about whether or not this person would have wanted to join the study. If your opinion is that he/she would have decided to take part, you would be given this information sheet to keep and be asked to sign a declaration form indicating your view allowing your relative to participate in the study. If you later decide that he/she no longer wishes to take part, please inform us and he/she will be withdrawn from the study. You do not need to give a reason and it will not affect the standard of care your relative receives.

**What does it involve?**

Assessment

The first stage will be assessing your relative’s swallowing and health. This will involve:

* A swallowing assessment to see whether and how well they can complete the swallowing exercises. This will take about 15 minutes. If they are unable to complete the exercises they will not be asked to participate in any further assessment or therapy for this study.
* If they can complete the exercises, one of the researchers will assess their stroke severity and quality of life at bedside – this will take about 15 minutes.
* The researchers will gather information from your relative’s medical notes about their swallowing and health since their stroke.

Usual care during the research period

* As long as they need it your relative will be under the care of a speech and language therapist
* Your relative’s swallowing will be assessed and reviewed as usual
* The speech and language therapist will make recommendations about what is safe for your relative to eat and drink

Therapy

To check whether this specific therapy is beneficial we need to compare it to the care that people with swallowing difficulties usually get. Your relative will be randomly assigned to one of three groups. The groups are selected by a computer which has no information about the individual – i.e. by chance. The groups will be as follows:

1. Standard dose feedback group – During approximately 35 minute therapy sessions the researcher will secure a pad underneath your relative’s chin to measure their swallowing muscles. People who have hair underneath their chin will need to have this shaved by nursing staff on the ward beforehand. They will be able to see a line on the computer screen which will move when they swallow. They will practice swallowing as per the therapist’s instructions and using feedback from the screen to alter the strength and timing of their swallow. The exercises are designed to be challenging as this is important for rehabilitation but they will be tailored to each individual to make them achievable. They may also do other swallowing exercises with their usual speech and language therapist or be asked to carry out exercises on their own. Over 2 weeks your relative will receive 10 sessions offered 5 days a week.
2. High dose feedback group – the therapy will be the same as above but over 2 weeks your relative will receive 20 sessions. This will mean having two therapy sessions a day.
3. Usual therapy group – Over 2 weeks your relative’s usual speech and language therapist will continue to review their swallowing, make recommendations about their eating and drinking and if appropriate they may practice swallowing exercises with them. They may also be asked to carry out some exercises on their own.

Re-assessment

After the therapy we will need to repeat the following assessments:

* A swallowing assessment at bedside – this will take about 15 minutes
* One of the researchers will assess your relative’s stroke severity and quality of life at bedside – this will take about 15 minutes
* The researchers will also gather information from your relative’s medical notes about their swallowing and health since their stroke
* At the point of discharge, you will receive a diary to complete about your relative’s swallowing and their health. You do not need to send it back but we will ask you about it when we call you at 3 months.

At 3 months

We will telephone your relative at home or wherever they are residing to do the following final assessments, which should take about 15 - 30 minutes:

* The researchers will ask you about your relative’s swallowing and health and their quality of life since their stroke - we may need to ask you some of the questions if your relative is unable to.

Here is a timeline of events:



**What happens after the 2 week period?**

If your relative continues to have swallowing difficulties after the 2 week period they will remain under the care of the speech and language therapy team for as long as the team feel is beneficial.

**Where will the research take place?**

We will come to your relative to carry out the assessments and therapy – whether that is on this ward or another ward. If they have been discharged home before the two weeks of therapy are complete, we will aim to contact your relative at 2 weeks to complete the re-assessments that can be carried out over the phone.

**Do they have to take part?**

We would like you to think very carefully about whether or not this person would have wanted to join the study. If your opinion is that he/she would have decided to take part, you would be given this information sheet to keep and be asked to sign a declaration form indicating your view allowing your relative to participate in the study. If you later decide that he/she no longer wishes to take part, please inform us and he/she will be withdrawn from the study. You do not need to give a reason and it will not affect the standard of care your relative receives.

**What are the possible benefits of taking part?**

We cannot promise the study will help your relative but the information we get from this study may help us to improve the rehabilitation we offer in the future.

**What are the possible disadvantages and risks of taking part?**

There have not been any side effects or safety concerns associated with this therapy in previous research. If your relative is assigned to one of the intervention groups this will take up some of their time.

**Expenses and payments**

Participants will not be paid to participate in the study.

**Involvement of the medical team/GP?**

If you agree for your relative to participate in this study a copy of the signed consultee declaration form will be filed in their medical records so their hospital medical team will be aware they are participating in this study.

**What will happen if I do not want my relative to carry on with the study?**

Your relative’s participation is voluntary and you are free to withdraw your declaration at any time, without giving any reason, and without their legal rights being affected. If you withdraw your declaration, then the information collected so far will not be erased and this information may still be used in the project analysis.

**What if something goes wrong?**

In case you have a complaint on your relative’s treatment by a member of staff or anything to do with the study, you can initially approach the lead investigator. If this achieves no satisfactory outcome, you should then contact PALS, Tel [ADD LOCAL PALS CONTACT].

**Will my relative’s taking part in this study be kept confidential?**

We will follow ethical and legal practice and all information about your relative will be handled in confidence.

If your relative joins the study, some parts of their medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to your relative as a research participant and we will do our best to meet this duty.

All information which is collected about your relative during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Where possible, information about them which leaves the hospital will have their name and address removed (anonymised) and a unique code will be used so that they cannot be recognised from it. However, sometimes we need to ensure that we can recognise them to link the research data with their medical records so in these instances we will need to know their name and date of birth. We will also need this information if we need to follow up their medical records as part of the research, where we may need to ask the Government services that hold medical information about them (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. We also ask your permission to check with the NHS Information Centre to check on your condition 3 months, after your stroke and to confirm your contact details. By signing the consent form you agree to the above.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Dr Jacqueline Benfield) is the Data Custodian (manages access to the data). This means we are responsible for looking after your relative’s information and using it properly. Your rights to access, change or move your relative’s information are limited as we need to manage it in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your relative’s rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your relative’s information and to read our privacy notice at:

<https://www.nottingham.ac.uk/utilities/privacy.aspx>.

This information will include your relative’s:

* Name
* Date of birth
* NHS number
* Address
* Telephone number

Your relative’s personal data will be kept for 1 year after the end of the study so that we are able to contact them about the findings of the study *and* possible follow-up studies. All other data (research data) will be kept securely for 7 years. After this time your relative’s data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your relative’s confidentiality, only members of the research team will have access to their personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that your relative could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

**What will happen to the results of the research study?**

It is likely that the research will be written up for submission to a journal. There will be no identifying information about any participants in any publications.

**Who is organising and funding the research?**

The research is being funded by the National Institute of Health Research (NIHR) Clinical Lectureship NIHR 302177.

**Who has reviewed the study?**

This study has been reviewed and approved by the XXXX NHS Ethics committees.

**Contact for Further Information**

If you require any further information regarding this study please contact:

* Dr Jacqui Benfield, Highly Specialist Speech and Language Therapist/Associate Clinical Lecturer

Tel: 01332 785891. Email: jacqueline.benfield1@nottingham.ac.uk

Or ask the nurses on the ward to contact the researcher Jacqui Benfield on your behalf

Thank you for your time.