Study title: Feasibility study of a supported self-management intervention for aphasia (StarStep study)

COMPLETE A QUESTIONNAIRE AND OBSERVATIONS

INFORMATION LEAFLET FOR STROKE SURVIVORS WITH APHASIA

You are being invited to take part in a research study

Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. This information sheet tells you about the study, what we would like to do and how we would manage the information. Please read this carefully and ask us if anything is not clear or if you would like more information. Talk to other people about the study if you wish.

Why me?

We are inviting you to take part because you have experienced aphasia (trouble communicating) after your stroke. Aphasia can cause difficulties with speaking, understanding what other people say, reading or writing.

Why are we doing this research?

We are trying out a new programme of one-to-one support to help stroke survivors build confidence and strategies to cope with aphasia. Speech and language therapists in the NHS service which is providing your care are trying out the new approach. You will receive the new programme in addition to the care usually provided by your speech and language therapist. . We want to find out how feasible it is to deliver. The findings from this study will help us to refine the support programme. We hope to test the new support programme in a larger trial in the future.

Who is organising and funding this study?

The chief investigator of this study is Dr Faye Wray who is running the study from the Academic Unit for Ageing and Stroke Research (a department of the University of Leeds based at Bradford Teaching Hospitals NHS Foundation Trust). The study is funded by the Stroke Association. The study sponsor is The University of Leeds.

What would be involved if I agree to take part?

We would like you to:

- **Talk to our researchers** and answer some questions about yourself (e.g. your age, gender, whether you live alone, whether you are employed). We will also ask to complete a brief assessment of your language (lasting between 5-10mins).
- **Complete some questionnaires**. We will ask you to complete some questionnaires about your health when you first agree to take part in the study and then around 6 months later. The questionnaires will take between 30-60mins to complete. The research team will contact you to arrange a face-to-face visit to complete the 6 month questionnaires. This will usually be done at home. Your speech and language therapist will also ask you to complete a very short (less than 5 mins) questionnaire about the therapy at the end of each session.
- **Take part in observations**. We would like to observe some of the care that you receive so we can see how the new approach works in practice. The research team will ask your speech and language therapist to video record the therapy sessions you have together. With your permission, a researcher may also sit in on one of the therapy sessions you have with your speech and language therapist. The researcher would not participate in any care or activity but would watch what was happening and make notes. This will only happen if there are unforeseen problems with the video recording.

You can decide if you would be happy to participate in the observations. Or if you would prefer to complete the questionnaires only.

We would also like to request consent to access your medical and care records so that we can gain information about the type of stroke you have had and how this has affected your health. This information will be collected by an authorised member of the research team and will be anonymised with a code number so you cannot be identified.

In addition, we may contact some participants in a few months' time to take part in an **interview** so we can gain your views on the therapy you have received. Not everyone will be contacted and, if you are, you can agree or refuse to take part in the interview at that point. The interview would take place at a time and a location that is convenient for you (probably your own home) and take about an hour.

How might the COVID-19 pandemic impact this research?

We will respect all current national and local safety guidelines with regard to COVID-19 e.g. wearing face masks and social distancing. Where it is not possible (or if you would not feel comfortable) to meet a researcher face-to-face to complete questionnaires or take part in an interview, there will be options to participate using an online platform e.g. Microsoft Teams or Skype instead. The researcher will support you to access the platform and help with answering questions or getting across your views.

Do I have to take part?

No, it is up to you whether you would like to take part or not. You do not have to give a reason if you decide not to take part. It will not affect your ongoing care if you decide not to take part.

How will we use information about you?

We will need to use information from you for this research project. This information will include your initials / name/date of birth/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. With your permission, we will inform your GP that you are taking part in the study. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. However, if we have concerns that you, or someone else, is at risk of harm then we may break confidentiality and inform the relevant health or social care services. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. The supplementary information sheet tells you more about this.

What are my choices about how my information is used?

- You can stop being 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.
- If you wish to withdraw your data from the study, please contact Faye Wray (using the contact details provided on page 6) within 2 weeks of the data (e.g. questionnaire, observation) being collected. It will not be possible to withdraw your data from the study after this time.

Where can I find out more about how my data is used?

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

- at https://www.hra.nhs.uk/information-about-patients/
- from our leaflet available from https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2020/08/My_data_and_research.pdf
- by asking one of the research team (see contact details below)
- by sending an email to the University data protection officer at dpo@leeds.ac.uk
- University of Leeds Privacy Notice is available to read at https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf

What are the possible benefits of taking part?

Being involved may not benefit you directly. However, it may help improve future services and support for stroke survivors with aphasia and their family members/friends.

Are there any risks from taking part?

You may find some of the topics covered in the questionnaires upsetting. You do not have to answer any questions you do not wish to. You may feel uncomfortable being observed or video recorded during therapy. You can stop the observation at any time.

What will happen to the results of the study?

We will send a summary of our findings to all participants at the end of the study. We also hope to publish the results of this study in an academic journal. If you would like a copy of the report, you can request one from the research team using the contact details at the end of this leaflet. We will share the results with other researchers at conferences and meetings, and through newsletters and academic journals. We may use anonymised quotations from the observation but you will not be identified in any report/ publication.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from the East of England - Essex Research Ethics Committee (Ref: 21/EE/0115). **The ethics committee will check that the research is done properly and that you are kept safe.**

What happens next?

If you decide to take part, you will need to sign a consent form. It says that you understand the research and have decided to take part. We can help you with filling out the consent form if needed. If we cannot meet face-to-face due to COVID-19, we may ask you to agree to take part in the study verbally (whilst being audio recorded) instead of signing a consent form. We will discuss this with you. If you do not wish to take part, you do not need to do anything. We are grateful to you for reading this information.

What if there is a problem?

If you would like to discuss this study with someone independent of the study team please contact: Clare Skinner, Faculty Research Office, Room 9.29, Level 9 Worsley Building, Clarendon Way, Leeds LS2 9NL Tel: 0113 343 4897 or email: governance-ethics@leeds.ac.uk . Please quote study title: Feasibility study of a supported self-management intervention for aphasia.

Sources of support:

The Patient Advice and Liaison Service (PALS) provides a confidential service, helping you to sort out any concerns you may have about the care provided in an NHS service and advising you of support agencies and other organisations that can help, for example the Stroke Association. PALS can be contacted on xxx or by e-mail: xxx.

Claims/insurance

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against [Add NHS Trusts here] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). The University of Leeds as sponsor for the study is able to provide insurance to cover for liabilities and prospective liabilities arising from negligent harm.

For more information please contact:

Faye Wray

01274 38 3400

f.d.wray@leeds.ac.uk

Academic Unit for Ageing and Stroke Research
Temple Bank House
Bradford Royal Infirmary
BD9 6RJ

Thank you for taking the time to read this information.

This study is organised and run by the Academic Unit for Ageing and Stroke Research (a department of the University of Leeds) at Bradford Teaching Hospitals NHS Foundation Trust. This study is funded by The Stroke Association. The sponsor for the research is the University of Leeds. The study has been approved by East of England - Essex Research Ethics Committee (Ref: 21/EE/0115).

ASR Academic Unit for Ageing and Stroke Research

UNIVERSITY OF LEEDS