Development of a core outcome set for clinical research on interventions for speech impairments in Stroke: COS-Speech Participant Information Sheet (PIS)

You are being invited to take part in a research study to gain consensus around what aspects of speech recovery after stroke are important to measure. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

- **Who will conduct the research?**

Dr Claire Mitchell, Human Communication Development and hearing, School of Health Sciences, The University of Manchester, UK.

Professor Jamie Kirkham, Biostatistics, School of Health Sciences, The University of Manchester, UK.

Professor Audrey Bowen, Professor of Neuropsychological Rehabilitation, Division of Neuroscience and Experimental Psychology, The University of Manchester, UK.

Dr Paul Conroy, Senior Clinical Lecturer in Speech and Language Therapy, Human Communication Development and hearing, School of Health Sciences, The University of Manchester, UK.

Dr Sarah Wallace, Research Fellow of Health and Rehabilitation Sciences, University of Queensland, Australia.

Dr Brooke-Mai Whelan, Lecturer in Speech Pathology, School of Health and Rehabilitation Sciences, University of Queensland, Australia.

What is the purpose of the research?

This research is about achieving consensus agreement of a core outcome set for research and clinical practice. This means we will seek agreement between 3 key groups to establish what aspects of speech recovery should be measured after stroke and how we should measure them.

The 3 key groups are stroke survivors, researchers and clinicians (mainly speech and language therapists) who have experienced (or worked with people who have experienced) dysarthria after stroke.

We want to recruit similar numbers from each group.

- **Am I suitable to take part?**

We would love you to get involved if:

You have had or still have dysarthria following a stroke, this can be a recent stroke or a stroke at any time in your life and live in the UK or Australia.

You have been involved in research or clinical practice that involves any sort of communication impairment as a result of stroke.

- **Will the outcomes of the research be published?**

We intend to publish our findings in academic journals and in more accessible ways in a blog and on Twitter.

- **Who has reviewed the research project?**

The project has been reviewed by The University of Manchester Research Ethics Committee (ref: Ref: 2022-13303-22550) and The University of Queensland Ethics Committee (ref: 2022/HE000641).

- **Who is funding the research project?**

This project is funded by the Stroke Association SA PDF 21\100017 and the National Institute for Health Research for Patient Benefit NIHR202748.

What would my involvement be?

- **What would I be asked to do if I took part?**

You will be sent an email asking if you are happy to carry out an online survey lasting 30 minutes to 45 minutes. Two months later you will be sent your results from this survey and asked to carry out another survey online via email. This will take about 30-45 minutes to complete.

Two months later you will be sent an email with all of the results from the three groups and asked if you would like to attend an online (zoom) meeting two hours long to discuss and agree the findings from the survey i.e. agree the core outcome set (COS-Speech).

Following the survey you will be invited to two follow up consensus meetings. If we have too many people from a particular group we will select in order of the first to respond with their completed consent form. These are online (zoom) meeting each one hour long:

- First consensus meeting to discuss the survey findings and vote on any that are uncertain following the survey, discussion to make sure everyone is in agreement
- Second consensus meeting to look at existing tests/scales/measures to see if any of these can be used with the agreed core outcome set

- **Will I be compensated for taking part?**

There is no compensation for taking part.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you do not wish to take part then do not complete the survey or attend the meeting.

If you do decide to take part you will be given this information sheet to keep and will be asked to tick a box to confirm consent prior to accessing the online survey.

If you decide to take part in the meetings, following the survey, you will need to complete a signed consent form.

If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect: email address and how this links to your online survey responses. This data will only be held by the UK researchers to be able to contact you. We will ask you your age, gender, and time since stroke as part of the survey questions. This information will be stored as part of that data on the survey software stored securely and only accessible to the UK research team.

If you attend the online consensus meetings we will take an audio recording of the meeting.

- **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information only in the UK in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research.

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. The research team will have access to the key that links this ID number to your personal information. As soon as we have analysed the findings and published the results the data will be fully anonymised (2 years from the start of the study).

For the research study we will be using a bespoke piece of software DelphiManager. This purpose built software is stored securely at the University of Liverpool data centre. This software will only be used by the researchers in this trial and not accessible to anyone else.

- Your participation in this research will be audio recorded in Zoom and your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

- **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact:

Dr Claire Mitchell, Claire.mitchell@manchester.ac.uk, tel: 01612753442

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher

Dr Claire Mitchell

Claire.mitchell@manchester.ac.uk

Tel: 0161 275 3442