MANCHESTER
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The University of Manchester

Development of an International Core Outcome Set for Post-Stroke Facial Palsy: COS-Post-Stroke Facial Palsy

Participant Information Sheet (PIS)

You are being invited to take part in a research study to gain consensus around what aspects of post-stroke facial palsy 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?

Mrs Havva Sumeyye Eroglu, Division of Psychology, Communication and Human Neuroscience, School of Health Sciences, The University of Manchester, UK.

Dr Claire Mitchell, Division of Psychology, Communication and Human Neuroscience, 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 Matthew Checketts, School of Psychology & Neuroscience Administration, University of Glasgow, UK.

➢ 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 2 key groups to establish what aspects of post-stroke facial palsy should be measured after stroke.

The 2 key groups we want to take part are researchers and clinicians who work with stroke survivors who have or had facial palsy or work with patients who have facial palsy after stroke.

➢ Am I suitable to take part?

We would love you to get involved if:

- You have been involved in research or clinical practice working with any sort of facial palsy as a result of stroke.

  OR

- You have been involved in research or clinical practice working with stroke survivors who have or had facial palsy.

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

We intend to publish our findings in academic journals and conference presentations.

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

This project has been reviewed by the Division of Psychology, Communication and Human Neuroscience research ethics committee at The University of Manchester. Ethics number: 2024-21316-38685

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 around 10 minutes. The survey will include basic demographic questions (gender, ethnicity, country of residence, and professional experience duration) along with the main survey questions. One month later, you will be sent your results from this survey and asked to carry out another survey online via email. If necessary, 3rd round survey will be sent.

One month later, following surveys, you will be sent an email with all of the results from the two groups and asked if you would like to attend a consensus meeting on Microsoft Teams two hours long to discuss and agree on the findings from the survey, i.e. agree on the core outcome set (COS-Post-Stroke Facial Palsy). 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. This is an hour-long online (Microsoft Teams) meeting:

- The consensus meeting will review the survey results to establish agreement on the core outcome set. During the meeting, participants will discuss any outcomes that remain uncertain after the survey and vote to reach a final decision. The goal is to ensure that all participants are aligned and in agreement on the findings.

- **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 your e-mail address and how this links to your online survey responses. We will also collect demographic information including your gender, ethnicity, country of residence, and duration of professional experience.

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 Qualtrics. The survey results on the Qualtrics will only be accessed by authorised members of the research team.

- Your participation in this research will be audio recorded in Microsoft Teams and your personal data will be processed by Microsoft Teams. 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, B.1.8 Room Ellen Wilkinson Building, The University of Manchester M15 6JA, or by telephone at (+441612753442), or by emailing claire.mitchell@manchester.ac.uk

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(s)

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