

Plain Language Statement

Department of Physiotherapy
School of Health Sciences
Faculty of Medicine, Dentistry and Health Sciences



Project:

Development of a “core set” of outcome measures for spasticity trials and clinical practice

Phase 1: Semi Structured Interviews

Project Supervisor:

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research. Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about. Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

If you decide you want to take part in this research project, you will be asked to sign the corresponding consent form either manually or electronically and return it to a member of the research team. By signing the consent form, you are telling us that you:

- Understand what you have read;
- Consent to take part in the research project;
- Consent to the use of the information that you share with us, in the manner outlined in this document.

What is this research about?

Spasticity is muscle tightness caused by neurological conditions such as stroke, brain injury and multiple sclerosis. Spasticity can cause pain, reduced flexibility or skin

breakdown and has been shown to negatively impact walking, arm use, personal-care, and quality of life. While there is a lot of research in the field of spasticity assessment and management, this research is hampered by a lack of consistency in the way that spasticity, and the associated problems that it may cause, are measured. This makes it difficult for both researchers and clinicians to compare results between studies and establish the most effective treatment options for people with spasticity.

To address this problem, other areas of healthcare such as stroke have developed a 'core set' of outcome measures (i.e. minimum accepted outcome measures) that trials need to measure and report when conducting research in their designated field. This has led to better reporting in clinical trials and greater capacity to compare the results of clinical trials. This project, which will be conducted internationally, aims to develop a core set of outcome measures for spasticity in order to enhance spasticity related research and optimise clinical care and patient outcomes. It will enable greater clarity, consistency, evaluation and comparison of spasticity trials.

Prior to developing the core set, it is important to establish what aspects of spasticity assessment are important to individuals (or their primary carer/family member) living with spasticity. You have been invited to participate in the first stage of this study because you are an individual with, or carer or family member of someone with spasticity.

What will I be asked to do?

Should you agree to participate you will be asked to take part in an online interview, completed via Zoom, with a member of the research team. The aim of these interviews will be to identify how spasticity impacts you, and what outcomes from spasticity treatment are important to you. This may include things like pain, joint flexibility, walking, arm use, how your limbs look or quality of life. It is anticipated that the interview will take approximately 30-45 minutes to complete. All interviews will be audio recorded and transcribed into text using the Zoom audio transcription function, to enable the researchers to re-listen to the interview, ensuring that no important content is omitted. You will have the opportunity to review the transcript and amend your responses, following the interview. Only the research team will have access to the password protected transcripts.

What are the possible benefits?

The main benefit resulting from this project is the opportunity to improve how spasticity research trials are conducted and reported, enabling greater comparison between trials and ultimately an improved outcome for individuals with spasticity following neurological injury.

What are the possible risks?

There is no foreseeable harm, minimal burden, and negligible risk associated with participation. Although unlikely, the interview may cause mild fatigue and time burden. You will be entitled to take breaks throughout the interview as needed and you do not need to talk about any aspect of your symptoms or condition that may lead to emotional discomfort.

Do I have to take part?

No, participation is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you decide to withdraw from the project, please notify a member of the research team as soon as possible. If you decide to withdraw from this research project, the researchers will not collect additional information from you. Any information already collected from you in the interview will still be used in this project, unless you request otherwise.

Will I hear about the results of this project?

We anticipate completing 10-15 interviews. Following the completion of these interviews you will receive an email summary of the results outlining:

- The spasticity assessment domains identified in already existing, international spasticity guidelines
- Additional spasticity assessment domains identified during the interview process

You will also be invited to participate in the subsequent stage of this project whereby academic experts, clinical experts, industry representatives and patients/carers will be invited to take part in a two or three round, online survey to determine which assessment areas should be included in the core set.

What will happen to information about me?

The aim of these interviews is to identify any assessment domains that are important to patients but have not necessarily been identified in published spasticity guidelines. These additional domains will then be included in the subsequent stages of the study, whereby clinicians, researchers, industry representatives and patients will be asked to vote on the domains that should be included in the core set. Once you sign this consent form, you will be given a unique participant number that will only be re-identifiable to the researchers named on this application. This information will be stored on a password protected document, in a separate folder to where the interview transcripts and results will be stored. All data collected throughout the interviews will be de-identified and no raw data from the interviews will be shared with anyone outside of the researchers named on this application. All data generated will be collected, managed, and stored following the protocols outlined in the University of Melbourne's "Management of Research Data and Records Policy". The data will be kept on a university system (OneDrive) accessed by secure password-protected computers, which will only be accessed by the researchers.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

All data will be held for 5 years after the last report is published. The data will be stored digitally by The University of Melbourne on password protected cloud software. After this time, the data will be destroyed to ensure confidentiality is maintained.

Who is funding this project?

No member of the research team will receive a personal financial benefit from your involvement in this research project.

Where can I get further information?

If you would like more information about the project, please contact the principal researcher:

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Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne [project ID 31748]. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.