**ERGO Number: 46996**

**Coping and Living with MND (CALM) study**

**Participant Information Sheet**



You are being invited to take part in the CALM research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information, before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part.

**What is the research about?**

This study aims to understand the experience of people with Motor Neurone Disease (MND) and their family/caregivers. It will explore the emotional impact of being diagnosed and living with this condition. The results from this study will be used to develop a set of online support tools to help support people with MND.

**What will happen next if I take part?**

If you agree to take part, you will be asked to fill a consent form and invited to take part in either a face-to-face or email interview (based on your preferred way of communicating) to capture your experience living with MND. The interviews will take place at a location convenient to you. We will find out about what adaptations are needed to make an interview possible and comfortable for you. We are interviewing patients and family/caregivers separately, so you don’t need to have a family member/caregiver to participate. Each interview will be audio recorded/written down via email and will last for around one hour.

**What do I do next?**

If you are willing to take part in the study, please complete the consent form and send it back to the researcher in the freepost envelope provided (or via email if you have received these documents via email). If you do not wish to take part in the study, you do not need to take any action.

If you have any questions, please do not hesitate to get in touch with Cathryn

(Email: C.L.pinto@soton.ac.uk Telephone: 023 80596652)

**Why have I been asked to participate?**

You have been invited to take part as you have a diagnosis of Motor Neurone Disease (MND) or are a family member/caregiver for a person with MND. It is completely up to you to decide whether or not you want to take part.

**Are there any benefits in my taking part?**

There are no direct benefits of taking part in the study. However, the information you give us will help us improve care for people with MND in the future. We will offer you a £10 Amazon voucher to thank you for your time and for taking part in the study.

**Are there any risks involved?**

We think there is very little risk of harm in taking part. Some people may find remembering and talking about their experiences distressing. You will be able to pause or end the interview at any time.

If you tell us anything that makes us concerned about your safety or the safety of others we may have to inform a member of the clinical team looking after you. We will ask you for these details in the consent form.

**What data will be collected?**

We will ask you to provide a few basic details (age, gender, employment, and living situation, diagnosis and current symptoms). This will be followed by the interview about your experiences.

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

The results will be used to design a set of online tools to help people cope with MND. Study findings will presented at conferences, published in academic journals, and used to educate students and health professionals. A summary of the findings can be made available on request. All study data will be anonymised before study results are presented. Direct quotations from your interview may be used in the study report and in the materials of the intervention. However, we will ensure you cannot be identified by these quotations.

**Who has funded the study?**

This study is funded by the Motor Neurone Disease Association (MNDA). The study will be carried out by PhD researcher, Cathryn Pinto, supervised by Dr. Dennison, Dr. Geraghty and Prof. Yardley from the University of Southampton. Prof Karen Morrison and Dr. Ashwin Pinto are project advisors .

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential. Your interview will be anonymised and any identifiable references will be removed in accordance with the Data Protection Act (2018) and research governance. You and your data will not be identifiable in any report or publication.

Personal data will be stored or accessed by the research team for 3 years and the data will be securely archived at the University of Southampton for 10 years after the study has ended. After this period, all data will be permanently deleted or destroyed.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part and we encourage you to take some time to think about it and to ask us any questions you have. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

**What happens if I change my mind?**

Once you have signed the consent form, you still have the right to change your mind and withdraw at any time until the data has been analysed (July, 2019). You don’t have to give a reason and your medical care or legal rights will not be affected. After the data has been analysed it will be difficult to separate your data from that of the other participants, as all the interviews stored will have been transcribed and anonymised.

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

*Thank you for taking time to consider this. We understand coping with an illness is not always easy. We hope that this study will contribute to the understanding the emotional concerns of people with MND and improve the way support is provided to address these.*

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you. Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it. Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed. To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).