**ERGO Number: 61216**

**Coping And Living well 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.

We understand coping with an illness is not always easy and we thank you for taking the time to consider taking part.

**What is the research about?**

**We are making a website** to **help people with MND and their family members** deal with the **emotional side of MND** (e.g. feeling worried, sad, angry, hopeless, or overwhelmed). Our website aims to help people to find ways to cope with these emotions and feel a little happier, calmer and more positive.

This research study will ask people with MND and their family members for **feedback** on the early drafts of this website. We will then make changes to the website so that it is as helpful and easy to use as possible.

**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 someone with MND.

We are interested in talking to people who may be struggling with difficult thoughts and feelings. We are also interested in talking to people who are doing okay emotionally right now.

It is completely up to you to decide whether or not you want to take part.

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

If you agree to take part, you will:

* Be asked to fill a consent form and fill in some questionnnaires about yourself
* You will then be emailed a link and instructions to using the website. You will be able to use this website for 4-6 weeks. You can use this website as often as you like, and however works best for you.
* After this time, you will then fill in some questionnaires and have an interview with a researcher. You can choose either a phone call or video call or written/typed interview, based on your preference.
* You can use this website either on your own or with the help of a family member. Depending on how you use it, we will interview you either separately or together with your family member, again based on your preference.
* The phone and video calls will be audio recorded and will last up to 60 minutes.

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

You might find that you pick up helpful tips and ideas about managing the emotional side of MND.

Your feedback will also help us improve the website for use with other people with MND and their families in the future.

We will also offer you a £10 Amazon voucher to thank you for your time and feedback.

**What do I do next?**

If you want to take part, please complete the consent form. 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 contact Cathryn

(Email: C.L.Pinto@soton.ac.uk) or [Tel: 023 8059 6652].

**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 three psychologists from the University of Southampton Dr. Laura Dennison, Dr. Adam Geraghty and Prof. Lucy Yardley.

**Are there any risks involved?**

We think there is very little risk of harm in taking part. You might feel upset or uncomfortable if the interview makes you think about your own emotions or from reading about other people’s experiences. However, the website offers information and tips for dealing with these emotions. If you feel you need any additional emotional support, we recommend that you contact someone from your healthcare team.

If you need a break during the interview we can always pause the interview or reschedule. If you find using the website or being in the study too difficult, you can stop at any point without giving us a reason.

**What data will be collected?**

We will ask you to complete questionnaires about yourself (age, gender, employment, living situation, diagnosis and current symptoms and emotions).

We will then let you use the website for 4-6 weeks and ask for your feedback through questionnaires and an interview. We will also look at information about how you use the website (e.g. which sections you look at, how long you spend using the website).

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

The study findings will be used to improve the website.

Findings will also be presented at conferences and seminars and be published in academic journals and written up in a PhD thesis. We will not include information that can directly identify you (e.g your name or where you live).

**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?**

You have the right to change your mind and withdraw at any time until the data has been analysed (July, 2021) by contacting the researcher and letting her know. If you withdraw from the study before July 2021, your data will be destroyed and not used for the purpose of this research. You don’t have to give a reason for your withdrawal and your medical care and legal rights will not be affected. After the data has been analysed (July 2021) it will be difficult to separate your data from that of other participants.

**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 interviews will be anonymised and any identifiable details 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.

All emails to you will always be sent via the researcher’s official University of Southampton email account. It is important to remember that email accounts can be compromised. We would therefore advise you not to include any personal information in the body of your email. Once the study is complete, you could also delete your emails with the researcher, so no one else can access this information. The forms and questionnaires you fill are created on secure platforms and it is safe to include personal information in these forms. The information from the forms and questionnaires will be stored in password protected documents in secure folders at the University of Southampton and be accessible only to members of the research team.

The audio recordings will be deleted once they have been typed up and all identifying details have been removed. Personal and anonymised data will be stored or accessed by the research team for 2 years and the data will be securely archived at the University of Southampton for 10 years after the study has ended.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring or audit purposes 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.

**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).

**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).