

University of Manchester Research Participant Information Sheet

Title of Research

Involving adults with severe ME/CFS symptoms in developing a NICE guideline on Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management

You are being invited to take part in a research study to explore the views and needs of patients with severe ME/CFS. This project has been commissioned by the National Institute of Health and Care Excellence (NICE). 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?**

The project is being led by Dr. Keith Geraghty, working with colleagues at the University of Manchester Centre for Primary Care.

➤ **What is the purpose of the research?**

The purpose of the study is to explore the needs of patients with severe ME/CFS. Our wish is to better understand the needs and views of patients with severe ME/CFS presentations and to provide NICE with up-to-date information that might help inform the NICE Guideline Committee as they undertake a review of treatment guidelines for this illness. We plan to recruit a selection of patients, in the time period available to us between October 2019 and November 2019 and to write up a report based on our findings that we will pass to NICE at the end of the project.

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

We also hope to publish a research paper from this project.

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

This project has been reviewed by The University of Manchester Research Ethics Committee (September 2019).

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

What would my involvement be?

➤ What would I be asked to do if I took part?

We are asking people with severe ME/CFS to take part in this study. This involves completing a short online survey. We anticipate that the survey will take you between 30 minutes to 1 hour to complete, however you may not want to do this in one sitting if it makes you feel unwell or aggravates your symptoms. We advise that you pace yourself and complete the survey in your own time. A family member or carer can assist you if needed. The survey will ask you a range of short questions about your illness, your care needs and your experiences of accessing health and social care.

➤ Will I be compensated for taking part?

We are not offering any compensation for taking part as we do not have funding for this. We greatly appreciate your participation in this project.

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

It is up to you whether or not you decide to take part. If you decide to take part, you will be given this information sheet and a consent form to sign (confirm you agree). You can contact us at any stage if you do not wish to take part or if you wish to withdraw from the study. 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 name
- Age
- sex
- How long you have suffered from ME/CFS
- Other less identifiable information

➤ Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with 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. 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:

Important note: UoM requires identifiable data to be anonymised as soon as the objectives of the project allow. The standard retention period for data once anonymised is 5 years unless funders or regulators have specified longer retention requirements.

Only the study team at The University of Manchester will have access to your personal information, but 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. Only the research team will have access to the key that links this ID number to your personal information. Your consent form and contact details will be retained for 5 years (electronic copies will be securely kept at our University data storage facility and hardcopies will be kept in a locked office within our faculty building. Data may be transferred electronically between researchers on and off-site, however only data that has removed personal identifiers will be shared in this way. All data sharing will involve password protected files.

We have a duty of care to participants which includes breaking confidentiality if you disclose information that indicates that your health and well-being are at serious risk. In such cases we might share the relevant information with qualified medical and or social care professionals.

Data Sharing Requests from Other Parties (other than our research team):

When you agree to take part in a research study, the information you provide may be liable to data sharing requests from other researchers and interested parties. We will only share data that does not include any personal identifiers (such as your name or contact details). We will only share data if requesters can guarantee data security, with a plan for data storage. We will only share data if you have given consent to do so.

Opt-Out Reminder: You are able to opt out of this study within 2 weeks after you complete the online survey. After this time your data may form part of a report or dataset that cannot be changed. You can have your personal details deleted at anytime. We will retain your contact details on a secure University server/storage facility in order to be able to remove you in future, if you so wish. This data will be kept for 5 years, before being destroyed/deleted permanently.

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?

You may contact any member of our research team at any time if you have a complaint or concern about your participation in this study or any other matter relating to this study. Email contact details are provided below.

CONTACT DETAILS FOR COMPLAINTS:

Dr. KEITH GERAGHTY or **Prof. ANEEZ ESMAIL** (Project principal investigator and Project lead)

Email: keith.geraghty@manchester.ac.uk

Email: Aneez.esmail@manchester.ac.uk

Tel: +44(0) 161 306 3990

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 Governance and Integrity Officer, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:

research.complaints@manchester.ac.uk or by telephoning 0161 275 2674.

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)

Dr. KEITH GERAGHTY or **Prof. ANEEZ ESMAIL** (Project principal investigator and Project lead)

Email: keith.geraghty@manchester.ac.uk

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Tel: +44(0) 161 306 3990