Developing a clinical assessment toolkit for people with ME/CFS and clinical services

Participant Information Sheet

You are being invited to take part in a research study to develop a clinical assessment toolkit for people with myalgic encephalomyelitis (ME) (also known as chronic fatigue syndrome (CFS) and ME/CFS specialist clinical services. Before you decide whether to take part, it is important that you understand why the research is being conducted and what it will involve. Please read this information before deciding whether to take part and discuss it with others if you wish. If anything is unclear or if you would like more information, please ask. My contact details are at the end of this document.

Who will conduct the research?

The project is led by Prof Sarah Tyson from the School of Health Sciences, University of Manchester, who has ME herself. Dr Peter Gladwell (North Bristol NHS Foundation Trust and BACME), Dr Keith Geraghty (University of Manchester), Dr Mike Horton (University of Leeds) and Russell Fleming (ME Association) are also on the research team.

What is the purpose of the research?

Our aim is to co-produce a series of patient reported outcome measures (PROMs) with people with ME/CFS (PwME/CFS) and clinicians in ME/CFS specialist services. This will help PwME/CFS and services identify, understand and quantify people's symptoms and disabilities; support goal setting and treatment planning, and monitor changes.

Working with the PwME/CFS's and clinicians' advisory groups we have produced draft versions of the PROMs, which have a questionnaire format. They measure people's symptoms; activity/ disability levels; post-exertional malaise; mood; clinical needs, and satisfaction with services (also known as a patient experience measure or PREM).

We have tried to make sure the PROMs capture the issues that are important to PwME/CFS and the forms are easy to complete, and to use in clinical practice (ie it fits in with other clinical processes and systems). We now need a large number of PwME/CFS to fill in the questionnaires (online) so we can complete a statistical analysis. This is called Rasch analysis and will enable us to remove any overlap between questions, remove any questions that don’t produce good quality information, and/or revise the wording of any questions which are unclear.

We will also explore how we can produce sub-scales so PwME/CFS do not have complete all of the questionnaires, all of the time. For example, we may be able to pull out a subset of questions which are most relevant for people with severe ME. Alternatively, there may be sub-scales for specific problems such as pain, sleep problems or autonomic dysfunction.

Am I suitable to take part? We are asking adults who have been diagnosed with ME/CFS or long covid in the UK to take part.

What will I be asked to do if I took part? You will be asked to complete the PROM questionnaires online. To minimise the energy demands, we send you one PROM at a time over several months. After you have completed the PROM, we will send you a reminder a couple of weeks later to ask you to repeat it. This is so we can test how the answers change over time. This helps us understand how symptom fluctuate and how well the PROM picks up any changes.

As well as the PROM, there will also be some questions about you. For example, your gender, age, how long you have had ME, and whether you have recieved care from a ME services etc.

We have worked with our PwME/CFS Advisory Group to minimise the demands of completing the surveys. You can take as long as you need to complete them. You can complete as many of the PROMs as you wish/ are able to.

If you need help from another person to complete the survey(s), or someone to complete the survey(s) on your behalf, that is fine.

If you prefer to use paper copy, or complete the survey by phone, that is fine too. Just contact Sarah On sarah.tyson@manchester.ac.uk to arrange.

You will not benefit directly from completing the questionnaires, but the results will help PwME/CFS and ME/CFS specialist services understand the issues that are important to PwME/CFS using measurement tools that are easy to use (for both PwME/CFS and the services) in the future.

There aren’t really any risks of taking part in the study. Of course, you should pace yourself carefully while completing the survey. Take as many rests/ pauses as you need.

We understand that living with ME/CFS can be difficult. If you like to know more about ME/CFS symptoms, you may find information from the ME Association helpful (in the 'What is ME?' and 'information' sections of the website The ME Association - The ME Association).

There is also a free helpline called ME Connect ME Connect - The ME Association if you would like to talk to someone directly, and information about local ME Support groups Local Support Groups - The ME Association

Will I be compensated for taking part? Unfortunately, compensation is not available for your time in completing the survey.

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. You can stop at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove responses as we will not be able to identify your specific data. This does not affect your data protection rights.

Data Protection and Confidentiality The only information we will collect that could identify you is your email address. All the data we collect (ie your responses to the survey questions) is confidential and only the research team will have access to any individual responses.

The information you provide (but not your email address) may be shared with researchers running other studies that share the same values. This is to support additional research into ME/CFS and is in accordance with The University of Manchester's Research Privacy Notice**.**

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. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

Will the outcomes of the research be published? We will make the PROMs freely available via the ME Association website. The results will be publicised via the ME Association and social media and by other ME charities. We will publish the findings in academic journals and scientific conferences.

Who has reviewed the research project? The University of Manchester Proportionate Research Ethics Committee

Who is funding the research project? The ME Association

What if I have a complaint? If you have a complaint, please contact Sarah in the first instance on Sarah.Tyson@manchester.ac.uk.

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 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 then please contact Sarah Tyson Sarah.tyson@manchester.ac.uk