HERITAGE Research: Understanding Long Covid (LC) and Myalgic Encephalomyelitis (ME/CFS): Improving Care After Infection

Patient Information Sheet: Clinic Observation

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Research on Long COVID and ME/CFS

Thank you for expressing an interest in the HERITAGE study. We would like to invite you to take part in this research project and are providing this information sheet so that you can learn more about the study and what participation would involve.

HERITAGE is a UK-wide health services research study funded by the National Institute for Health and Care Research (NIHR). The study aims to improve understanding of the experiences of people living with Long COVID and Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), and to help inform the future design and delivery of NHS services for these conditions. The study has been reviewed and approved by the London-Surrey Research Ethics Committee.

We are inviting people with Long COVID and/or ME/CFS, carers, and healthcare professionals to take part in different parts of the study. Please take time to read the following information carefully and discuss it with others if you wish. If you decide to take part or have any questions, please contact the research team using the details provided at the end of this information sheet.

Why are we doing this research?

- People with Long COVID and/or ME/CFS want to have better quality of life and better quality of healthcare.
- The information you provide will help researchers understand the impact of long COVID and ME/CFS on people's lives and how the NHS cares for them.
- This research aims to help the NHS design better healthcare for people living with Long COVID and/or ME/CFS.

How are people with Long COVID and/or ME/CFS involved?

- People with Long COVID and/or ME/CFS are taking part in this research, by providing information about their health and their health care.
- People with these conditions have been involved in the project from the very start.
- They helped design the research and get funding.
- They helped write this document and will be involved in all stages of the research.
- We are also involving staff who provide support and health care to patients with Long COVID and/or ME/CFS.

What will I be doing?

- As part of the HERITAGE study, a researcher from the University of Leicester will be spending approximately a week at four UK-based project sites.

- The purpose of this is to observe how LC and ME/CFS services are running.
- We are particularly interested in patient-clinician interaction, service delivery and referral processes.
- As you are a patient at one of our project sites, we would like to ask you if our researcher can observe you whilst you are in your Long COVID and/or ME/CFS appointment.
- The researcher will take notes about the care and support you receive and how the service works.
- The researcher will not get involved in the care and support you receive in any way and will not identify you in their notes.
- You can ask for the researcher to leave at any point.

You can take part in HERITAGE observations if you:

- Are aged 18 or over
- Are able to provide informed consent
- Are able to communicate in English
- If you are currently using, have been referred to, or recently were discharged from existing NHS specialist LC/ME/CFS services at HERITAGE study sites (Leeds, Leicester, Hertfordshire, Cornwall).
- For those living with LC, have had LC symptoms for >2 years (persistent LC)

Do I need to prepare for the Observation

- You do not have to prepare for the Observation.

Can I have someone with me?

- You are welcome to have someone with you for support.
- We will ask this person to read this document and to consent to take part as well. #

Do I have to take part?

- No, taking part in this research is up to you.
- You can stop at any time, without giving a reason.
- If you don't take part, or you decide to stop, this won't affect your care by the NHS or any health professional, now or in the future.

What should I consider?

- The main thing to consider is whether you are comfortable with a member of the research team observing your appointment.
- Remember, you do not need to take part, particularly if you think your health might suffer.

Will I benefit from taking part?

There are no direct benefits to you from taking part, but we hope that it will improve the care of people with Long COVID and/or ME/CFS in the future.

Will I get paid for taking part?

No, there is no payment for taking part in this research.

How do I agree to take part?

- We have provided you with a research consent form along with this information sheet.
- If you decide to take part and your appointment is in person, we will invite you to complete a paper consent form.
- If your appointment is online, we can email a consent form for you to sign and return, or we will invite you to give your verbal consent (which we will audio record).

Can I change my mind later?

Yes, you can change your mind and stop your participation in HERITAGE at any time, without giving a reason. If you choose to leave the study, we will ask you what you want to do with the information you have already given us. You will have up to two weeks from the date of your participation to withdraw your data. You can email us to let us know and we will destroy all of your associated data immediately. After two weeks, it may no longer be possible to destroy your data as it may have been integrated into the broader dataset. More details on this can be found on the research website (https://heritage.leeds.ac.uk/).

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Contact details

People will use this information to do the research or to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code (pseudonym) instead.

University of Leeds is the sponsor of this research.

The University of Leicester will be responsible for looking after your identifiable information, and the University of Leeds will be responsible for looking after your anonymised information. We will share your information related to this research project with the following types of organisations:

- The University of Leeds (research sponsor)
- The University of Oxford (research partner)
- The University of Leicester (research partner)
- ELAROS 24/7 Ltd (approved data processor providing the app and secure platform)
- NHS staff at participating clinics (only where relevant to your care and to the study)
- University of Leicester-approved transcription service

We will keep all information about you safe and secure by:

- using secure systems to store your data
- limiting access only to people who need it
- replacing your name and contact details with a study code (pseudonym) wherever possible
- keeping audit trails to show who has accessed your data and why

International transfers
Your data will not be shared outside the UK.

How will we use information about you after the study ends?
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of five years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?
You can find out more about how we use your information:

- our website www.heritage.leeds.ac.uk
- by asking one of the research team
- by sending an email to Heritage@leeds.ac.uk
- by sending an email to the University of Leeds Data Protection Officer: dpo@leeds.ac.uk
- by ringing us on 0113 243 1751
- HRA link: www.hra.nhs.uk/patientdataandresearch.

How will information from my observation be included in project reports?

With consent, we will include some participants' anonymised quotes in our publications. You will not be named or identifiable in any of our publication activities.

How will I be safeguarded during this research?

In the rare event that you disclose information which indicates that you or someone else may be at risk of harm, we may need to take appropriate action to ensure safety. This may include breaching confidentiality and sharing relevant information with appropriate health or social care professionals or safeguarding services.

Where possible, we would seek to discuss this with you before taking any action. However, if there is a serious concern or an immediate risk of harm, we may need to act without your consent.

If we have concerns about your wellbeing or care needs during the study that do not indicate immediate risk, we may signpost you to relevant support services or other sources of help.

Who is conducting this research?

- The HERITAGE research is funded by the National Institute for Health and Care Research.
- The Chief Investigator is Professor Manoj Sivan from the University of Leeds.
- Dr Gemma Hughes is leading on the qualitative work including observations from the University of Leicester.
- Only approved researchers from the University of Leeds, University of Oxford, University of Leicester and NHS staff will have access to the information you give us.
- This study has been reviewed and approved by the London – Surrey Research Ethics Committee.

How do I ask questions?

For questions about the observations, you can contact Dr Gemma Hughes on gemma.hughes@leicester.ac.uk 0116 373 6741 or Dr Jo Alexander on joanne.alexander@leicester.ac.uk 0116 252 2673

For questions about the research, you can contact the Chief Investigator. He will arrange for someone to get back to you quickly.

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If I have worries or complaints during the research, what I do?

If you have any worries or complaints about this research, please contact the University of Leeds Research Governance office:
Email: governance-ethics@leeds.ac.uk

If you are worried about your care, the Patient Advice and Liaison Service can be contacted via the NHS Choices website:
Web: https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/
Phone: 0113 206 6261

If you are worried about the use of your information, please contact the University of Leeds Data Protection Officer:
Email: dpo@leeds.ac.uk
Phone: 0113 243 1751

If you are unhappy with the response from the University of Leeds Data Protection Officer, you can contact the Information Commissioner's Office (ICO):
Web: https://ico.org.uk/make-a-complaint/
Phone: 0303 123 1113

More details about this process are available on the research website https://heritage.leeds.ac.uk/ This includes a plain English Patient Data and Research leaflet, from the NHS Health Research Authority which explains how health and care researchers use information from patients, service users and other participants in research.

Thank you for considering taking part in HERITAGE