Chief Investigator – Dr Nicola Baker (Clague-Baker)
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Study title: A pilot study to identify the feasibility for a definitive study that will investigate the effectiveness of pacing with a heart rate monitor for people with Myalgic Encephalomyelitis and long COVID.

INFORMATION LEAFLET

You are invited to take part in a research study. Before you decide whether or not to take part, we would like to explain why the study is being done and what it will involve. Please read the following information and ask us if anything is not clear, or if you would like more information, using one of the contact options listed above.

What is the purpose of this study?

The aim of this study is to conduct a pilot study to identify the acceptability, effect sizes, rates of recruitment and retention and outcome measures for a definitive study that will investigate the effectiveness of pacing with a heart rate monitor for people with Myalgic Encephalomyelitis (ME) and long COVID. There is growing anecdotal evidence that pacing with a heart rate monitor is being utilised as a management strategy for people with ME and Long COVID. However, there is a lack of formal studies in this area.

Why have I been invited?

You have been invited because you have ME or Long COVID and could use pacing with a heart rate monitor and we believe, therefore, that you may be eligible to participate in the study.

What will happen if I decide to take part?

Please read this information sheet. You have already spoken to the researcher about the trial and you fit the inclusion criteria for the trial. However, we would like you to read this information sheet carefully to make sure you want to take part. If you decide after reading the information sheet, that you don't want to take part, please contact Dr Nicola Clague-Baker – nicola.baker@liverpool.ac.uk. If however, you would like to take part in the study, the researchers have already arranged to come and see you so you do not need to contact them again.

On the day of the assessment (arranged to fit into your schedule), you will be asked to fill out the consent form and three questionnaires (which can be completed in your own time if it is too much on the day of the assessment). Your medical history and medications will also need to be recorded but you can send that through separately if it is too much to do it all in one session. You will then lie for 5 mins, sit for 5 mins and stand for up to 10 mins and your blood pressure (BP) (see BP monitor), heart rate (HR) and oxygen levels (see pulse oximeter) will be taken before and after each activity. You will then be asked to record your BP, HR and oxygen levels for a week before the start of the trial and also record any post-exertional malaise you have during that week and the activities you do during that week. Some of you will also wear a heart rate variability monitor during that week (see HRV monitor) or an accelerometer (see accelerometer) or take lactic acid levels for a week (see lactic acid monitor).

HRV monitor

Pulse oximeter

BP Monitor

Accelerometer

Lactic acid monitor

After these measures you will be randomised into Group 1, Group 2 or Group 3. Groups 1 and 2 will receive a heart rate monitor to wear for 8 weeks and group 3 will not receive a heart rate monitor. All groups will be able to attend online pacing sessions every week for four weeks with Professor Todd Davenport.

At the end of the 8 weeks the researcher will return and redo the BP, HR and oxygen levels in lying, sitting and standing and will ask you to do this again for a week as well as wearing a HRV monitor or accelerometer or take lactic acid readings as you did in the first week. You will also again be asked to record your activity levels and any post-exertional malaise you have during that week. At the end of that week the researchers will return and take all the equipment.

Finally, you will be asked to take part in an online interviews to discuss your experiences of using HR monitors if you have used them. If you haven't used the monitors you will be asked your thoughts on taking part without using the hr monitor and your thoughts on the pacing advice. The interviews will be audio recorded. There will no identifiable personal data collected during the recordings, and all data will be securely stored in a password-protected University of Liverpool computer. The

recording will be transcribed using the online transcribing function on zoom. The written transcripts will be stored for the recommended ten years but the recordings will be deleted once the transcription has been checked. We will ask you if you would like to read the transcript of your recording to check what you said and to add anything else after the focus group.

Do I have to take part?

Only if you want to.

Participation is voluntary, you may refuse to participate. You do not need to tell us why you do not want to take part. If you choose not to participate, your decision will in no way affect your future healthcare.

What are the possible disadvantages and risks of taking part?

During the assessment you will only be asked to complete activities that you do as part of everyday life. You will not be asked to exercise. It is recognised that due to Covid19 it is extremely important to thoroughly clean and sterilise the equipment. We will ensure the appropriate medical cleaning procedures are used for all the equipment you will be using. Due to the requirements of Covid19 we will also ensure that all researchers wear a mask while visiting you as required by the Department of Health and the Chartered Society of Physiotherapy.

Are there any benefits of taking part in this study?

There are no direct benefits to taking part. However, the aim of the study is to explore the use of pacing with a heart rate monitor so your answers might help people with ME and Long COVID in the future. In addition, this will inform a larger study investigating the effect of pacing with a heart rate monitor for people with ME and Long COVID.

Are there any costs involved?

No

Withdrawal options and your rights

Your participation in this study is entirely voluntary and refusal will not affect any health care. You are free to withdraw at anytime without giving a reason, without your medical care and legal rights being affected.

Data protection & confidentiality

The study complies with Government & the University of Liverpool's data protection policy as well as the University's research ethics requirements. Information to identify you are: your gender and age. All information provided will be kept strictly confidential. The information from the study will be kept in a password-protected university computer that only the research team will have access to. The data from this study will be retained for ten years. Information will be kept on the University of Liverpool secure databases and will not be stored on the cloud.

What if things go wrong? Who to complain to.

If you have a concern about any aspect of this study, you should ask to speak with the researchers, who will do their best to answer your questions, or contact the Principal Investigator, Dr Nicola Clague-Baker (Nicola.Baker@liverpool.ac.uk), Tel. 07912950671. If you are not satisfied with the response you receive from the investigator, then there is a formal university complaints procedure. This involves contacting the Research Ethics and Integrity Office at ethics@liv.ac.uk. When contacting the Research Ethics and Integrity Office, please provide details of the name or description of the study (so that it can be identified), the researcher(s) involved, and the details of the complaint you wish to make.

The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.

What will happen with the results of the study?

The results will be analysed and discussed by the research group. The results of the study may also be presented in research reports, scientific conferences and/or journals and be made available to people with ME via the PhysiosforME website. The results may act as baseline information that guides future research by other investigators.

Who has reviewed this study?

All research involving human subjects must receive approval from the University of Liverpool Ethics Committee before it can go ahead. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that the study carries no more than minimal risk, and that you have been given sufficient information on which to make an informed decision.

Who is organising and funding the research?

This study is being conducted by a team of experts at the University of Liverpool, PhysioforME, the facebook group: ME/CFS – Pacing with a Heart rate monitor #2, Professor Todd Davenport and the Visible team particularly Harry Leeming.

Further information/Key contact details

Principal Investigator: Dr Nicola Clague-Baker at Nicola.Baker@liverpool.ac.uk

Thank you.