ISRCTN10554129 https://doi.org/10.1186/ISRCTN10554129

Pacing with a heart rate monitor for people with myalgic encephalomyelitis (ME) and long COVID

Submission date
04/08/2022

Recruitment status
No longer recruiting

Registration date
26/10/2022

Overall study status
Completed

Last Edited
04/04/2023

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Myalgic encephalomyelitis, also called chronic fatigue syndrome or ME/CFS, is a long-term condition with a wide range of symptoms. The most common symptom is extreme tiredness. For some people, coronavirus (COVID-19) can cause symptoms that last weeks or months after the infection has gone. This is sometimes called post-COVID-19 syndrome or "long COVID"
The aim of this study is to conduct a pilot study to identify the acceptability, sample 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.

Who can participate?
1. The International Consensus Criteria for Myalgic Encephalomyelitis will be used for people with ME and the presence of post-exertional malaise will be part of the inclusion criteria for people with long COVID.
2. People with different severities of ME will be recruited ranging from mild to moderate ME

What does the study involve? (for participants)
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).
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 interview 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.

What are the possible benefits and risks of participating?
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.
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.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
March 2022 to June 2023

Who is funding the study?
1. The ME Association (UK)
2. Visible (UK)
3. Stockport ME support group (UK)

Who is the main contact?
Dr Nicola Clague-Baker
Nicola.Baker@liverpool.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Nicola Clague-Baker

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
11373

Study information

Scientific 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

Study objectives
The aim of this study is to conduct a pilot study to identify the acceptability, sample 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/07/2022, University of Liverpool Ethics committee (Brownlow Hill, Liverpool, L69 3GB, UK; +44 151 794 8290; ethics@liverpool.ac.uk), ref: 11373

Study design
Observational feasibility pilot study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
People with myalgic encephalomyelitis and long COVID using pacing with a heart rate monitor

Interventions
On the day of the assessment (arranged to fit into the schedule of the participant), they will be asked to fill out the consent form and three questionnaires (which can be completed in their own time if it is too much on the day of the assessment). The medical history and medications will also need to be recorded but they can send that through separately if it is too much to do it all in one session. They will then lie for 5 mins, sit for 5 mins and stand for up to 10 mins and their blood pressure (BP), heart rate (HR) and oxygen levels will be taken before and after each activity. They will then be asked to record their BP, HR and oxygen levels for a week before the start of the trial and also record any post-exertional malaise they have during that week and the activities they do during that week. Some of them will also wear a heart rate variability monitor during that week or an accelerometer or take lactic acid levels for a week.
After these measures, they 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 them to do this again for a week as well as wearing an HRV monitor or accelerometer or take lactic acid readings as they did in the first week. They will also again be asked to record their activity levels and any post-exertional malaise they have during that week. At the end of that week, the researchers will return and take all the equipment.
Finally, they will be asked to take part in an online interview to discuss their experiences of using HR monitors if they have used them. If they haven't used the monitors they will be asked their thoughts on taking part without using the hr monitor and their thoughts on the pacing advice. The interviews will be audio recorded. There will be 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 them if they would like to read the transcript of their recording to check what they said and to add anything else after the focus group.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)

Heart rate monitor

Primary outcome measure
Activity levels measured either with a HRV monitor (firstbeat) or an actigraph accelerometer at baseline and at 8 weeks

Secondary outcome measures
Measured at baseline and at 8 weeks:
1. Blood pressure measured with a sphygmomanometer
2. Lactic acid measured with a lactic acid monitor - Lactate Pro2
3. Heart rate and oxygen levels measured with a pulse oximeter
4. Good day/Bad day questionnaire
5. Depaul SQ - SF questionnaire (ME and CFS symptomatology)
6. PROMIS SF - Physical function questionnaire
7. PROMIS SF - Fatigue questionnaire

Overall study start date
09/03/2022

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. The International Consensus Criteria for Myalgic Encephalomyelitis will be used for people with ME and the presence of post-exertional malaise (PEM) will be part of the inclusion criteria for people with long COVID
2. People with different severities of ME will be recruited ranging from mild to moderate ME

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
47

Key exclusion criteria
1. People with severe and very severe ME
2. People who are already using pacing with a heart rate monitor
3. People with long COVID without PEM

Date of first enrolment
05/09/2022

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
PO Box 147
Liverpool
United Kingdom
L69 3BX

Sponsor information

Organisation
University of Liverpool

Sponsor details
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Sponsor type
University/education

Website
http://www.liv.ac.uk/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
The ME Association

Results and Publications

Publication and dissemination plan
Two publications will be produced - one related to the feasibility of the study and one related to the qualitative data

Intention to publish date
30/12/2023

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	09/06/2022	10/08/2022	No	Yes