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Is it feasible to take physiological measurements for people with myalgic encephalomyelitis (ME) in their own homes?

Submission date
01/08/2022

Recruitment status
No longer recruiting

Registration date
18/08/2022

Overall study status
Completed

Last Edited
18/08/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims:
People with myalgic encephalomyelitis (PwME) have abnormally low levels of VO_2 maximum scores measured with maximum cardiopulmonary exercise tests. They reach their anaerobic thresholds quicker and are slower to recover than healthy controls. They also produce greater levels of lactic acid when exercising compared to healthy people and have an impaired capacity to recover from acidosis. This means that at maximum exercise capacity PwME have abnormal aerobic metabolism, but it is not clear if this is the case at normal levels of activities. PwME are reluctant to undertake maximal exercise testing due to post-exertional malaise (PEM) so a test that might identify abnormal metabolism at normal levels of activity may be beneficial. In addition, this study might help to validate the use of heart rate monitoring as an intervention to pace activity and prevent PEM. The aims of this feasibility study therefore will be to explore the acceptability and feasibility of the testing protocol for people with different levels of ME severity, and to assess recruitment rates, the choice of outcome measures, and monitor adverse events during testing.

Who can participants?
People aged 18 years and over with different severities of ME will be recruited ranging from mild to very severe ME. Recruitment will be via online promotion. Healthy volunteers are also recruited.

What does the study involve?
Once informed consent has been obtained, the researchers will attempt to measure the participants' physiological responses during everyday activities completed in the their home environment. They will ask the participant what activities they feel they could do/would like to do while wearing a portable VO_2 system and a heart rate variability monitor. Activities could include getting out of bed, washing and dressing, making breakfast, making a bed, washing up and going up and down stairs. In addition, lactic acid levels, blood pressure, heart rate and oxygen saturations will be taken regularly throughout the testing. They will continue to wear the heart rate variability monitor and accelerometer for up to 6 days and where possible their blood pressure, heart rate, oxygen levels and lactic acid levels will be monitored daily. They will

also be asked to fill out a fatigue severity scale and a diary for the week where they will document the severity of the symptoms of any post-exertional malaise (fatigue, pain, cognitive function etc). The participants will give feedback about the acceptability and feasibility of the procedure and outcome measures; recruitment rates and adverse events will be monitored throughout.

What are the possible benefits and risks of participating?
There may be no benefits to taking part. However, the aim of the study is to help determine whether a larger study is feasible. Participation will therefore help people with ME in the future. Participants will be able determine their physiological responses to everyday activities. These tests are regularly used for patients who have cardiac or respiratory disease without complications. It is therefore expected that they should be tolerated by people with ME. Participants will only be asked to complete activities that they do as part of everyday life. They will not be asked to exercise.
It is recognised that due to COVID-19 it is extremely important to thoroughly clean and sterilise the equipment. The researchers will ensure the appropriate medical cleaning procedures are used for all of the equipment. They will also ensure that there are 7 days between each test so that the equipment is thoroughly clean before the next use. Due to the requirements of COVID-19 we will also ensure that all researchers wear Personal Protective Equipment as required by the Department of Health and the Chartered Society of Physiotherapy.

Where is the study run from?
1. University of Leicester (UK)
2. University of Manchester (UK)
3. Oxford Brookes University (UK)

When is the study starting and how long is it expected to run for?
May 2021 to October 2021

Who is funding the study?
The ME Association (UK)

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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
RM62G1105

Study information

Scientific Title
Feasibility of investigating oxygen consumption (VO2), heart rate, blood pressure, lactic acid levels, and activity levels of people with myalgic encephalomyelitis during normal daily activities

Study objectives
The aim of this study is to investigate whether it is feasible to take physiological measures of people with myalgic encephalomyelitis in their own homes to determine if these measures are normal during everyday activities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/12/2020, University of Leicester Medicine and Biological Sciences Research Ethics Committee (University Road, Leicester, LE1 7RH; no telephone contact provided; cjt14@le.ac.uk), ref: 28139

Primary study design
Observational

Study design
Observational case series feasibility study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Myalgic encephalomyelitis

Interventions
Following obtaining informed consent, due to the energy limitations of the participants, the information sheet and Fatigue Severity scale (FSS) will be sent ahead of time so the participants can read in their own time. Since taking medication varies considerably between individuals, the participants will be asked to follow their normal regime in relation to medication and other therapies. They will be asked to avoid eating and asked to only drink water before taking part in the study. On the day of testing, once informed consent is obtained, a Fatigue Severity Scale was completed and physiological responses during everyday activities performed in a standard order will then be measured in the participants' home environments. The participant will be asked what activities they feel they could do/would like to do, and the running order finalized for that individual, while wearing a portable metabolic system (PMS)(CORTEX), a heart rate variability

(HRV) monitor (Firstbeat) and while their blood pressure (BP), heart rate (HR), oxygen saturation (O_2 sat) and lactic acid (LA) (COSMED) will be taken. LA will be taken once at the beginning and once at the end of all the activities. BP, HR, O_2 sats will be taken before and after lying for 5 minutes, before and after sitting for 5 minutes, before and after standing for up to 5 minutes, before and after 5 minutes in the bathroom (not all participants), before and after going down the stairs (not all participants), before and after 5 minutes in the kitchen (not all participants), before and after going upstairs (not all participants) and before and after 5 minutes of cognitive activity. The HRV and PMS will be continually collecting data throughout all activities.

At the end of the testing procedure, the participants will remove the mask and the metabolic system will stop recording data. However, the participants will continue to wear the HRV and accelerometer for up to six additional days. The participants will be left with instructions to continue to record their BP, HR, O_2 sats and lactic acid every morning and evening for the next 5 /6 days. They will also be asked to record their activity and any post-exertional malaise (PEM) over that time period. If they felt they had PEM they will be asked to take their HR, BP, O_2 sats and lactic acid during the period of PEM. Finally, they will be asked to record the quality and quantity of sleep each night.

After the 6 days of data collection, the researcher will return to collect the equipment and gather feedback about the process. The participants will give feedback about the acceptability, that is, a) whether they were able to wear and tolerate the equipment, b) the response to the metabolic testing on the same day and following days, c) the cognitive effort of completing the tasks and d) any additional information they want to add to inform the process. Finally, they will be asked to fill out an FSS at the end of the testing. The data from the PMS, HRV, BP, HR, lactic acid, and O_2 sats will be collated.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
VO_2 and respiratory exchange ratio measured using a portable metabolic system at a single timepoint

Key secondary outcome(s)
1. Heart rate variability using a firstbeat device measured on the day of testing and for up to 5/6 days afterwards
2. Lactic acid using a COSMED device - lactate pro 2 measured on the day of testing and for up to 5/6 days afterwards
3. BP, HR, O_2 saturations, Blood Pressure measured using a digital sphygmomanometer, Heart Rate and Oxygen saturations measured using a pulse oximeter, on the day of testing and for up to 5/6 days afterwards
4. Accelerometry using an actigraph device which measures activity levels for up to 5/6 days afterwards

Completion date
26/10/2021

Eligibility

Key inclusion criteria
People with myalgic encephalomyelitis and healthy controls

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Below the age of 18 years
2. People with very severe ME

Date of first enrolment
04/05/2021

Date of final enrolment
26/09/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leicester
Leicester University
University Road
Leicester
United Kingdom
LE1 7RH

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
ME Association

Alternative Name(s)
Myalgic Encephalopathy Association, Myalgic Encephalomyelitis Association, The ME Association, MEA

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

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 3	31/08/2021	05/08/2022	No	Yes