

# A study to identify if it is possible to measure lactate in health participants and people with myalgic encephalomyelitis during everyday activity

<b>Submission date</b> 12/04/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/04/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/12/2024	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Myalgic encephalomyelitis (ME) is a “complex, acquired multi-systemic disease with a profound dysfunction/dysregulation of the neurological control system resulting in faulty communication and interaction between the nervous system and major body systems”. Up to 80% of cases of ME are post-viral. Symptoms include fatigue, post-exertional malaise (PEM), difficulties with thinking and memory (cognitive), pain and many more symptoms. The defining feature of ME is PEM after physical, cognitive, emotional and social activity. There are over 30 symptoms of PEM including brain fog, muscle pain, fatigue, flu-like symptoms and difficulty sleeping. There is a delay between a triggering activity and the onset of PEM usually 2-7 days after but this may vary. Symptoms usually last days to weeks, but again can vary. It is unclear what causes PEM. One area of research using cardiopulmonary exercise testing (CPET), exercising to the maximum on a bike or treadmill, has shown that people with ME switch from aerobic to anaerobic metabolism too soon leading to an increased production of lactate as a by-product of anaerobic metabolism. People with ME have raised lactic acid during these CPET tests and this happens sooner than healthy comparators. However, people with ME say that they feel that they have a buildup of lactate during everyday activity. No research has explored this in healthy people or in people with ME. The aim is to conduct a pilot study to identify the feasibility of measuring the lactate levels of people with ME and healthy volunteers.

### Who can participate?

People with ME, using the ICC diagnostic criteria (excluding the very severe), and 20 healthy volunteers (matched with the people with ME by age and sex)

### What does the study involve?

The study involves doing a 10-minute stand test, collecting lactate levels over 3 days (7 on day 1, 4 on day 2 and 7 on day 3), and filling out three questionnaires and activity and symptom diaries over the 3 days of testing. People with ME will be tested in their own homes and healthy participants either in their own homes or at the University of Liverpool.

What are the possible benefits and risks of participating?

Repeated use of a lactic acid monitor over 2 non-consecutive days can cause discomfort in the fingertips used to test. Carrying out the 10-minute stand test for people with orthostatic intolerance (OI) can cause dizziness and there is a risk of falls. Therefore, this test will be carried out by a qualified physiotherapist who has conducted this test with many people with OI and has been qualified for over 30 years. If the participant demonstrates any abnormalities with this test she will stop the test and monitor the participant until normal values are achieved. Any abnormalities will be recorded and reported to their GP. For people with ME, taking part will identify if they have abnormal levels of lactic acid compared to a healthy person their age and gender. For everyone, this is important information that could be used to help understand the physiological differences between people with ME and those without. Participants will be helping people with ME in the future to determine differences they may have and can help clinicians learn if there is a way to help people with ME. Both groups will be entered into a draw to receive £50.

Where is the study run from?

The University of Liverpool (UK)

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

January 2024 to December 2024

Who is funding the study?

The ME Association (UK)

Who is the main contact?

Dr Nicola Clague-Baker, [nicola.baker@liverpool.ac.uk](mailto:nicola.baker@liverpool.ac.uk)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Nicola Baker (Clague-Baker)

### ORCID ID

<https://orcid.org/0000-0002-4513-2889>

### Contact details

Physiotherapy Department

University of Liverpool

j128 Johnston Building

The Quadrangle

Brownlow Hill

Liverpool

United Kingdom

L69 3GB

+44 (0)7912950671

[nicola.baker@liverpool.ac.uk](mailto:nicola.baker@liverpool.ac.uk)

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

13358

# Study information

## Scientific Title

A pilot study to identify if it is feasible to measure lactate in health participants and people with myalgic encephalomyelitis during everyday activity

## Study objectives

No hypothesis as it is a feasibility study

The aim is to carry out a pilot study to determine the feasibility of measuring lactate levels of healthy and myalgic encephalomyelitis (ME) participants during everyday activity.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 23/01/2024, Central University Research Ethics Committee, University of Liverpool (Brownlow Hill, Liverpool, L69 3GB, United Kingdom; +44 (0)151 794 8290; ethics@liverpool.ac.uk), ref: 13358

## Study design

Pilot feasibility study

## Primary study design

Observational

## Study type(s)

Other

## Health condition(s) or problem(s) studied

Myalgic encephalomyelitis

## Interventions

Adverts are placed on the ME Association and PhysiosforME website as well as their Facebook pages and Twitter pages with a copy of the participant information sheet. If the participant is interested they are directed to contact the PI Dr Nicola Clague-Baker by email. She will then follow up with an email to arrange a follow-up telephone call or Zoom call. The participant will

then speak to Dr Clague-Baker to explain the study and ask any questions and then see if they fit into the inclusion criteria for the study. If they are suitable a date for the first appointment is arranged.

On the day of the assessment (arranged to fit into the participant's schedule – at home if they are a person with ME and at the university if they are a staff member or a student at the university), they will be asked to fill out the consent form and two questionnaires (which can be completed in their own time if it is too much on the day of the assessment). Their medical history and medications will also 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 minutes and stand for up to 10 minutes and their blood pressure (BP), heart rate (HR) and oxygen levels with a pulse oximeter will be taken before and after each activity.

They will then be asked to record their lactic acid levels seven times on an active day, four times on the second day and seven times on the third day using a lactic acid monitor. Seven times: 1. on waking, 2. 1 hour after breakfast, 3. Before lunch, 4. 1 hour after lunch, 5. Before dinner, 6. 1 hour after dinner, 7. Before going to bed. Four times: 1. on waking, 2. 1 hour after breakfast, 3. 1 hour after lunch, 4. Before going to bed. They will also be asked to record their activity (type and time) and food and drink (type and time). The research assistant will provide the lactic acid monitors for the participants without ME. She will teach them how to use the device and will also provide printed information about the procedure. The PI will provide the lactic acid monitors for the participants with ME. She will teach them how to use the device and will also provide printed information about the procedure. In addition, the researchers will ask them to wear an elasticated belt with an accelerometer or pedometer over the 3 days so that they can record their activity levels. The PI will also be available via phone and email if they have any problems with the devices or the use of the devices. After the 3 days the PI will return to pick up the questionnaires, diary and equipment (if an ME participant) and the research assistant will do the same for the healthy participants.

## **Intervention Type**

Other

## **Primary outcome(s)**

Lactate measured using a Lactate Pro-2 monitor over 3 days, day 1, day 2 and day 3

## **Key secondary outcome(s)**

1. Fatigue and ME symptoms measured with the Depaul Symptom Questionnaire - short form - once on assessment
2. Physical function measured with the PROMIS Short form - fatigue - once on assessment
3. Fatigue measured with the PROMIS Short form - physical function - once on assessment

## **Completion date**

30/12/2024

## **Eligibility**

### **Key inclusion criteria**

The International Consensus Criteria (ICC) will be used for people with ME. People with different severities of ME will be recruited ranging from mild to severe ME.

20 people without ME will be matched to the ME participants based on age and gender. They will be recruited from the University of Liverpool student and staff population and family members and friends of the ME participants.

Additional inclusion criteria:

1. No history of medical conditions
2. Able to give informed consent

### **Participant type(s)**

Healthy volunteer, Service user

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

100 years

### **Sex**

All

### **Total final enrolment**

38

### **Key exclusion criteria**

1. People with very severe ME
2. Unable to take self-measurements with the portable lactic acid monitor

### **Date of first enrolment**

06/02/2024

### **Date of final enrolment**

01/08/2024

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Wales

### **Study participating centre**

**All recruitment is online**

United Kingdom

-

## Sponsor information

### Organisation

University of Liverpool

### ROR

<https://ror.org/04xs57h96>

## 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

Individual participant information will be provided for each participant.

The name and email address of the investigator/body who should be contacted for access to the datasets: Dr Nicola Clague-Baker ([nicola.baker@liverpool.ac.uk](mailto:nicola.baker@liverpool.ac.uk))

The type of data that will be shared: Anonymised results of all the outcome measures.

Dates of availability: December 2024.

Whether consent from participants was required and obtained: Yes, required and obtained.

Comments on data anonymization: Data is anonymised on the first assessment.

**IPD sharing plan summary**

Available on request