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Study title:

Feasibility of investigating oxygen consumption (VO_2), heart rate, blood pressure, lactic acid levels and activity levels of people with Myalgic Encephalomyelitis during normal daily activities.

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?

This aim of this study is to work out the best way to investigate physiological responses during everyday activity in people with Myalgic Encephalomyelitis (PwME). In the United States a test has been developed which can be used to diagnose ME which involves exercise testing over two days. Although this can be very useful, PwME are often reluctant to take the test as it can trigger post-exertional malaise and a 'crash'. We want to know whether a similar test can be developed using everyday activities rather than exercise testing, which is less likely to exacerbate symptoms. The first stage to doing this is to work out whether the equipment used for these types of tests in healthy

people is suitable for people with different levels of ME severity and how the testing methods would need to be adapted.

We also want to work out some details about how to complete a bigger trial such as how many people we can recruit and the best way to contact them.

Why have I been invited?

You have been invited because you have Myalgic Encephalomyelitis and we believe, therefore, that you may be eligible to participate in the study.

What will happen if I decide to take part?

If you decide to take part you will be visited by a researcher in your home who will explain the study and show you the equipment which you will need to wear. If you decide this is still acceptable you will be asked to complete the consent form.

The main part of the study is to wear equipment used to measure your physiological responses while undertaking everyday activities. The activities tested depend on what you are able to do and we will choose them with you on the 1st visit. You will NOT be asked to do anything you don't normally do. You will NOT be asked to do any exercise. However, it is important that they are tested first thing in the morning (or whenever you usually get up) so that we are measuring your response to the tested activities and not anything you may have done earlier in the day. So on the 1st visit, you will choose from a list of 'early morning activities' such as getting out of bed, getting washed and dressed, going downstairs, getting breakfast, washing up, cleaning etc. As we need to do the testing before you get up, we will need to make arrangements for us to be able to enter the house so we can fit the equipment while you are still in bed.

Then you will wear the following equipment while you complete your chosen activities. The main equipment is a portable metabolic analyser which looks like picture 1. It fits securely around your face so that the amount of oxygen you take in and the amount of carbon dioxide you breathe out can be measured. This information is digitally transferred to a laptop. The analyser is lightweight and the straps are stretchy elastic.

At the same time, you will also wear a heart rate monitor which sticks to your chest with two adhesive stickers (see picture 2) and a pulse oximeter (see picture 3) so we can see how your heart rate and oxygen levels change with the activity. We will also check your blood pressure during these activities using a typical blood pressure monitor like the one in picture 4. Finally, we will measure your blood lactate levels (see picture 5). This will involve pricking your finger and putting a drop of blood on the strip that sticks out of the monitor.

Picture 1

Picture 2

Picture 3

Picture 4

Picture 5

Picture 6

Once the ‘everyday activities’ have been measured, we would like to continue to monitor your responses to activity over the rest of the week. We will remove the metabolic analyser but ask you to continue to use the heart rate, blood pressure and lactate monitors and the pulse oximeter for the following week. You will wear the heart rate monitor all day, but only use the other monitors once per day.

You will also wear an accelerometer (see picture 6), that measures your activity levels. This is worn around the waist during your waking hours for the next seven days and monitors how long you spend lying, sitting or standing and how many steps you take. Finally, you will record your symptoms once per day using an app, called the ‘Bearable app’. You will also complete a brief questionnaire (the Fatigue Severity Scale) about the severity of your fatigue symptoms on the 1st and last day.

After six days, the researcher will visit your home to collect the equipment and will ask you a few questions about your experience. You will therefore be involved in the study for six days.

Do I have to take part?

Only if you want to.

Participation is voluntary, you may refuse to participate or withdraw from the study at any time. You do not need to tell us why you do not want to take part. If you choose to withdraw or not to participate, your decision will in no way affect your future healthcare. It may be that the investigator or sponsor of the study consider that it is in your interests to withdraw you or stop the study altogether.

What are the possible disadvantages and risks of taking part?

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. 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 of the equipment you will be using. We will also ensure that there is seven days between each test so that the equipment is thoroughly clean before the next use. Due to the requirements of Covid19 we will also ensure that all researchers wear Personal Protective Equipment as required by the Department of Health and the Chartered Society of Physiotherapy.

Are there any benefits of taking part in this study?

There may be no benefits to taking part. However, the aim of the study is to help determine whether a larger study is feasible. Your involvement will therefore help people with ME in the future. Personally, you will be able determine your physiological responses to everyday activities.

Are there any costs involved?

No, in fact we have funding to provide £100 per person taking part in the study to provide renumeration for your time.

Withdrawal options and your rights

Your participation in this study is entirely voluntary and refusal will not affect any health care. You may, without giving reason, refuse to take part or withdraw from the study without reason at any point.

Data protection & confidentiality

The study complies with Government & the University of Leicester's data protection policy as well as the University's research ethics requirements. Information to identify you are: your initials, 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 researcher and assistant will have

access to. A copy of the Informed Consent Form will be kept and you will be given a copy. The records will identify you only by a number (not your hospital number) and your initials. The information from this study will be retained for five years. If you agree to participate in this study, your General Practitioner will be informed, unless you state otherwise.

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 (njc36@le.ac.uk), Tel. 0116 252 3305. If you are not satisfied with the response you receive from the investigator, then there is a formal university complaints procedure. In the first instance write to the chair of the Medicine and Biological Sciences research ethics committee, currently Dr. Chris Talbot (cjt14@le.ac.uk).

What will happen with the results of the study?

The results will be analysed and discussed by the researcher. The results of the study may also be presented in research reports, scientific conferences and/or journals and be made available to pWME via the ME Assiocation (which funded the study). 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 College of Medicine Biological Sciences and Psychology Committee for Research Ethics Concerning Human Subjects 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 Leicester, University of Manchester and Oxford Brookes University. It is being funded by The ME Association.

Further information/Key contact details

Principal Investigator: Dr Nicola Clague-Baker at njc36@le.ac.uk

If you are happy with the above and have no questions, please complete the consent form.

Thank you.