



LIVERPOOL JOHN MOORES UNIVERSITY
Participant Information Sheet For healthy males and females aged 18-45
years old

LJMU's Research Ethics Committee Approval Reference:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study: Effects of Acute Exercise on Thermal Sensory Function

School/Faculty: Sport and Exercise Sciences, Faculty of Science

Name and Contact Details and status of the Principal Investigator: Dr David Low, Reader, School of Sport and Exercise Sciences, Liverpool John Moores University, d.a.low@ljmu.ac.uk, 0151 904 6244

Name and Contact Details of the Investigators: Mr Sam Thomas (PhD student), School of Sport and Exercise Sciences, Liverpool John Moores University, s.d.thomas@ljmu.ac.uk.

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You are being invited to take part in a research study. Before you decide it is important for you to understand why the study is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

1. What is the purpose of the study?

The skin is the largest and most accessible organ in humans, and acts as a barrier between our internal and external environments. It also helps regulate blood flow and body temperature through a vast array of structures, such as small blood vessels called capillaries. Cardiovascular disease is the leading cause of death globally, and the risk of disease is higher with ageing and inactivity. The small vessels of the body, such as those in your skin, are thought to be affected by cardiovascular disease before the larger vessels, such as those supplying your brain and heart.

We know that the function of skin blood vessels are positively affected by regular physical activity, but the effect of a single bout of exercise, the acute change, on skin thermal sensory function is less well understood. The purpose of this study is to examine thermal sensory function before, immediately following, and 1 hour after 30 minutes of cycling exercise at 50% and 80% of your age-predicted maximal heart rate. We will also examine thermal sensory function in the absence of exercise at these time intervals in a further visit.

2. Why have I been invited to participate?

You have been invited because you are male or female, healthy and aged 18-45 years old.

The inclusion criteria for taking part are:

- Male or female healthy volunteers aged 18-45 years old, recreationally active (<3 hours/week)
- No cardiovascular diseases, physical injuries or medical conditions preventing participation in exercise
- Able to attend 4 sessions spaced roughly 1 week apart (time between sessions may differ for female participants due to testing needing to take place in the early follicular stage of the menstrual cycle).

The exclusion criteria for taking part are:

- Smoking
- Medical disease
- Local infection on forearms or calves
- Limited/affected lower limb physical activity
- Currently on medication
- Aged > 45 years old

You were identified as a potential participant through an email sent to either a student or staff cohort within Liverpool John Moores University or we spoke to you in person about the study. 11 other participants will be recruited to the study.

3. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw at any time by informing the investigators without giving a reason and without it affecting your rights.

4. What will happen to me if I take part?

Before participation, you will be required to complete a health and physical activity questionnaire. This is to ensure you are suitable to take part, and that there aren't any reasons you can't take part. No information from this screening will be shared and the data will be securely stored and destroyed after the study has finished if you participate, or destroyed immediately if you cannot participate.

A full verbal explanation of all the different tests and procedures will be provided and you will be given an opportunity to ask any questions you may have about the study. If you would like to participate in the study, you will also be asked to sign a consent form. Subsequently, we will plan the testing days. You will then be invited into the laboratories at Liverpool John Moores University on 4 occasions, roughly 3-7 days apart, to perform the tests (see below). Before each visit, you must fast from food for at least 4 hours, and should not exercise or consume alcohol or caffeine for 24 hours prior to testing. Water can be consumed up to arriving at the laboratory.

Initial Visit

Female participants will be asked to complete a menstrual cycle questionnaire. You will complete an incremental cycling protocol to measure your $VO_{2\text{ max}}$ (aerobic fitness) before being familiarised with the testing procedures. The cycling test involves cycling at progressively harder intensities until you cannot

continue, e.g., maximal exercise, and will usually last 8-12 minutes. We will measure the amount of oxygen you breathe in using a special facemask connected to a computer. We will also measure heart rate using a belt placed around your chest.

Experimental Visits

You will then be required to attend the laboratories on 3 further occasions to perform cycle exercise for 30 minutes at 50% (one visit) and 80% (one visit) of your maximum heart rate and on another “no-exercise” visit where you will be required to sit comfortably for 30 minutes without exercising.

In all visits, a thermode (small square device) will be placed on your non-dominant forearm and calf to assess your thermal sensory function before, immediately after exercise or the seated period and again 60 minutes later. The temperature of the thermode will be increased at a rate of 1°C/s and you will be required to click a computer mouse as soon as you feel a change in temperature and again when you feel that the temperature is uncomfortable upon which the temperature of the thermode will then immediately return to normal. You will then be exposed to 4 different temperatures (in 2°C steps) ranging from 38°C to 44°C and asked to rate each one in terms of both heat and discomfort on a 0-100 scale. This will be repeated twice on both the forearm and calf before, immediately after the exercise or seated period and again 60 minutes later.

Blood pressure will also be obtained using a cuff placed around your upper arm at regular intervals. The cuff will tighten around your arm whilst measuring your blood pressure. A thin belt will also be placed around your chest to continually monitor your heart rate. We will also ask you to rate your perceived exertion using a 6-20 scale to describe how hard you think the exercise is.

If you would like, we can report any significant findings directly related to you (e.g. abnormal findings) back to you in person by the Principle Investigator. Please be aware though that the research team are not clinicians so any such findings should be further assessed by your local GP.

We will not contact you for future research studies.

5. What are the possible disadvantages and risks of taking part?

Exercise will be moderate to hard, so you will be warm, sweating, flushed etc. You may feel a bit dizzy after exercise but you will soon be seated or laying down after exercise and any symptoms will disappear at this point. The exercise may also result in a delayed muscle soreness experienced in the 2-4 days following the testing, however this will not last more than a few days and will not adversely affect your health. High intensity exercise may result in musculoskeletal injury, however, this is unlikely, as cycling is a low impact activity and exercise bouts will be limited to 30 minutes.

You will feel some discomfort during the thermal sensory test as the temperature of the thermode gets to an uncomfortable/painful sensation, however this will be temporary and will immediately stop once you press the mouse button. The experimenter can also immediately stop the test via the computer and/or remove the thermode from your skin as well if needed. There will be no lasting effects from this test.

At any time during the experiment, you are free to voluntarily terminate the procedure and stop the experiment. If you experience an adverse event during or after an experiment please inform the research team.

6. What are the possible benefits of taking part?

There are no personal benefits associated with participating in this study, but the data will be useful for researchers investigating the effects of exercise and thermal sensory function.

7. What will happen to the data provided and how will my taking part in this project be kept confidential?

The information you provide as part of the study is the **research study data**. Any research study data from which you can be identified (e.g. from identifiers such as your name, date of birth etc.), is known as **personal data**. Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed).

If necessary, personal data will be stored confidentially for 5 years after the study has finished. Personal data will only be accessible to the research team. Personal identifiable data/information will not be transferred outside of the European Economic Area.

Personal data collected from you will be recorded using a linked code – the link from the code to your identity will be stored securely and separately from the coded data.

You will not be identifiable in any ensuing reports or publications.

Anonymised data might be used for additional or subsequent research studies and we might share anonymised data with other investigators (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

8. What will happen to the results of the research project?

The investigators intend to publish the results in a PhD thesis and or a journal article.

9. Who is organising and funding the study?

This study is organised and funded by Liverpool John Moores University.

10. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, the Liverpool John Moores University Research Ethics Committee (Reference number: 18/SPS/038).

11. What if something goes wrong?

If you have a concern about any aspect of this study, please contact the relevant investigator who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact the chair of the Liverpool John Moores University Research Ethics Committee (researchethics@ljmu.ac.uk) and your communication will be re-directed to an independent person as appropriate.

LJMU holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation. This does not affect your legal rights to seek compensation.

12. Data Protection Notice

The data controller for this study will be Liverpool John Moores University (LJMU). The LJMU Data Protection Office provides oversight of LJMU activities involving the processing of personal data, and can be contacted at secretariat@ljmu.ac.uk. This means that we are responsible for looking after your information and using it properly. [LJMU's Data Protection Officer can also be contacted at secretariat@ljmu.ac.uk](#). The University will process your personal data for the purpose of research. Research is a task that we perform in the public interest.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.

You can find out more about how we use your information by contacting secretariat@ljmu.ac.uk. If you are concerned about how your personal data is being processed, please contact LJMU in the first instance at secretariat@ljmu.ac.uk. [If you remain unsatisfied](#), you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/>

14. Contact for further information

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Co-Investigators

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Sam Thomas, s.d.thomas@2016.ljmu.ac.uk

Thank you for reading this information sheet and for considering to take part in this study.

Note: A copy of the participant information sheet should be retained by the participant with a copy of the signed consent form.
