

**Participant Information Sheet for Adults**

UCL Research Ethics Committee Approval ID Number: 0326/019

UEL Research Ethics Committee Approval ID Number: 2122-0105

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET****Title of Study:** Age and sex differences in the metabolic response to exercise: pilot study**Department:** UCL Great Ormond Street Institute of Child Health**Name and Contact Details of the Researcher(s):**Dr Evelyn Maniaki [evelyn.maniaki.20@ucl.ac.uk](mailto:evelyn.maniaki.20@ucl.ac.uk)Dr Andy Galbraith [A.J.Galbraith@uel.ac.uk](mailto:A.J.Galbraith@uel.ac.uk)**Name and Contact Details of the Principal Researcher:**Prof Jonathan Wells [jonathan.wells@ucl.ac.uk](mailto:jonathan.wells@ucl.ac.uk)**1. Invitation Paragraph**

You are being invited to take part in a pilot study that is part of a bigger PhD research project. Before you decide, it is important for you to understand why the research 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 you wish to take part; your participation is completely voluntary. Thank you for reading this.

**2. What is the project's purpose?**

Exercise benefits health through diverse metabolic pathways and is central to healthy aging. However, intense exercise also challenges the body, causing cellular damage that must be repaired. This means that we need to identify the level of exercise that can optimise health, and this level might potentially differ by age and sex. Our research aims to tackle this question, by studying the metabolic responses of the body both to exercise, and during subsequent recovery. We will assign study participants to a carefully controlled exercise protocol and collect biological samples to study the metabolic effects. However, before we can conduct our main study, we first need to make sure that our protocols are appropriate for the study population.

The pilot study aims to a) capture the broad views of participants on the main study design protocol using informal interviews, and b) assess the potential exercise protocols by asking participants to undertake them and utilise their feedback. Data from the pilot study will be used to inform the study design of the main study.

**3. Why have I been chosen?**

We are inviting 5 adults aged 54-57 years to participate in the pilot study.

To take part, you would need to be fluent in English, be able to walk one-quarter of a mile and climb 10 steps without difficulty, and to generally be of good health. You will not be able to take part if you have a disease, disability or other condition that would impair participation in physical activity, or if you have an implanted cardiac pacemaker, defibrillator, or other electronic medical devices. Due to the ongoing pandemic, you will also not be able to take part if you are showing any symptoms related to COVID-19.

**4. Do I have to take part?**

Taking part in the study is entirely voluntary; it is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. You can withdraw at any time without giving a reason. If you decide to withdraw, you will be asked what you wish to happen to the data you have provided up to that point.

## **5. What will happen to me if I take part?**

The pilot study will involve an informal face-to-face interview which will not be audio / video recorded, and two exercise protocols, one on a treadmill and one on a bike, at the Dockland campus of University of East London (East Building, University Way, London E16 2RD). The research will take place on a single day, over the course of approximately 2 hours.

Before you take part, we will ask you to complete an online inclusion questionnaire where we will ask some questions about your health status to confirm that you are eligible, and it is safe for you to participate in the study. We will record your consent electronically at this stage. If you do take part, we will ask you to record your consent in writing before proceeding further and arranging the face-to-face interview. For most of the in-person part of the study, you will be asked to wear a face mask to prevent the spread of Coronavirus – the researcher (Evelyn Maniaki) will do the same.

For the in-person part of the study, the researcher will start by giving a short PowerPoint presentation describing the main study design, focusing on what will happen on the day of data collection. Following this, she will first ask open-ended (e.g., does it sound interesting, what would you change, what questions do you have), then follow-up questions to get more specific comments depending on your answers. This will last approximately 30 minutes and she will make digital notes. You will then have the opportunity to familiarise yourself with the equipment that will be used in the proposed exercise protocols. You will put on the scientific equipment that is used to measure your heart rate (chest strap) and expired breath (mask), then you will do first the treadmill then the bike protocol. Each protocol will last approximately 4 minutes, but you can stop each protocol sooner if you decide to. There will be suitable breaks between each protocol (15-30 minutes) during which you will take the equipment off, relax, have a drink, and share your thoughts on the protocols with the researcher which she will make a note of (e.g., did the equipment fit you well, was it too cumbersome for you etc). The undertaking of both protocols, including breaks, will take approximately 90 minutes.

The equipment will be turned on to ensure it is working correctly and it is measuring the expected parameters. However, no physiological or performance data will be recorded or saved from you while you are undertaking either exercise protocol. The only data that will be collected will be your thoughts on them.

## **6. What are the possible disadvantages and risks of taking part?**

None of the topics that will be discussed should cause you any distress. The risks associated with the exercise protocols are low as you will not be asked to undertake them to voluntary exhaustion, and you can stop at any time. However, if at any point during the undertaking of the exercise protocols you develop chest pain, shortness of breath, dizziness, or other concerning symptoms then you should inform the research and all procedures will cease. An automated external defibrillator and on-site trained staff are available to deal with medical emergencies, including the researcher herself.

A number of additional measures will also be taken to reduce the risk of spreading Coronavirus. The researcher is triple vaccinated and will have performed a lateral flow test prior to meeting you. A distance of at least 1 metre will be maintained at all times, and windows will be open (weather-permitting). In addition, all the equipment you will be using will be cleaned using appropriate disinfectants between participants.

## **7. What are the possible benefits of taking part?**

We will refund reasonable travel expenses and will be offering you a £5 Love2Shop voucher as a token of appreciation for your time. It is hoped that this work will inform the design of the main study, which will in turn help us identify the level of exercise that can optimise health.

## **8. What if something goes wrong?**

This study has been reviewed and approved by two Independent Research Ethics Committees. This means that a group of individuals whose priority is your safety and well-being believe the research is of minimal risk to you. However, no research project is completely immune to unforeseen risks. It is important for you to know that you have the right to claim damages in a court of law in the unlikely event any harm should occur as a result of you taking part in this study. If you wish to raise a complaint about the study, you should first contact the Principal Investigator, Jonathan Wells ([Jonathan.wells@ucl.ac.uk](mailto:Jonathan.wells@ucl.ac.uk)). If you feel that your complaint has not been handled to

your satisfaction, you can contact the Chair of the UCL Research Ethics Committee ([ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)) or the Chair of the UEL Research Ethics Committee ([researchethics@uel.ac.uk](mailto:researchethics@uel.ac.uk)).

**9. Will my taking part in this project be kept confidential?**

All the data collected during this pilot study will be anonymised with an assigned participant number, so that your name will not appear in the same place as the information we recorded. In this way, all information that we collect about you will remain completely confidential, and only the researchers on the study will have access to it. You will not be able to be identified in any ensuing reports or publications. Any materials containing your personal identifiers will be encrypted and stored on UCL's Research Data Storage Service.

**10. Limits to confidentiality**

Confidentiality will be respected unless there are compelling and legitimate reasons for this to be breached. If this was the case, we would inform you of any decisions that might limit your confidentiality.

**11. What will happen to the results of the research project?**

We will contact you via e-mail or post when the pilot study finishes and share with you the decisions we will have made on the main study's design. The digital notes from your session can also be sent to you if you wish to be informed of them. This pilot study will constitute part of Dr Evelyn Maniaki's PhD thesis and is intended for publication in relevant scientific journals and presentation at national and international scientific meetings or conferences. Nevertheless, you will not be identifiable in these reports.

**12. Local Data Protection Privacy Notice**

**Notice:**

The data controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data and can be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in health and care research studies, click [here](#).

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:

First and last name

Full postal address

E-mail address

Phone number

Month and year of birth

Sex

Health (physical)

The lawful basis that would be used to process your *personal* data will be performance of a task in the public interest.

The lawful basis that would be used to process *special category personal* data will be for scientific and historical research or statistical purposes.

Your personal data will be processed until the end of the data collection period. If we are able to anonymise or pseudonymise the personal data you provide, we will undertake this and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

**13. Who is organising and funding the research?**

The sponsor of the research is UCL Great Ormond Street Institute of Child Health. The funder of the research is the London Interdisciplinary Doctoral Programme, which is funded by the Biotechnology and Biological Sciences Research Council (BBSRC).

**14. Contact for further information**

Please contact Jonathan Wells ([jonathan.wells@ucl.ac.uk](mailto:jonathan.wells@ucl.ac.uk)) for further information.

You will be given a copy of this information sheet and a signed consent form to keep.

**Thank you for reading this information sheet and for considering taking part in this research study.**

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