Participant Information Sheet For Female Exercisers

UCL Research Ethics Committee Approval ID Number: **15505/004**

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of Study: The Effects of Energy Availability on Nutritional Status and Female Hormone Networks Female Exercisers.

Department: UCL Division of Medicine, Faculty of Medical Sciences

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Name and Contact Details of the Researcher(s):
BSc Students: Henrietta de Assis (henrietta.assis.21@ucl.ac.uk), Ciara Trollip (Ciara.trollip.21@ucl.ac.uk)

MSc Students: Francesca Testa (francesca.testa.23@ucl.ac.uk), Alexa Eichelmann (alexa.eichelmann.23@ucl.ac.uk) and Phoebe Redding (phoebe.redding.23@ucl.ac.uk)

Honorary Clinical Lecturer Supervisor and medical doctor: Dr Nicky Keay (n.keay@ucl.ac.uk)

Name and Contact Details of the Principal Researcher: Dr Adrian Slee (a.slee@ucl.ac.uk)

1. **Invitation Paragraph**
   You are being invited to take part in a UCL student 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. Please contact the student researchers if you have any queries (contact details above).

2. **What is the project's purpose?**
   Low Energy Availability (LEA) in exercisers occurs due to a high training load and potential eating restriction due to various demands, knowledge, expectations and pressures. This phenomenon has been described as REDs (relative energy deficiency). The study will aim to look at the awareness of the syndrome and identify indicators of LEA and its impact on the nutritional status and hormonal profile of female exercisers.

   Phase 1 of the study will involve completing an online questionnaire. The questionnaire has some health and REDs-related questions and asks for information on areas such as nutrition, exercise patterns and injuries.

   Phase 2 will involve selected participants to perform a finger prick test (hormone profiling) and body measurements (e.g. heart rate, blood pressure, height, weight and muscle mass etc) as well as a dietary assessment and an interview (individual or focus-group setting, depending on preference) to determine the impact of low energy availability on female exercisers. In particular, the interview/focus-group will cover in more depth areas around REDs and how it might have affected you in different ways. Please feel free to ask the Researchers about this. We think that this information might be helpful for potentially developing early screening tools for assessing and treating REDs in the future.

3. **Why have I been chosen?**
   You have been invited to take part in this study as you are a female exerciser aged 18 or above who is currently exercising 3 or more hours a week, not pregnant or taking hormonal contraception or have been diagnosed with prolactinoma.

4. **Do I have to take part?**
   The decision to take part in the study is completely up to you. If you have any questions, please don't hesitate to ask. If you decide to take part, you will be given this information sheet to keep, and a signed consent form will be given. You can withdraw at any time without giving a reason and without affecting anything. If you decide to withdraw you will be able to withdraw your data up to 8 weeks after questionnaire.

5. **What will happen to me if I take part?**
   Once you have decided to take part and are recruited onto to the study all participants will be asked to complete a questionnaire, but only a selected subgroup will be invited to have capillary blood testing and have dietary intake and body measurements (e.g. heart rate, blood pressure and anthropometric measurements) assessed. The questionnaire will be filled out online using a Microsoft Forms weblink. Anthropometric data collection will be carried out in-person at UCL and you will be invited to come to central Bloomsbury campus at a suitable timeslot. The logistics of finger prick blood testing will be administered in line with requirements for data security. If your blood tests uncover any underlying conditions this will be highlighted to you so that you can discuss this with your GP. This research will last until the mid-2024 and it is expected that it will take up to about 1 hour of your time.

   If you are doing the study with MSc students, Alexa Eichelmann and Francesca Testa, and Phoebe Redding, you will also be invited to take part in a semi-structured interview, individually or in a focus group, depending on your preference. Please feel free to only complete components you feel able to or want to, as we do not want you to feel burdened in any way. With regards to any sensitive issues that might arise through the interview/focus group discussions, the Medical Practitioners Dr Keay and Dr Testa will be available for support, guidance and signposting to relevant organisations or resources.

6. **What are the possible disadvantages and risks of taking part?**
   The finger prick blood tests might induce a temporary discomfort.
   There is also a possibility that during interviews/focus-group participation discussions that you might feel uncomfortable discussing any sensitive issues e.g. around health effects of REDs. As mentioned above the Medical Practitioners Dr Keay and Dr Testa will be available for support, guidance and signposting to relevant organisations or resources.

7. **What are the possible benefits of taking part?**
   Benefits include a discussion with review and explanation of your blood tests. The results from this study might also help with future research and management of REDs which would help bring about changes to female exercisers and support the health and performance of healthy athletes. You will be contributing data to an under-researched area, supporting future interventions, and understanding of REDs in athletes of all ages.

8. **What if something goes wrong?**
   If you wish to raise a complaint you can contact Dr Nicky Keay, Dr Adrian Slee, or the head of department - If you feel that it hasn't been appropriately answered you can also

contact the Chair of the UCL Research Ethics Committee – ethics@ucl.ac.uk .All complaints will be taken very seriously and investigated appropriately.

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

Your participation will be kept confidential, however during the data collection your data will be stored with some identifiers like initials and age. However, this information is stored within password protected files within UCL system. All the information that we collect about you during the research study will be kept strictly confidential. You will not be able to be identified in any ensuing reports or publications.

10. Limits to confidentiality

- Please note that assurances on confidentiality will be strictly adhered to unless evidence of wrongdoing or potential harm is uncovered. In such cases the University may be obliged to contact relevant statutory bodies/agencies.
- Confidentiality will be respected subject to legal constraints and professional guidelines.
- 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?

All your personal data will be shared with you (results from the questionnaire, anthropometry, and blood tests). The final written paper will also be sent out once completed and in the event of publishing, information on how to access this will be sent to you. All the data will be published anonymously.

12. Local Data Protection Privacy Notice

Notice:

The 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

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:

- Name and date of birth
- Medical history
- Blood tests
- Anthropometry (e.g. height and weight etc)

The lawful basis that would be used to process your *personal data* will be for research.

The lawful basis used to process *special category personal data* will be for research.

Your personal data will be processed so long as it is required for the research project. It will be stored until January 2025 and then all personal identifiers will be deleted to keep it anonymous. 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.

Intended recipients will be BSc and MSc students, Dr Adrian Slee and Dr Nicky Keay for research purposes and then write up. All information will be published with any personal information fully anonymised.

13. Who is organising and funding the research?

UCL, Division of Medicine

14. Contact for further information

Please contact: Henrietta de Assis (henrietta.assis.21@ucl.ac.uk), Ciara Trollip (Ciara.trollip.21@ucl.ac.uk), Dr Francesca (francesca.testa.23@ucl.ac.uk), Alexa Eichelmann (alexa.eichelmann.23@ucl.ac.uk) and Phoebe Redding (phoebe.redding.23@ucl.ac.uk).

Or for any further queries, Dr Nicky Keay (n.keay@ucl.ac.uk), and Dr Adrian Slee (a.slee@ucl.ac.uk).

This information sheet will be sent to you as a copy and a signed consent form.

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