

Research Ethics Form

Section 1

Your details

a) Researchers

Primary Researcher

Liam Pope (22014342)

b) Title of Proposed Project

A Patient and Public Involvement in a Study Targeting Cardiovascular Health in Females with Low Energy Availability

c) Programme Title and Level of Study

NUTRITION

d) Research Dates

I confirm that I will not start my research before ethical approval has been given

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End Date:

2024-12-08

e) School

First School

NUTRITION AND FOOD SCIENCE

First Supervisor Name

Richard Webb

Second School (if applicable)

NUTRITION AND FOOD SCIENCE

Second Supervisor Name (if applicable)

Denise Roche

g) Professional Guidelines Referenced

INVOLVE and GRIPP2 guidelines (INVOLVE, 2012; Staniszewska, 2017).

Section 2

Who will be taking part in your research?

a) Will other people be taking part in your research?

Human participants

Section 3.1

General

a) Full title of the research project

A Patient and Public Involvement in a Study Targeting Cardiovascular Health in Females with Low Energy Availability

b) Aims and Objectives

The aim of this study is to conduct a patient and public involvement (PPI) to gain insights into the feasibility of a study investigating cardiovascular health in females with low energy availability. The objectives of this study are: (1) to explore the perspectives, experiences, and preferences of potential participants regarding the feasibility of the study; (2) to identify potential barriers and facilitators to the recruitment and retention of participants in the study; and (3) to use insights gained through the PPI to refine the study design, recruitment, and retention of participants.

c) Please give a brief outline of the research study

In recent years, Patient and Public Involvement (PPI) has played a significant role in shaping healthcare interventions to be more patient-centred (Mockford et al., 2011). Particularly for complex interventions (CIs), involving potential participants in the design process is critical for success (NIHR, 2016). Funding bodies such as the National Institute for Health Research and the Medical Research Council emphasize the importance of PPI in all stages of research involving CIs (INVOLVE, 2012; MRC, 2006). Studies that conduct PPI report improvements in intervention design and subsequent research success (Abayomi et al., 2019).

Insufficient energy availability, known as low energy availability (LEA), can cause disruptions to homeostatic mechanisms in humans and is exacerbated by sports and exercise (Areta et al., 2021). This can lead to hormonal, metabolic, and physiological dysregulations, including cardiovascular abnormalities (De Souza et al., 2014). While studies supporting this are limited, recent literature suggests that correcting LEA may reverse cardiovascular and metabolic abnormalities (Grosman-Rimon et al., 2019; Nattiv et al., 2007). Despite this, there is a lack of research on the links between LEA and cardiovascular disease risk in females (Mountjoy et al., 2018).

Only one randomized control trial (RCT) has attempted to correct LEA in exercising women. The REFUEL trial by De Souza and colleagues asked exercising women with amenorrhea to consume an additional 352 kcal.day⁻¹ over 12 months (De Souza et al., 2022), resulting in improved menstrual frequency but not bone mineral density or estrogen levels. However, the study did not examine how LEA and its correction may affect cardiovascular risk markers or the role of individual macronutrients in driving changes.

The research team has proposed a study aimed at investigating cardiovascular health in females with LEA. To achieve this, the team plans to collect demographic data, anthropometric measurements, as well as blood and urinary samples, and assess dietary and physical activity measures. However, performing a PPI study is vital to determine its relevance, accessibility, scope and appropriateness for the target audience. This not only promotes compliance but also facilitates the recruitment and retention of participants in future research. Therefore, the aim of this study is to conduct a PPI investigation with physically active females to gain insight into the perspectives of one research project concerning the implications of LEA on cardiovascular risk markers.

The lead researcher, Liam Pope, will facilitate a planned presentation and group discussion question list during a single session held at Liverpool Hope University in one of the classrooms in the Health Sciences Building. The session will use a focus group/interview methodology and last approximately 1-2 hours.

Participants will be asked questions assessing their knowledge and understanding of low energy availability and cardiovascular health. Additionally, questions associated with the study such as design and recruitment to obtain feedback. Questions such as How do you think this study could be improved to better meet the needs of the target population, and do you have any concerns or questions about the study design or its implementation? The planned presentation and discussion guide can be viewed in the supporting documents.

The recruitment of participants will be carried out through the Sona System and targeted approaches such as social media posts, physical postings, and word of mouth in local sports clubs. The team aim to recruit a total of ten active females. The sessions will approximately last between 1 and 2 hours and use a focus group/interview methodology. Video digital recording will not be used to encourage open discussion. Instead, audio voice recordings of the presentation and group discussion will be recorded over Microsoft Teams to ensure accurate data collection. Please see below (3.3 c) how we will ensure anonymity and confidentiality in recording the session. The transcript developed will be validated by the participants once produced. The transcript will then be subjected to thematic analysis using Braun and Clarke's step-by-step guide (Braun, Clarke, Hayfield et al., 2019). Themes will be identified and defined, and relevant quotations will be selected from the transcripts to support interpretation.

To ensure compliance with INVOLVE (2012) and GRIPP2 guidelines (Staniszewska et al., 2017), three females will be recruited as PPI assessors. The PPI assessors will be involved in all aspects of the project and contribute to edits of the paper. Interested applicants will express their interest via email followed by an interview process where participants will be assessed for suitability for the role. The lead and co-researchers will make the final decision on the selection of the PPI assessors. PPI assessors will be paid a total of £200 for the full support throughout the project at the end of the study in one sum. Those participants who become PPI assessors will be required for six meetings. In exceptional circumstances, those assessors might be required for more meetings.

d) Some types of research must be referred (by the Faculty Ethics Research Sub-Committee) to the University Research Ethics Sub-Committee. Therefore, please state here if your research involves or may involve deception, the use of covert methods, matters involving national security, illegal activity or might endanger the University's reputation. Please also highlight the key aspects which cause it to fall into one or more of these categories.

N/a

e) Where will the study take place and in what setting? If in a workplace, or if the participants are from a workplace (e.g. a school), identify what your connections are with that workplace

The study will take place at Liverpool Hope University within the Health Sciences building in one of the classrooms.

f) Give a brief description of your target sample (e.g. age, occupation, gender)

Active to elite females aged between 18-35 years old.

g) Is the participation individual or as part of a group?

Both Individuals and Groups of participants

j) How will participants be selected, approached and recruited? Identify clearly and analyse fully any issues of power relations that might arise, and say what steps you will take to alleviate them. This applies particularly if the location of the research is a place of the researcher's own employment, or if they have other strong links with the participants.

Multiple methods will be used to recruit individuals, including via the Sona System, social media posts, local advertisements around the area, and reaching out to local sports clubs and communities to spread the word. Please see the attached documents in Section 4 for examples of advertising materials.

k) Is written consent to be obtained?

No

Please state why. As free and informed consent is essential, you need to give strong and convincing reasons for not obtaining informed consent.

While no formal consent is required for a PPI study (NHS, 2018), this will include a term of reference so participants have a clear understanding of what their involvement will entail and that they are able to make an informed decision about whether or not to participate. These terms of reference will clearly outline the nature and purpose of the study, the potential risks and benefits involved, as well as the participants' rights and confidentiality.

How will the participants' right to withdraw be ensured?

Individuals will have the assurance that they can withdraw from the study at any stage and the that their data will be destroyed.

Section 3.2

Risk & Ethical Procedures

a) What potential risks are there of physical harm to participants? Please specify, and explain any steps you will take to address them.

The length of the focus group/interview discussion or the seating arrangements may cause physical discomfort for some participants. To address this risk, the researcher should provide breaks, refreshments, and comfortable seating arrangements. The duration of the presentation and group discussion is expected to take between 1 to 2 hours.

b) What potential psychological risks are there to participants? In particular, how might participation in this research cause discomfort or distress to participants? Please specify, and explain any steps you will take to address these issues.

Participants may feel uncomfortable or vulnerable discussing sensitive topics in front of others. To address this risk, the researcher should create a supportive and non-judgmental environment and provide an opportunity for participants to opt out or take a break if they feel overwhelmed. Furthermore, appropriate signposting to the relevant charities will be implemented if necessary including Mind, NHS Every Mind Matters, Samaritans and Rethink Mental Illness.

c) Are there any risks to you as the researcher (and / or your co-researchers, if you have any) in this project? If so, outline the steps you will take to minimise them.

N/a.

d) Will the participants receive any reimbursements for taking part in this research?

Individuals will gain a better understanding of low energy availability and its impact on cardiovascular health. This will enable them to make more informed decisions about their health.

e) Does any aspect of your research require that participants be naïve (i.e. they are not given full or exact information about the aims of the research)? Please explain why and give details of the debriefing procedures you would use when the need for the naiveté is over

N/a

Section 3.3

Data Management

a) Where and how do you intend to store any data collected from this research? Give details of steps you will take to ensure the security of any data you collect.

Data will be stored on a password-protected laptop that will be stored in a secure location. Data will also not be stored on easily movable devices such as USB keys or CD ROMs.

b) What steps will you take to safeguard the anonymity and confidentiality of personal records?

Respondents' names will be coded to ensure anonymity and confidentiality.

c) Will this research require the use of any of the following?

Video Recordings

No

Audio Recordings

Yes

Photos

No

Observation of participants

No

Please provide a more detailed explanation of how you will ensure confidentiality and anonymity

In order to maintain ethical standards, the lead researcher will ensure that

informed consent is obtained from participants prior to recording any audio and that they understand how the recordings will be used. This should include providing information on how confidentiality and anonymity will be maintained. To protect the identity of participants, the lead researcher will assign them pseudonyms or code names instead of using their real names. Audio recordings will be stored securely password-protected devices to prevent unauthorised access. Any identifying information such as participant names or contact details will be kept separate from the recordings. During the data analysis, only the pseudonyms or code names assigned to each participant will be used and no identifying information will be used. When disseminating research results, the lead researcher will avoid including any identifying information about participants and instead use pseudonyms or code names. Finally, upon completion of the research, the lead researcher will securely destroy any audio recordings to prevent any accidental or intentional breaches of confidentiality.

d) Deletion of personal data

I will destroy all personal data recorded by the end of my degree programme

You should NOT make this point dependent on a successful outcome of your studies.

Date you will delete the data

14/03/2026

Section 4

Consent Forms, Research Information Sheet and Additional Documentation

a) Consent Form

Uploaded Files:

- [Terms of Reference for PPI Assessors.docx](#)

c) Research Information Sheet

Uploaded Files:

- [Terms of Reference.docx](#)

d) Research Materials

Uploaded Files:

- [Email Recruitment Example.docx](#)
- [Examples of text in posts.docx](#)
- [Group discussion questions - 5.docx](#)
- [PPI Presentation.pdf](#)
- [PPI Study Advert 2.pdf](#)
- [PPI Study recruitment.docx](#)