



University of the
Highlands and Islands
Oilthigh na Gàidhealtachd
agus nan Eilean

The effect of exercise training on appetite control and free-living energy intake in older adults: A pilot study.

This participant information sheet describes the study and explains what we are asking you to do. Ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this leaflet and considering whether to take part in the study.

Introduction

The University of the Highlands and Islands (UHI) are conducting a new research study. We are investigating the effects of exercise class participation on appetite and food intake in people aged between 65-80 years. The study is led by Dr Daniel Crabtree (UHI), with assistance from Dr James Cobley (UHI), Dr Angelique Stalmach (UHI), Dr Holger Husi (UHI), Kirsty Hickson (RD; UHI) and Dr Adrian Holliday (Newcastle University).

Purpose of the research

The NHS advise community-living people aged ≥ 65 years who are concerned about a loss of appetite to follow physical activity guidelines, as they state that increasing physical activity will stimulate appetite. However, there is insufficient scientific evidence to support advice that physical activity prevents the age-related decline in appetite and food intake, due to the limited number of studies that have been conducted in people aged ≥ 65 years. This study aims determine the effects of a supervised 4-week exercise intervention on appetite and food intake in people aged 65-80 years with a low body weight, low physical activity levels and poor appetite.

Do you have to take part?

No. It is up to you to decide whether to take part. If you decide to take part, you are still free to withdraw at any time, without giving a reason. If you withdraw your consent during a research session, the session will stop, and the researcher will delete any research data that has been collected. Paper-based notes will be disposed of in confidential waste and relevant recordings, files and database entries will be deleted. The same process will apply if you withdraw after a research session.



What are you asking me to do?

If you decide to take part, you will be asked to attend three visits to the Active Health Exercise Lab (AHXL), Inverness. You will also be asked to attend three exercise classes per week for four weeks at Inverness Leisure.

AHXL Visit 1:

During this visit we will discuss the study and decide whether you are eligible or not to participate in the study. During the visit, your height and body weight will be measured and your body mass index (BMI; measure of weight compared to your height) calculated. You will also be asked to complete questionnaires. If you are eligible to participate in the study, then we will ask you to record the food and drink you consume and your physical activity for 7 consecutive days. We will ask you to record the food and drink you consume using a food diary and your physical activity using a physical activity monitor and a diary.

AHXL Visit 2:

The day prior to this visit, we will ask you to collect a stool sample at home from a normal bowel movement. **Please note, this is an optional measure and if you are not willing to provide a stool sample, then you may still participate in the study.**

Prior to arriving at the AHXL between 7-9am, we will ask that you fast (no food, only water) overnight and collect your first morning urine, using a container that we will provide. You will be asked to refrain from consuming alcohol and taking part in vigorous physical activity in the 24 hours prior to the visit. Upon arrival at the AHXL, we will measure your body weight and your body composition (amount of muscle and fat in your body). Your hand grip strength will be measured and your lower body strength and endurance will be assessed using the sit-to-stand test. The sit-to-stand test will measure how many times in 30 seconds you can stand up and sit down on a chair. The number of calories you burn at rest will also be measured. During this time, you will lay down on a bed for 30 minutes and breath normally into a device that measures the oxygen you breath in and the carbon dioxide you breath out. You will then be presented with a meal consisting of porridge oats, whole milk, natural yoghurt and honey and asked to consume the meal within 5 minutes. You will be asked how hungry and full you are before and for 3 hours after the meal and blood samples will be taken. The visit will last approximately 4 hours.

Following the visit, you will be asked to record the food and drink you consume for the rest of the day using a food diary. Furthermore, you will wear a physical activity

monitor and complete a physical activity diary and asked to avoid strenuous physical activity following the visit.

Exercise Classes:

The exercise classes will be delivered by a High Life Highland exercise instructor 3 times per week for 4 weeks at Inverness Leisure. The classes will last 1-hour, involve aerobic and resistance exercises and be of a moderate intensity. During the classes you should be breathing harder than normal but able to hold a conversation. You will be asked to wear a heart rate monitor during the classes, so that we can monitor the intensity of the classes. Please note taking part in the study does not provide you with free access to High Life Highland facilities, only the exercise studio during the exercise classes.

AHXL Visit 3:

Visit 3 will be the same as Visit 2, but you will also be asked to complete some additional questionnaires.

Furthermore, after you have completed Visit 3, you will be asked to record the food and drink you consume and your physical activity for 7 consecutive days.

Focus group:

You will be invited to attend a focus group that will be conducted on Microsoft Teams with other participants in the study, to discuss your experience of the exercise classes and the effects of the classes on your appetite and diet. Focus groups will be audio recorded, these recordings will be destroyed once transcribed and are anonymised. The focus group will last approximately 1 hour.

Why are you asking me to take part?

You have been chosen because you expressed an interest in participating and you meet the inclusion and exclusion criteria listed below.

Inclusion Criteria

- Aged 65-80 years
- BMI between 20 and 23 kg·m²
 - Please contact the researcher for information about BMI or access the NHS BMI calculator to calculate your BMI (<https://www.nhs.uk/live-well/healthy-weight/bmi-calculator/>)
- Low appetite
- Not engaging in regular exercise



- Doing less than 150 minutes of moderate to vigorous physical activity per week
- Non-smoker
- Weight stable (± 2 kg for the previous 3 months)

Exclusion Criteria

- A non-communicable disease (for example, cardiovascular disease, cancer, respiratory disease)
- Muscle injury in past 2 months
- Illness in the past 6 weeks
- Dieting within the last 3 months
- Change to your regular physical activity in last 6 months
- History of eating disorders
- Currently taking medication known to affect metabolism or appetite
- Dislike of or allergic to research meal contents

What are the possible risks of taking part?

If you feel unwell, or light-headed or experience muscle cramps/strain and/or joint injury during the exercise classes you should inform the exercise instructor and stop exercising immediately. If symptoms persist after the exercise class, contact your local GP.

In order to reduce these risks we would ask that you:

1. wear appropriate exercise clothes and shoes during the classes
2. be well hydrated prior to and during the classes
3. avoid eating 2 hours prior to the classes
3. avoid alcohol within 12 hours of the classes
4. be rested and avoid significant exertion for 24 hours prior to the classes
5. report any medication use to the instructor prior to the classes

You will also complete a warm-up prior to each class and a cool down afterwards. If at any stage of the class you request to stop exercising, the instructor will immediately advise you to cease the class.

The exercise classes will be conducted at a High Life Highland leisure facility by a qualified, first aid trained exercise instructor. First aid equipment and a defibrillator will be readily available during each class, to be used in the event of a medical

emergency. During the exercise classes, High Life Highland risk assessments and appropriate health and safety measures will be adhered to at all times.

IMPORTANT

If you have any chest pain, shortness of breath, or leg pain; feel light-headed or dizzy; feel sick or unwell; or feel that you wish to stop for any reason at any time during the exercise classes; STOP EXERCISING. Alert the instructor immediately.

You may experience slight discomfort and/or bruising as a result of the blood sampling. However, blood sampling will be done by qualified NHS Highland staff and every caution will be taken to ensure minimal discomfort and bruising.

You will be free to withdraw from the study at any stage and you will not have to give a reason and your personal data will be removed.

What are the possible benefits to taking part?

You may receive some direct mental or physical benefits from participation in terms of increasing your physical activity levels. In addition, you will have the opportunity to help shape the development of future research investigating the relationship between physical activity and appetite. We will provide you with a summary of the main findings of the study, if requested.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concern about any aspect of the way you have been approached or treated during the course of this study, then please contact the University of the Highlands and Islands Research Ethics Committee (REC) UHI Research Ethics Officer (details at the bottom of the sheet).

What will happen to my data?

All data will be anonymised as much as possible. Your name will be replaced with a participant number or a pseudonym, and it will not be possible for you to be identified in any reporting of the data gathered. The University of the Highlands and Islands is registered with the Information Commissioner's Office who implements the Data Protection Act 2018. All personal data will be processed in accordance with the

provisions of the Data Protection Act 2018. Electronic data files will be password-protected and stored on password-protected computers, to which only researchers directly involved in the study will have access (please see Introduction for researchers involved in the study). Electronic data will be shared between the researchers involved in the study using the University of the Highlands and Islands supported, file sharing platform, 'SharePoint'. The SharePoint site created for the purposes of the study will only be accessible to researchers directly involved in the study, only they will be granted permission to access study-related data. An area within this SharePoint site will be created for the High Life Highland exercise instructor to access important information about you, such as your medication requirements and your emergency contact details. These data, will be kept until the end of the research process, following which all data that could identify you will be destroyed. The results may also be published in a scientific journal or presented at a conference. However, your results will be completely anonymous in this forum. All the data collected from the wearable technology will be stored on a secure UHI server. The data will not be passed on to 3rd parties in respect of the use of data for secondary research purposes. The data collected for the study may be used for further research, follow-up research or for secondary research outside of this research project.

The following are your rights in respect of this processing:

- The right to access your personal data
- The right to rectification if the personal data we hold about you is incorrect
- The right to restrict processing of your personal data
- The right to request erasure (deletion) of your personal data, noting that under GDPR provisions there are certain points at which data (even if requested) may not be deleted, e.g. following an actual publication of the results in a journal or other form (as the data will already be in the public domain), or at later stages of the research project
- The right to data portability

You also have the right to lodge a complaint with the Information Commissioner's Office about our handling of your data.

I think I may be interested in taking part, what should I do?

Please ensure that you have read the above information thoroughly. If you have any questions about the information within this document, then please do not hesitate to contact the Principal Researcher (please see contact details below).

You will be asked to visit the Active Health Exercise Lab, Inverness to discuss the study, have your height and weight measured to calculate your BMI and complete questionnaires. If you are deemed eligible to participate (please see inclusion and exclusion criteria above), then you will be asked to give informed consent before any further data are collected.

Thank you for taking the time to read this information sheet. Please feel free to contact the Principal Researchers should you have any questions related to this study.

Who is organising and funding the research?

The study is being carried out by the University of the Highlands and Islands, Division of Biomedical Sciences. The exercise classes are being developed and provided by High Life Highland.

I have some questions about the study

For more information around the study or to ask any questions you have please contact:

Dr Daniel Crabtree by emailing: daniel.crabtree@uhi.ac.uk

Further contact details

If you have any questions/concerns, during or after the research project or wish to contact an independent person to whom any questions may be directed please contact:

University of the Highlands and Islands Research Ethics Committee (REC)
UHI Research Ethics Officer
University of the Highlands and Islands, 12b Ness Walk, Inverness, IV3 5SQ.
Telephone: 01463-279349
Email: research.ethics@uhi.ac.uk

This investigation was granted ethical approval by the University of Highlands and Islands Research Ethics Committee and/or Faculty Research Ethics Subcommittee on [insert date]