



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

Participant Information Sheet

Department: The Centre for Health Science, Division of Health Research.

Title of Study: Physical activity monitor validation study

Date: _____

Introduction

The University of the Highlands and Islands are conducting a new research study. We are investigating how accurate various activity monitors are during a range of activities. The study is led by Dr Daniel Crabtree, Dr David Muggeridge and Dr Trish Gorley.

What is the purpose of this study?

Monitoring physical activity has become a key element of public health practice due to the substantial health benefits associated with PA. Wearable monitors are being used increasingly to monitor physical activity in research studies within the field of exercise and health science. Physical activity-related interventions are using activity trackers for self-monitoring, goal-setting, and measurement. Before more widespread use of these trackers occurs in research studies, for either intervention or measurement purposes, it is important to establish their accuracy and consistency.

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.

What will you do in the project?

As a participant you will be asked to visit the Centre for Health Science, Inverness on two separate occasions, with each visit lasting approximately 2 hours. Please avoid caffeine and alcohol ingestion and exercise in the 24 hours before each visit. We will also ask you to wear a range of activity monitors for three days during your normal daily life.

Protocol:

When attending your initial visit (**Visit 1**), you will be asked read and sign a participant information sheet. We will then ask you to provide written informed consent before any data collection takes place. Following this, we will perform initial measurements that include

measures of your height, weight, body fat percentage, muscle mass, and blood pressure. We will then place activity monitors on your thigh, wrist, chest and waist. We will also attach a mask to your face where we will monitor your breathing

You will then partake in three sedentary activities. These activities will include no task, TV watching and completion of a cognitive task (e.g crossword or puzzle). During these activities you will be required to be seated. Following the sedentary tasks we will ask you to cycle on a stationary bike for 5 minutes at two different intensities. Lastly, we will ask you to walk, jog and run on a treadmill. During the treadmill task the intensity will get progressively harder until volitional exhaustion. Throughout all activities we will monitor the air you breathe in and out via the facemask attached to computer hardware and they physical activity monitors will continuously monitor your movement.

Following the treadmill task we will remove the facemask but you will continue to wear the activity monitors. We will ask you to continuously wear the devices for three days before returning to the lab. During the three days we will also ask you to record your physical activity, sleep cycle and any non-wear of the devices.

After three days we will invite you back to the laboratory to complete **Visit 2**. During visit 2 you will be monitored in the same way as visit 1, however the activities you perform will be different. Firstly, we will ask you to perform four high intensity sprints each lasting for 30 seconds on a stationary bicycle. After each sprint you will get 3 minutes to recover before completing the next sprint. After the 4th sprint we will ask you to sit down for 30 minutes. We will continue to monitor your expired air throughout these 30 minutes. You will then perform four high intensity sprints on the treadmill. Again, you will have 3 minutes of recovery between each sprint. Following the final sprint we will ask you to rest in a seated position for another 15 minutes before being free to leave the laboratory.

Why have you been invited to take part?

You have been invited to take part in this study because you have volunteered and because you meet the requirements of the following inclusion/exclusion criteria:

The inclusion criteria are:

- Males and females
- Aged 18-60 years
- Moderate to high level of physical activity

The exclusion criteria are:

- Low level of physical activity
- Chronic medical condition (e.g. cardiovascular disease, cancer, respiratory disease)
- Currently recovering from a lower body injury
- Illness in the past 6 weeks

What are the potential risks to you taking part?

The exercise testing requires the participant to apply maximum effort and, as a result, there are potential risks. The risks include abnormal heart beats, abnormal blood pressure responses, muscle cramps, muscle strain and/or joint injury, delayed muscle soreness (1 to 2 days afterwards), light headedness and fatigue.

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

1. wear appropriate exercise clothes and shoes for testing
2. be well nourished and hydrated prior to testing
3. avoid alcohol within 12 hours of testing and food and caffeine within 3 hours
4. be rested and avoid significant exertion or exercise for 24 hours prior to your test
5. report any medication use to the researcher prior to testing

You will also complete a warm up prior to testing and a cool down after testing. If at any stage of the test you request to stop the test, the researcher will immediately cease testing.

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

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 test; THE TEST SHOULD BE TERMINATED IMMEDIATELY. Alert a member of staff immediately.

What happens to the information in the project?

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 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. 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.

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
- 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.

What happens next?

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 Researchers (please see contact details below).

You will be asked to complete a personal details form and a physical activity questionnaire, please return these to the Principal Researchers. If you are deemed eligible to participate (please see inclusion and exclusion criteria), then you will be asked to visit the Centre for Health Science to complete visit 1. You will be asked to give informed consent before any data are collected.

Following your participation in the study, you will be provided with feedback, including information about your body weight, body mass index, body fat, muscle mass, blood pressure and fitness status (VO₂max).

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.

Contact details

If you have any questions or concerns regarding the research project, you may contact:

Principal Researchers

Dr Daniel Crabtree / Dr David Muggeridge

Centre for Health Science

Old Perth Road

Inverness

IV2 3JH

daniel.crabtree@uhi.ac.uk / david.muggeridge@uhi.ac.uk

+44(0)1463 279405 / +44(0)1463 279569

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 (FREC)

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 (delete as appropriate) on date_____.

----- Name of volunteer	----- Date	----- Signature
----- Name of person taking consent	----- Date	----- Signature

Please retain one copy of the Participant Information Sheet for the Participant and one for the Researcher.