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

Participant Information Sheet

Department: The Centre for Health Science, Division of Biomedical Sciences.

Title of Study: Does polyphenol supplementation suppress the increase in oxidative stress and inflammation caused by reduced physical activity?

Date:_____

Introduction

My name is Dr Daniel Crabtree and I am a Research Fellow in Physical Activity from the Centre for Health Science at the University of the Highlands and Islands. The study also involves co-investigators, Professor Ian Megson, Dr Katarzyna Goszcz, Dr James Cobley, Dr David Muggeridge, Mrs Kirsty Hickson (Registered Dietician) and Dr Trish Gorely from the Centre for Health Science at the University of the Highlands and Islands.

What is the purpose of this study?

We are undertaking a research study investigating the role of diet during a period of reduced physical activity. The title of the study is: Does polyphenol supplementation suppress the increase in oxidative stress and inflammation caused by reduced physical activity?

Periods of reduced physical activity because of, for example, limb immobilization or bed rest, have been associated with an increased risk of developing metabolic diseases. However, nutrients found in our diet can contribute towards preventing such harmful health conditions, including the nutrient, 'polyphenol', which can be found in plant-based foods (i.e. fruit and vegetables).

We are investigating if polyphenol supplementation, during 1-week of step-count reduction, protects against the negative health consequences associated with decreased physical activity compared to a placebo supplement.

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 4 occasions, with each visit lasting between 1-2 hours. We will ask you to stop eating and only consume water twelve hours prior to your arrival at the Centre for Health Science for visits 2, 3 and 4. In addition, we will ask that you refrain from caffeine, strenuous exercise and alcohol 24 hours prior to visits 2, 3 and 4.

Initial/baseline measurements:

During **visit 1** you will be asked to provide written informed consent and read and sign the participant information sheet before any data collection takes place.

You will be asked to record your step-count and diet for a period of 7 days (baseline step-count and diet). You will be given a physical activity monitor to measure your step-count and a diet diary with a set of kitchen scales to record your diet. You will be asked to limit your tea and coffee intake to a maximum of 4 cups per day and limit your dark chocolate and red wine intake during these 7 days and for the remainder of the study. In addition, if you are currently consuming a dietary supplement, then you will asked to refrain from consuming the supplement during these 7 days and for the reminder of the study.

Step-reduction intervention:

Following the 7 day physical activity and diet recording period, you will return to the lab **(visit 2)**. A small blood sample will be taken to measure several substances within the blood that are of interest to this study. In addition, one of the substances in the blood that we are interested in can be measured without blood sampling using a non-invasive device placed on the skin called an AGE reader. You will also undertake initial measurements that include height, weight, body fat, muscle mass, blood pressure and mood. Furthermore, we will assess your muscle function by measuring your handgrip strength and your one repetition maximum during a leg press and leg extension exercise. In addition, you will complete two short physical fitness assessments on a stationary bike. The first test will require very little exertion (i.e. easy to breath and carry a conversation), whereas the second test will require greater effort (i.e. vigorous breathing and difficulty talking). Two further blood samples will be taken after the exercise tests.

You will be randomly allocated to either the experimental group (polyphenol dietary supplement) or the control group (placebo dietary supplement). Regardless of which group you are assigned to, you will reduce your step-count by 75% of your baseline average for 7 days (i.e. if your baseline step-count average was 10 000 steps per day then you will be asked to reduce your step-count to 2500 steps per day for 7 days). You will maintain your baseline diet and will also consume either a polyphenol dietary supplement or a placebo dietary supplement, depending on your group allocation. The supplements will be consumed as one capsule one hour after your breakfast and another capsule one hour after your dinner, both with a glass of water. Independent of which group you are allocated to, you will also complete the mood questionnaire on the evening of each day, at the same time of day, and complete a 3-day (including 1 weekend day) diet diary.

You will be asked to consume your final capsule 12 hours prior to **visit 3**. During Visit 3, one small blood will be taken and AGE reader, body weight, body fat, muscle mass and blood

pressure measurements will be taken. You will also be asked to complete a mood questionnaire and complete the strength and fitness tests again.

Return to normal activity:

Following visit 3, you will increase your step-count back to your baseline step-count average for 7 days. If you are in the experimental group, you will continue to consume the polyphenol supplement and if you are in the control group, you will continue to consume the placebo supplement. In addition, you will complete the mood questionnaire on the evening of each day, at the same time of day, and complete a 3-day (including 1 weekend day) diet diary.

You will be asked to consume your final capsule 12 hours prior to **visit 4**. During Visit 4, one small blood will be taken and AGE reader, body weight, body fat, muscle mass and blood pressure measurements will be taken. You will also be asked to complete the mood questionnaire and complete the strength and fitness tests again.

You will be informed about which supplement you were taking (polyphenol or placebo) following your completion of the study.

Why have you been invited to take part?

I am looking for volunteers to participate in the project.

The inclusion criteria are:

- Males
- Aged 18-30 and 50-65 years
- Moderately active (i.e. participating in activities that take moderate physical effort and make you breathe somewhat harder than normal), as determined by a physical activity questionnaire

The exclusion criteria are:

- Physically inactive or high level of physical activity, as determined by a physical activity questionnaire
- Currently taking medication to control a long-term medical condition (for example, cardiovascular disease, cancer, diabetes, autoimmune disease)
- Currently recovering from an injury, which has reduced your physical activity
- Illness in the past 6 weeks

What are the potential risks to you taking part?

There is a small risk of some slight bruising where blood will have been taken. However, every caution will be taken to ensure minimal bruising.

If, when you are required to reduce your daily step-counts for 1 week, you feel unwell or weak, you will be advised to stop the study, continue with your normal daily routine and to contact your GP. In addition, following the week in which your step-count will be reduced, you may experience a small reduction in your physical fitness, however, this is reversible. You will

complete fitness tests during visit 2 to establish your baseline fitness and the tests will be repeated twice following the step-reduction week. If, having completed the study, your fitness has not returned to baseline fitness levels, then support will be offered to enable a complete recovery.

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

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 on participants 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 (see Introduction) will have access. 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. Paper-based data will be stored in a locked filling cabinet to which only the main investigator (Dr Daniel Crabtree) will have access. These data, including blood samples, will be kept until the end of the research process, following which all data that could identify you will be destroyed.

The results may be published in a scientific journal and presented at scientific conferences and public engagement events. However, your results will be completely anonymous.

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 Researcher (Dr Daniel Crabtree), please see contact details below.

If you are interested in participating in the study, you will be asked to complete a personal details form and a physical activity questionnaire, please return these to the Principal Researcher. 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. During visit 1, you will be asked to give informed consent before any data are collected. If you do not meet the eligibility criteria for the study, then the information you have provided within the personal details form and the physical activity questionnaire will be destroyed.

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, physical fitness, diet and blood pressure.

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

Contact details

If you have any questions/concerns/complaints during or after the research project, you may contact:

Principal Researcher
Dr Daniel Crabtree
Centre for Health Science
Old Perth Road
Inverness
IV2 3JH
daniel.crabtree@uhi.ac.uk
+44(0)1463 279405

Further contact details

If you have any questions/concerns/complaints, during or after the research project and 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 on February 26th 2018.

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

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