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: Calorie Restriction Diets in Obese Males – Effects on Circulating Vasculogenic Cells.

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 Andrew Treweeke and Mrs Kirsty Hickson from the Centre for Health Science at the University of the Highlands and Islands, Professor Stephen Leslie from NHS Highlands, Dr Mark Ross from the Department of Sport, Exercise and Health Science at Edinburgh Napier University and Mr Fraser Hinchliff (MSc student) from the University of Aberdeen.

What is the purpose of this study?

We are undertaking a research project in the role of diet and cardiovascular health. The title of the project is: Calorie Restriction Diets in Obese Males - Effect on Circulating Vasculogenic Cells.

Calorie restriction diets have become very popular in those looking to lose weight. This may also have a beneficial impact on cardiovascular health by reducing metabolic stress on the body.

Circulating angiogenic cells (CAC) are a population of cells that circulate in the blood and positively affect blood-related health by maintaining blood vessel strength. These cells are affected by metabolic stress and those who gain weight show reduced number and function of these cells. We are investigating if calorie restriction diets (5:2 diet, 8-weeks long) can positively affect these CACs as well as body weight and blood pressure in overweight males.

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. You will be asked to come in for visit 2 and 3 after an overnight fast and having refrained from caffeine, exercise and alcohol the 24 hours prior.

Visit 1:

You will undertake initial measurements that include height, weight, waist and hip and blood pressure, in addition to completing two health questionnaires. You will then be randomly assigned to either the experimental group or the control group. The experimental group will follow a calorie restricted diet for 8 weeks (please see below for details) and the control group will continue to follow their usual diet for 8 weeks. You will also be given a 7-day diet diary to complete the following week. This visit should take no longer than one hour.

Visit 2:

During visit 2, you will be asked to report to the Centre for Health Science after an overnight fast and having refrained from caffeine, alcohol and exercise for 24 hours prior to the visit. A small blood sample will be taken to measure several substances within the blood that are of interest to this study. Body fat and muscle mass measures will also be taken. In addition, you will be given 3 x 7-day food diaries and questionnaires related to your appetite (i.e. feelings of hunger and fullness) to complete during week 1, week 4 and week 8 of the study.

Visit 3 (optional):

Visit 3 will take place 4 weeks into the 8-week diet. During visit 3 you will be asked to report to the Centre for Health Science after an overnight fast and having refrained from caffeine, alcohol and exercise for 24 hours prior to the visit. Height, weight, body fat and muscle mass, waist and hip circumference and blood pressure will be measured.

Visit 4:

Visit 4 will take place following the 8-week diet. During visit 4, you will be asked to report to the Centre for Health Science after an overnight fast and having refrained from caffeine, alcohol and exercise for 24 hours prior to the visit. A small blood sample will be taken to measure several substances within the blood that are of interest to this study. Height, weight, body fat and muscle mass, waist and hip circumference and blood pressure will be measured.

The experimental group diet:

After visit 2, you will be asked to undertake an 8-week dietary regime (5:2 diet whereby you choose 2 non-consecutive days of your normal week and consume only 25% of your normal calorie intake, as calculated by us, and during the remaining 5 days you may consume whatever foods and drinks you want). For the 8-week dietary intervention, you will be given suggestions

for meals for your 2 chosen, non-consecutive, calorie restricted days (these days are not to be the same as any day you are operating heavy machinery or planning strenuous activity).

The control group diet:

After visit 2, you will be asked to maintain your normal diet for a period of 8 weeks.

Why have you been invited to take part?

I am looking for volunteers to participate in the project.

The inclusion criteria are:

Overweight Males (BMI>30 kg/m^2) aged 30-40 years.

The exclusion criteria are:

- Body Mass Index of less than 30 (measured in the laboratory through height and weight measurements) and smokers
- Taking medication affecting the immune system
- Routinely using ibuprofen and/or aspirin, anti-depressants, and/or medications designed to alter blood pressure or cardiovascular function and hormone replacement therapy will be excluded from the participant population, as these may affect results of the study
- Participants also reporting major affective disorders, HIV infection, hepatitis, chronic/debilitating arthritis, central or peripheral nervous disorders, previous stroke or cardiac events, were bedridden in the past 3 months, suffer from known cardiovascular disease or autoimmune diseases will all be excluded from the study
- Participants with current cardiovascular disease (CVD), diabetes or neurological disorders
- Participants must also be free from infectious disease for 6 weeks prior to study
- Participants currently following a dietary regime designed to promote weight loss
- Physically active >2 x per week of structured exercise

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, on a calorie restriction day, you feel unwell or weak, you will be advised to stop the diet and continue your normal diet.

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. 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 or presented at a conference. 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.

You will be asked to complete a personal details form and return this 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 for additional eligibility screening (please see Visit 1). You will be asked to give informed consent prior to the additional eligibility screening and, should you be eligible, any other procedures proceeding that.

Following your participation in the study, you will be provided with feedback, including information about your body weight, body mass index, body fat and muscle mass, 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 or concerns regarding 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, 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 on October 23rd 2017.

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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.