LIVERPOOL JOHN MOORES UNIVERSITY
PARTICIPANT INFORMATION SHEET

Study Criteria

Inclusion:

- Aged 18-55 years
- Healthy
- Willing to participate

Exclusion:

- Smokers
- Medical history of cardiovascular/metabolic disease, including diabetes and high blood pressure.
- Family history of cardiovascular disease (first degree relatives)
- On medication known to influence the cardiovascular system
- BMI of <18 or >30 kg/m^2
- Known food allergies or special dietary requirements
- Vaccination (<1 week) due to induced systemic inflammatory reaction

Title of Project

Does acute oral epicatechin ingestion have a beneficial effect upon cerebrovascular function in healthy adults?

Name of Researcher and School/Faculty

Principal Investigator: Kirsty Roberts
Research Supervisors: Dr David Low, Dr Nicola Hopkins, Prof Dick Thijssen
School: School of Sport and Exercise Sciences
Liverpool John Moores University
Contact details: k.a.woodward@2014.ljmu.ac.uk

You are being invited to take part in a research study. Before you decide it is important that you understand why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not.

1. What is the purpose of the study?

Consumption of foods high in flavonoids such as fruit, vegetables, tea and cocoa, have shown positive effects on cardiovascular health, particularly in helping to lower blood pressure and improve vascular function. However, little is known about the impact of flavonoids on cerebral blood flow which is important for overall cardiovascular health and cognitive function.

This research study will investigate the acute effect of the flavonoid “epicatechin” (found in tea and dark chocolate) on cerebral blood flow and cognitive function in 20 healthy adults.

2. Do I have to take part?

No, it is entirely up to you to decide whether you want to take part in the study. If you do, then you will be asked to complete a medical information form to assess whether you are suitable for the study, and an informed consent form. You are free to withdraw from the study at any point without giving a reason and your status will not be affected should you wish to take part in any future studies/treatments.

3. What will happen to me if I take part?

Before participation, you will be required to complete a health questionnaire to determine whether you are eligible to take part in the study. We will exclude people with a history of cardiovascular disease, high blood pressure, high cholesterol, diabetes, food allergies or special dietary requirements and/or smokers. No information from this screening will be shared and the data will be securely stored and destroyed after the study has finished.

The questionnaire will be followed by a full verbal explanation of all of the different tests and procedures. If you would like to participate in the study you will also be asked to sign a consent form. Subsequently, we will plan the testing days.

The study involves **3 separate visits** to the physiology laboratory in the Tom Reilly Building, Byrom Street, Liverpool John Moores University: 1 familiarisation session and 2 laboratory visits.

Familiarisation session: you will be shown the equipment that we will use to measure cerebral blood flow and a computerised memory task that you will be asked to complete during each laboratory visit will be demonstrated.

Laboratory visits: the procedures you undergo during each testing session are exactly the same. **Each visit will last for approximately 4 hours**.

Before each visit, we will ask you to undertake an overnight fast (>10 hours). However, it is important that you remain hydrated by drinking plenty of water. You will also be asked to abstain from alcohol and to avoid vigorous exercise for 24-hours before testing.

On arrival to the laboratory, we will perform baseline measures of cerebral blood flow and you will be asked to complete a computerised memory task, before you are asked to consume 2 capsules of the test product which contain a total of 100mg of epicatechin or placebo (microcrystalline cellulose) and a glass of water. You will then be asked to relax for 2-hours, during which time you may read or watch television on an iPad. After 2-hours, we will repeat the cerebral blood flow measures and computerised memory task. You may take comfort breaks as necessary during the lab visits.

During each visit, we will assess the following:

- **Height and weight** – will be measured by standing on a stadiometer and electronic scales, respectively.

- **Blood pressure** – a very small cuff will be placed around the middle finger and inflated to a low pressure to obtain continuous measurements. We will also measure blood pressure from a cuff placed around your upper arm at intervals throughout your laboratory visit.
- **Cerebral blood flow** - Ultrasound probes will be placed on the temple of the head and held in place with a head band (Figure 1). You will wear a mouthpiece which measures the amount of air that is breathed in and out. Whilst we are measuring the blood flow to the brain, you will be asked to undertake a series of sit-to-stand movements (2 blocks of 5-min each). Following this the amount of oxygen and carbon dioxide which you are breathing will be altered slightly by you breathing more quickly for a short period of time (approx. 1-min) and breathing air with extra carbon dioxide so we can measure how brain blood flow responds.
- **Cognitive function** - you will be asked to complete a short computerised working memory task during the baseline measures and 2-hours following consumption of the test product. This test will be demonstrated to you at the familiarisation session.

Figure 1. Measurement of brain blood flow

4. Are there any risks / benefits involved?

You will receive a £50 Amazon voucher for your participation in this study.

If we find that you have any results that are outside of the normal range for a healthy population, we will advise you of these results and recommend you to visit your GP for further advice.

There are no known side effects or contraindications associated with ingesting the dose of the test supplements. The headband worn during brain blood flow measurement can be a little tight and can therefore cause some slight discomfort; a familiarisation session will be offered to potential participants, to confirm whether or not they wish to continue with the study. You may feel slightly dizzy during these tests, although this is unlikely. There are no other known side effects from the test product or the study.

At any time during the experiment, you are free to voluntarily terminate the procedure and stop the experiment. There are no benefits associated with participating in this study, but

the data will be useful for researchers investigating the effects of flavonoids on cardiovascular health.

5. Will my taking part in the study be kept confidential?

All the information collected will remain strictly confidential and confidentiality will be maintained in any reports generated. All data will be anonymised. All information and data will be stored in accordance with the current Data Protection Act. A secure site for data storage will be used within the Research Institute for Sport and Exercise Science, Liverpool John Moores University and data will be stored for a period of 5 years. All computer files will be password protected and subject identities coded so that the investigators alone can gain access to participant information and data cannot be traced back to any participant. The personal/contact details will be stored separately from the health screening information. We will not disclose individual results to anyone unless you specifically request such information that is relevant to you. However, we will combine all the results from the many participants taking part in the study, and publish any important results in medical journals and in the departmental reports. This will not affect the security of the information given for this study and confidentiality will be maintained.

What to do if you wish to take part?

If you do wish to take part in this study, please contact the principal investigator (by email or telephone, given below). Please note that you are free to withdraw from this project at any time. Furthermore, signing the consent form does not release or waiver any rights that you have. Participation in this investigation is voluntary and you have the right to withdraw from this investigation at any point with no explanation.

Kirsty Roberts
Principal Investigator
k.a.woodward@2014.ljmu.ac.uk

This study has received ethical approval from LJMU's Research Ethics Committee (17SPS013).

If you any concerns regarding your involvement in this research, please discuss these with the researcher in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.