

Participant Information

You are being invited to take part in a research study. Before you decide to take part it is important you understand why the research is being done, and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

What is the purpose of this study?

Our previous work has shown that a juiced blackcurrant extract can inhibit enzymes which play a major role in preserving normal brain function. These enzymes are called monoamine oxidase (MAO) A and B. However, a commercially available powdered blackcurrant extract had no impact on the activity of the enzymes. The extract was heavily processed and fortified, a process which potentially denatures the enzyme inhibiting compounds. These data illustrate that the degree of processing may alter the benefits of berry fruit, a factor which is crucial when developing a potentially neuro-protective extract which is both stable and accessible for use in further chronic nutritional interventions.

Can I participate?

For this study we are looking for adults who are aged between 18 & 35 and generally healthy. Participants will be required to attend visits at the NU-Food research facility, Newcastle University. Participants are not able to participate if they are; pregnant, currently taking over the counter or prescription drugs, consume

vitamin or nutritional supplements, have a BMI above 40m², have a sensitivity to any of the ingredients in the trial drink or suffer from any known learning disability. All inclusion and exclusion criteria will be discussed and confirmed during your screening visit.

Do I have to take part?

It is up to you to decide whether or not to take part. On reading this information sheet if you are interested in taking part, you will first be asked to attend a 'Screening Visit' where we will find out if you meet the specific requirements for being a volunteer for this study. If you do, you will be asked to sign a consent form. However, you will be free to withdraw from the study, without having to give a reason, at any time up to the end of your final visit.

What will happen to me if I take part?

If you decide to take part and you are a suitable volunteer for the study, you will be asked to consume a drink made from a freeze dried blackcurrant powder and a control drink made from sugar and water.

What else do I have to do?

If you agree to take part we will ask you to visit **Newcastle University's NU-Food Facility in the Agriculture Building**. The first visit is the 'Screening Visit' where we will ask you some questions about your general health and eating habits. During this visit you will be briefed on the aims and objectives of the study and invited to ask any questions you may have. If you are suited to take part in the study, you will then be asked to attend 3 further sessions in the NU-Food facility each lasting 5 hours. On each of these visits you will be asked to arrive in the NU-Food research facility at 8:30am after a 12 hour fast. A 10ml venous blood sample will be taken by a trained

phlebotomist. You will then be asked to complete a 20 minute set of computer tasks designed to assess your attention and memory.

You will then be asked to consume one of 3 drinks on each day. There are 2 drinks which contain differing amounts of blackcurrant powder and a sugar matched placebo drink.

Further 10ml blood samples and cognitive measurements will be taken at 60min and 4h post treatment consumption. You are free to leave the research centre and eat and drink as you wish during the 3h between the 60min and 4h period, during this time you will be asked to complete a food diary. Each of the three study visits will be separated by one week.

What are the possible disadvantages and risks of taking part?

We are not aware of any risks or disadvantages of this study, other than the inconvenience of attending the visits.

You will be asked to give 3 venous blood samples per visit so there is a risk of localised bruising and momentary pain during the procedure. The research centre has experienced phlebotomists who will make the procedure as comfortable for you as possible.

What are the possible benefits of taking part?

You will be able to try a product which may have a positive effect on your physiological status, such as mood, attention and cognitive function.

You will receive a £25 Eldon Square voucher as a thank you for taking part.

What will happen if anything goes wrong?

First aid trained staff are on duty in the facility to provide immediate care during the very unlikely event of an adverse event during a study day visit.

Any complaints you have about this study should be made to Dr Anthony Watson Newcastle University (anthony.watson@ncl.ac.uk or 0191-208 8935) and will be fully investigated.

Will my taking part in this study be kept confidential?

Any information, which is collected about you during the course of the research, will be kept strictly confidential.

What will happen to the study results?

When the study is completed, the data will be anonymised, so we will no longer be able to link specific data with any one person. We will then carry out statistical analysis to determine how much effect consumption of the blackcurrant extract had upon MAO activity. Once the study results are published, we will send you a summary report of the results, and, if you wish, a copy of the publication, as well as answer any questions you may have about the outcomes. However, this may take a number of years after the end of study. In any case we will still send you a summary of our findings in a layman's language.

Who is organising and funding the study?

The study is organised by Newcastle University and is part of the research activities/ projects of our academic staff.

Who has reviewed the study?

This study has been reviewed by Newcastle University's SAE Faculty Ethics Committee.

Finally, thank you very much for having taken the time to read this information sheet and for your interest in the study.

Overview of the trial

- 3 study visits each lasting 5 hours (only in the facility for 2)
- 2 different strengths of blackcurrant drink and a placebo
- 3, 10ml blood samples per visit
- 3 assessments of attention and memory per visit
- 3 hour food diary



Assessing the effects of the consumption of a freeze dried blackcurrant powder on MAO-B activity in healthy adults

Information Sheet for Volunteers

Newcastle University
School of Agriculture, Food & Rural Development
Agriculture Building
Newcastle upon Tyne
NE1 7RU

Research team: Olivia Hughes
Anthony Watson

Telephone: 0191 208 3592
e-mail: nu.food@ncl.ac.uk

