Participant Information Sheet

Can a blackcurrant extract improve daily blood sugar control?

Location(s):
School of Sport & Exercise Sciences, Liverpool John Moores University

Investigators:
Mr Andrew Nolan, Dr Sam Shepherd, Dr Juliette Strauss, Dr Matthew Cocks, Prof Claire Stewart

You are being invited to participate in a research project. However, before you give consent to participate in this study, it is important that you completely understand why this research is being completed and what will be required of you. Please ensure that you take time to read through this information sheet. If there are any areas that are not clear, or that you would like more information on, feel free to contact the researchers who will be happy to provide this information for you.

What is the purpose of the study?

Increased sedentary time combined with regular consumption of high energy foods have been shown to increase the risk of obesity and type 2 diabetes. Research has shown that modern working environments contribute to this issue by reducing physical activity in the workplace. These long periods spent sitting can lead to an inability to effectively manage blood sugar following a meal, which has been shown to be a major risk factor in the development of metabolic complications.

Interest in the bioactive compounds found in plant based foods has increased recently; primarily due to their ability to improve disease risk. Anthocyanin, a subclass of flavonoids found in New Zealand Blackcurrant (NZBC) has been shown to have anti-inflammatory and antioxidant properties as well as being able to control the digestion of sugar following a meal. As such, anthocyanins may be able to positively affect health. Therefore, this project aims to see if 7 day supplementation of NZBC is effective at improving blood sugar control under free-living conditions.

Who can take part?

You are likely to be eligible for this study if you fulfil the following criteria:

- Aged 20-55 years
- Overweight/obese (BMI >25 $kg.m^{-2}$)
- Healthy (no known cardiovascular diseases)
- Not simultaneously taking part in another scientific/clinical study
- Not involved in regular structured activity (i.e. engaged in 1 h or less per week for at least 1 year).
- Not currently consuming a high polyphenol diet (this will be determined at the initial meeting with the researcher).

Meeting any of the following criteria will prevent you from participating in the study: pregnancy, breastfeeding, individuals with a blackcurrant allergy, metabolic or cardiovascular disease.

Do I have to take part?

No. Taking part in this study is entirely voluntary. If you would like to participate you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw will not affect your rights, or any future treatment or service you receive.

May I be excluded from the study?

Yes. You can be excluded from the study at any time point if you do not adhere to the study conditions.

What will happen to me if I take part?

If you agree to take part in the study, you will first be required to attend the Tom Reilly Building for a short meeting (~20 min). In this meeting, you will initially have an opportunity to ask any questions about the study before being asked to provide written, informed consent for the study (although you may take longer if you wish). We will then ask you to complete questionnaires about your general health, levels of physical activity, and dietary habits. Your height and weight will also be measured, and body composition assessed using bioelectrical impedance which determines fat and lean tissue mass through electrical resistance. This requires you to stand on a set on scales, which will direct a small unnoticeable electric current through your body and will determine the amount of different tissue (muscle, bone, fat) based on the level of resistance to the current. Finally, we will provide you with a 3 day food diary to complete and return to the research team.

Following this meeting you will be asked to undertake 2 experimental trials (separated by a minimum of 2 weeks). Each trial will be identical in all respects except for the supplement provided to you. The experimental trial is detailed below.

Experimental protocol:

Visit 1: On day 1, you will attend the laboratory in the morning without having consumed breakfast and a blood sample (10ml, equivalent to half a tablespoon) will be taken from a forearm vein of one arm. After this you will be fitted with a commercially-available continuous glucose monitoring system (CGMS). A small sensor will be inserted under the skin on your arm by a researcher to check glucose levels in tissue fluid (see picture). These are designed for self-monitoring of glucose levels in people with diabetes and are therefore designed for comfort and convenience. Furthermore, medical practitioners are not required to insert or remove them.
The sensor will stay in place for 8 days. You can exercise while wearing the monitor, with the exception of any watersports (e.g. swimming). You can however shower with the CGMS device as it will be shielded from this type of contact with water. You will also be given a week's supply of NZBC or placebo capsules (detailed below).

Visit 2: On day 7 you will attend the laboratory in the morning without having consumed breakfast and a cannula (small flexible tube) will be inserted into a forearm vein of one arm to allow us to obtain blood samples at various time-points. After the first blood sample sample (10 ml, equivalent to half a tablespoon) you will consume a standardised drink replicating a mixed meal, and additional blood samples (5 ml, equivalent to a teaspoon) will be taken after (15, 30, 45, 60, 90, 120, 150 and 180 min). After this test, you will remain in the Tom Reilly building for the remainder of the day. During this time, you will have access to an office so that you can complete your usual working tasks (equipped with a desk, computer and networked phone). Lunch will be provided to you at ~12.30pm and will consist of foods you habitually eat (detailed below). You will be able to leave the laboratory at ~4.30pm and we will also provide your evening meal.

On day 8, you will also consume a standardised diet (as detailed below) but are otherwise able to undertake your daily tasks. On day 9 the CGMS will be removed, which can be done by you and will simply involve pulling the monitor off the skin and disposed of with normal household waste. The removal will not cause any bleeding and will not require treatment of the wound.

Supplement
During the trial, you will ingest two 300mg capsules of NZBC extract per day for 8 days. Each daily dose is equivalent to 166 blackcurrants. This dose provides over four times the amount of blackcurrants typically ingested by the average person in a normal day. The placebo will be microcrystalline cellulose, a product made from refined wood pulp, usually used as a bulking agent in, for example, vitamin supplements. Neither you nor the investigators will know whether you are ingesting the NZBC extract or the placebo. You will take the capsules daily with a glass of water. Between experimental trials, there will be a minimum washout period of two weeks.

Dietary control

All food for days 7 and 8 will be provided to you by the research team as pre-packaged meals. You must consume only the food provided during this period. The amount of food we provide will be based on the amount that you normally eat (which we will work out using your 3 day food diary), but consist of recommended daily allowances of carbohydrate (50%), fat (30%) and protein (20%). The diet will also contain low amounts of flavonoids. The diet will be replicated across all experimental trials. You will be informed of any food that requires storage in a refrigerator or special cooking instructions.

Risks:

The most obvious risks to you involve blood sampling, continuous glucose monitoring and consumption of the New Zealand Blackcurrant extract. If at any point during the protocol you feel uncomfortable or unable to continue, testing will be ceased immediately.

Blood sampling:

Blood samples will be taken on several occasions. You will feel a sharp pain when the needle is inserted but this will be short-lived. The researchers are also experienced in this technique so the pain experienced will be minimal. You may also develop a small bruise on your arm, which can be prevented by applying pressure on the arm when the cannula has been taken out (the researcher will remind/instruct you to do this). A finger prick blood sample will be taken from one finger. You may experience some sensitivity where the blood sample is taken, but this will be short-lived and normally only last ~24 hours. It is also possible that the mixed-meal test may reveal an abnormal result. In this case, the abnormal result will be communicated to you, and we will advise you to make an appointment with your GP.

Continuous glucose monitoring (CGM):

CGM is a sensor that is worn continuously (on the arm) for up to two weeks. It continuously records blood sugar levels and stores it in its memory so that it can be downloaded and analysed by us later. It will tell us how this diet affects your sugar levels. It is a little painful to insert (like having a blood test), but once it is inserted, a small fibre remains underneath the skin while the sensor itself sits comfortably on your skin without problems. You can wear it in the shower or when playing sports. When used in studies of up to 50 diabetic people, about 3 of them developed redness at the site, about 1 of them developed a small bruise, and none of them got an infection – so this is a safe procedure due to the precautions taken by the researchers during the insertion process (and you are extremely unlikely to get an infection). If any adverse reactions become apparent by you or the researchers then you will be withdrawn from the study and advised to contact a doctor.

Supplement

Although unlikely, there is a small chance of an allergic reaction in response to the supplement. During visit 1 you will be asked about your allergy history, and the Research Team may deselect you for the study if you are especially allergy prone. Symptoms of an allergic reaction may include; sneezing, wheezing, runny nose, coughing, nettle rash (hives) swelling, itchiness (eyes, lips throat or roof of mouth), shortness of breath and sickness. The supplement should be kept out of the reach of children, and stored in a dry place. These instructions will be written on the container that we provide the supplement in. If you experience any symptoms or are concerned after taking the supplement we recommend you stop taking the supplement and contact the Research Team and your GP. If for any reason you visit your GP during the course of the study, we advise that you tell your GP that you are taking the supplement in order that your GP can make an informed decision about any subsequent treatment.

Reimbursement

We will reimburse you £50 for your time spent taking part in the research, including travel expenses. This will also be the case even if you do not complete the study. This can be claimed through completion of the standard University claim form (please ask a member of the research team for more details).

Confidentiality:

All data and samples will be labelled with a code, not with your name. Only the research team which is in contact with you has access to the link between the code and your name. The results of this study are expected to be published in a scientific journal, but names of participants will never be published.

Rights:
It is your choice whether or not you wish to take part in this study. If you wish to take part in this study, you will be given this information sheet to read and be asked to sign a consent form. You are reminded that if you decide to take part in the study, you are still free to withdraw at any time without provision of reason. Requests for a copy of the results attained will be honoured following study completion and publication in a scientific journal.

What happens if something goes wrong on the day of the trials?
All procedures have been included within Liverpool John Moores University Liability Insurances and if you are harmed in any way by taking part in this research project your normal rights apply and you may have grounds for legal action.

Complaints procedure:
If you have any complaints regarding the way you have been treated or anything else relating to the study you can contact the university research ethics committee- Email researchethics@ljmu.ac.uk or telephone 01512312121 who is independent from the research team and will investigate the matter fully.

What happens now?
You will be asked to complete an informed consent form to confirm that you are happy to participate in this study. You will be asked to keep a copy of this information sheet and the signed consent forms.

Thank you for your time, and if you want to participate in the study or have any further questions, please feel free to contact any of the investigators listed below.

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