A berry healthy heart study: How do berries help the heart?

Participant Information Leaflet

We would like to invite you to join ‘A berry healthy heart study’ at the University of Aberdeen Rowett Institute, which is expected to start from April/May 2019. This study requires 36 participants to test the benefits of taking a berry extract on heart health. Before you decide whether to participate, it is important for you to understand why we are doing this research and what it will involve.

Please take time to read this information leaflet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, we would be delighted to assist.

If you are interested in learning more about the study or taking part, please let us know by telephone, or email, or use the reply slip and freepost envelope provided and we will contact you.

Thank you for your time and consideration.
What is the purpose of the study? People who are overweight and have higher than recommended levels of blood sugar and/or cholesterol are at increased risk of heart disease. One potential way to help manage these risk factors is to use a natural, food supplement as a safer and more tolerable alternative to drugs.

This research study aims to find out whether a commercially-produced berry extract improves heart health in overweight individuals who are generally healthy but at moderate risk of heart disease. The berry to be studied is an underused berry reported to contain one of the highest levels of natural protective compounds amongst berries. Our goal is to test whether taking a daily dose of an extract of this berry, equivalent to eating a handful of fresh berries, for 12 weeks improves heart health and function. We aim to recruit overweight men to participate in this nutritional study, provide blood samples, and allow us to measure their blood pressure and blood vessel health at the start and end of the study.

Why have I been contacted? We are approaching you because we understand that you may be eligible to take part. We aim to recruit 36 generally healthy men aged 40 – 75 years, who are overweight [waist circumference 94 cm (37 inches) or more], non-smoker or stopped smoking for at least a year, and have one of the following:

- blood pressure higher than 120/80 mmHg
- blood sugar moderately higher than recommended levels
- blood cholesterol moderately higher than recommended levels

Do I 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. Your decision has no influence on your eligibility to participate in future research.

What will be my involvement if I take part? To find out if the berry extract improves heart health, we will compare the effects of the berry extract against that of a placebo ‘dummy treatment’, which looks like the berry extract but contains no active ingredient. If you choose to join the study, we will ask you to take part for a period of 28 weeks. During that
time, you will receive each of the two treatments (berry extract or placebo) separately, each lasting for 12 weeks at a time. The order in which you receive the berry extract or the placebo will be selected randomly by a computer. Half of the 36 people will start with the berry extract, followed by the placebo, and the other half will take the placebo first followed by the berry extract. To make sure that the true effects of the berry extract are being studied, neither you nor the study team will know which treatment group you are in.

If you are interested in taking part, we will send you more information and arrange to see you at the Rowett Institute, Foresterhill, Aberdeen, at a time convenient to you.

If you choose to take part, we will ask you to sign a consent form and attend nine morning appointments (1 – 2 ½ hours) at Foresterhill over 28 weeks. These will be scheduled at a time that suits you from 7:00 am, Monday to Friday. Designated free parking will be available. During these appointments, we will:

- Ask you to complete a short questionnaire.
- Take a small blood sample, and measure your weight and blood pressure on 5 occasions.
- Perform a non-invasive ultrasound scan of the artery in your upper arm on 4 occasions to measure your blood vessel health.

We will hand you an initial supply of the treatment on your second appointment and arrange for further supplies to be delivered to you.

**What are the possible benefits of taking part?** There will be no immediate direct benefit to you personally. However, the information we collect may help find ways to decrease the risk of developing heart disease in healthy populations with moderate risk factors and inform policy.

**What are the possible risks of taking part?** We do not expect any side effects related to the dietary treatment. You may experience slight
staining of the mouth when consuming the berry extract or placebo and we will provide simple guidance to minimise this. The inflations of the blood pressure cuff may cause some discomfort. To minimise this, we advise you to stay as still as possible during the measurement to avoid multiple inflations at the time of recording. A small amount of nitrate spray will be used during ultrasound scan of your artery, which, in some, may cause short lived headache, dizziness, or increased heart rate.

**Will my taking part in the study be kept confidential?** All information which is collected about you during the research will be kept strictly confidential and will be held securely.

**Who is organising and funding the research?** This research is organised by the Rowett Institute in collaboration with the Cardiac Research Facility of the University of Aberdeen. The Rural Environment science and Analytical Services (RESAS) programme from Scottish Government is funding the research.

**Contact for further information**
If you have any questions or are interested in taking part in this research, please let us know and we will send you more information. You can telephone us, email us, or use the reply slip and freepost envelope. Our contact details are:

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Thank you for taking the time to read this information leaflet. We hope that you have found it useful in deciding whether or not to take part in ‘A berry healthy heart study’.