

Dose-response effects of wild blueberries on appetite and cardiovascular health

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Registration date 15/11/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/10/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of this study is to establish the dose-dependent ability of anthocyanin-rich wild blueberries to inhibit the post-meal rise in blood glucose and thereby activate gut-brain signalling through delayed starch digestion. Anthocyanins are found abundantly in blueberries and have been shown to have many beneficial activities. The study builds on the hypothesis that the presence of undigested starch along the gut can stimulate gut hormone secretion and thereby control appetite through gut-brain communication.

Who can participate?

Healthy male and female volunteers aged 18-56 years with no medical conditions and not taking medication

What does the study involve

Participants will be asked to come to the study facilities on four occasions to receive a placebo or blueberry product in three different dosages in a random order, with at least 5 days break between study visits. Participants will have measurements taken before consumption of a high-carbohydrate meal and the test drink.

Continuous glucose monitoring will be used to determine glucose response, and venous blood samples will be taken at each visit in regular 30-minute intervals up to 180 minutes to measure insulin and satiety hormone levels. Satiety will also be determined through hunger/satiety ratings taken periodically across the study day.

The researchers will also measure acute blood pressure changes following the intervention and perform cognitive tests at baseline and after 1.5 hours, timed to coincide with the expected maximum presence of anthocyanins in the circulation.

What are the possible benefits and risks of participating?

There are no direct benefits from participation in the study other than the participants being compensated for their time. There are a few risks to participation, mainly pertaining to drawing blood samples through cannulation which can leave bruises and is also associated with a risk of feeling dizzy or fainting.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
June 2022 to October 2023

Who is funding the study?
Wild Blueberry Association of North America (USA)

Who is the main contact?
Dr Christine Bosch, c.bosch@leeds.ac.uk

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Effects of wild blueberry on obesity – a pilot dose-response study targeting starch digestion and satiety through activation of gut-brain axis

Study objectives

The principal hypothesis of this study is that consumption of increasing concentrations of an anthocyanin-containing blueberry drink would decrease postprandial glucose concentration and increase satiety hormones in a dose-dependent manner. It was further hypothesized that a blueberry intervention would beneficially impact cognitive function under the postprandial high carbohydrate load, compared to placebo.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 24/03/2023, University of Leeds Psychology Ethics Committee (University of Leeds, Leeds, LS2 9JT, United Kingdom; +44 (0)113 343 7601 ; psyc-ethicssubmissions@leeds.ac.uk), ref: PSYC-855

Study design

Single-centre randomized double-blind placebo-controlled crossover study

Primary study design

Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Reduction of postprandial glycaemia

Interventions

The study is conducted using a counterbalanced crossover trial design, with each participant acting as their own control. Participants will attend the lab on four separate occasions, separated by at least 5 days. After completing baseline measurements, participants will be asked to consume a high-carbohydrate breakfast (70 g carbohydrates) with a different study drink at each visit. Drinks include a placebo (0 mg anthocyanins) or three freeze-dried blueberry beverages containing 150, 300 or 450 mg anthocyanins. Interstitial glucose, blood pressure, Visual Analogue Scales and cognitive function are measured across a 3-hour study period as well as venous blood samples to analyse postprandial satiety hormone concentrations (insulin, GLP-1, PYY and GIP).

Participants will be randomised to intervention order in a counterbalanced method using “visual basic for applications” coding in Excel. The same coding applies to counterbalancing each form of the cognitive tests.

Intervention Type

Supplement

Primary outcome(s)

Interstitial glucose measured by continuous glucose monitoring at baseline and every 15 minutes across a 3-hour postprandial period

Key secondary outcome(s)

1. Blood pressure measured using an automatic blood pressure monitor at baseline and every 30 minutes
2. Appetite measured using visual analogue scales at baseline and every 30 minutes
3. Incretin hormones measured using venous blood samples from cannulation at baseline and every 30 minutes
4. Cognitive function measured using the Visual Verbal Learning test (VVL), Corsi Block tapping test (Corsi) and the Rapid Visual Information Processing task (RVIP) at baseline and at 90 minutes after consumption of the drink

Completion date

28/10/2023

Eligibility

Key inclusion criteria

1. Between 18 – 56 years of age
2. Body mass index (BMI) <27.0 kg/m²
3. Be in general good health (with no known food allergies/intolerances)
4. Not taking any medication/s known to affect blood pressure, blood glucose (like diabetic medication) or cholesterol
5. Not be pregnant or planning a pregnancy within the next 3 months. Not have been pregnant

or lactating within the previous 6 months

6. Not menopausal

7. Like all the study foods and test products (checked at screening)

8. Be a non-smoker (for at least the last 6 months)

9. Sufficient fluency in the English language to be able to understand the study instructions and questionnaires

10. Willing to visit the laboratory for a screening session (1 hour) and 4 test mornings (8.00 am – 12.00 pm)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

56 years

Sex

All

Total final enrolment

24

Key exclusion criteria

1. Age <18 or >=56 years

2. BMI >27 kg/m²

3. Blood donation <3 months prior to the study or for the full duration of the study

4. Food allergy, intolerance, restriction or avoidance of the study beverage or control beverage or history of anaphylactic reaction to any food

5. Habitually consuming >14 units/week of alcohol in women or >21 units/week in men in the last 3 months

6. For women: pregnancy, lactation, perimenopause

7. No access to mobile phone and internet

8. Simultaneous participation in other relevant studies

Date of first enrolment

01/04/2023

Date of final enrolment

28/10/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Leeds

Woodhouse Lane

Leeds

United Kingdom

LS29JT

Sponsor information

Organisation

Wild Blueberry Association of North America

Funder(s)

Funder type

Research organisation

Funder Name

Wild Blueberry Association of North America

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Available on request

Study outputs

Output type

[Participant information sheet](#)

Details

Date created

Date added

30/10/2024

Peer reviewed?

No

Patient-facing?

Yes