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

Submission date
28/10/2024

Recruitment status
No longer recruiting

Registration date
15/11/2024

Overall study status
Completed

Last Edited
30/10/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Contact name
Dr Christine Bösch

ORCID ID
http://orcid.org/0000-0001-6705-5709

Contact details
School of Food Science and Nutrition
University of Leeds
Leeds
United Kingdom
LS2 9JT
+44 (0)800 915 0402
c.bosch@leeds.ac.uk

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Lucy Ellis

ORCID ID
http://orcid.org/0000-0002-0750-7248

Contact details
School of Psychology
Leeds
United Kingdom
LS2 9JT
+44 (0)1133437000
fs15lre@leeds.ac.uk

Type(s)

Scientific

Contact name
Prof Louise Dye

ORCID ID
http://orcid.org/0000-0002-2331-4227

Contact details
School of Food Science and Nutrition
Leeds
United Kingdom
LS29JT
+44 (0)800 915 0402
l.dye@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
See study outputs table

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

Secondary outcome measures
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 (VVLT), Corsi Block tapping test (Corsi) and the Rapid Visual Information Processing task (RVIP) at baseline and at 90 minutes after consumption of the drink

Overall study start date
01/06/2022

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
56 Years

Sex
Both

Target number of participants
24

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
England

United Kingdom

Study participating centre
University of Leeds
Woodhouse Lane
Leeds
United Kingdom
LS29JT

Sponsor information

Organisation
Wild Blueberry Association of North America

Sponsor details
Wild Blueberries
PO Box 100
Old Town
Maine
United States of America
04468
+1 (0)207 581 1862
administrator@WBANA-US.com

Sponsor type
Research organisation

Website
https://www.wildblueberries.com/health-benefits/research/

Funder(s)

Funder type
Research organisation

Funder Name
Wild Blueberry Association of North America

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/01/2025

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/10/2024	No	Yes