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Acute effects of hibiscus sabdariffa on cardiometabolic markers and cognitive function

Submission date
07/06/2024

Recruitment status
No longer recruiting

Registration date
20/06/2024

Overall study status
Completed

Last Edited
03/03/2025

Condition category
Circulatory System

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

Plain English Summary
Background and study aims
Hibiscus is a plant from the Malvaceae family which contains polyphenols, predominantly anthocyanins. Evidence suggests that the consumption of hibiscus has a beneficial effect on reducing blood pressure and in modulating lipids. However, despite evidence that other anthocyanin-containing plants can have a favourable impact on cognitive function, there is no evidence thus far which outlines any potential benefit of hibiscus consumption on cognitive function in human clinical trials. The pilot study aims to examine the effect of anthocyanin-rich hibiscus sabdariffa tea on blood pressure, glucose and cognitive function in metabolically challenged individuals.

Who can participate?
Adult participants (age 18-55 years old) who have at least one risk factor for cardiovascular disease such as, but not limited to, high blood pressure/mild hypertension (SBP between 130-159 and DBP >80-99 mmHg), overweight (>27 kg/m2) but not morbidly obese (BMI >35 kg/m2). Participants will not be taking any medication.

What does the study involve?
Participants will be randomly allocated to consume either a hibiscus concentrate or a placebo (alongside a small breakfast consisting of two slices of toast and butter) on two separate occasions using counterbalancing with at least a 5-day washout between study visits. During each visit, participants will complete a baseline set of measurements, including blood pressure, wearing a continuous glucose monitor (CGM) and cognitive function. Participants will then consume the test beverage. Blood pressure will be measured every 10 minutes. The CGM measures interstitial glucose every 15 minutes and the same monitor will be worn across both study visits. Cognitive function is assessed again at 90 minutes post-consumption of the test drink and meal.

What are the risks and benefits of taking part?
There are no direct benefits for participants taking part, however, participants are compensated for their time attending the study. There are small risks associated with wearing the CGM such as minor bruising.

Where will the study run from?
The Human Appetite Research Unit, University of Leeds

When is the study starting and how long will it run for?
November 2023 to March 2024

Who is funding the study?
Lucy Ellis is supported by the Emma and Leslie Reid Scholarship Fund from the University of Leeds. The Hibiscus concentrate was kindly donated by Ibis Organics.

Who is the main contact?
Prof Louise Dye, l.dye@leeds.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomized, single-blind, placebo-controlled study assessing the acute effects of hibiscus sabdariffa on cardiometabolic markers and cognitive function in metabolically challenged individuals

Study hypothesis
Hibiscus sabdariffa (hibiscus) is an anthocyanin-containing plant and currently, there are no human studies which assess cognitive effects after ingesting hibiscus. However, there are multiple RCTs which assess the cognitive-enhancing effects of anthocyanins. The main hypothesis is that consumption of hibiscus will significantly lower blood pressure (both systolic and diastolic) in a population of participants with high blood pressure. Additionally, the second hypothesis of this study is that hibiscus consumption will improve at least one outcome from the cognitive test battery chosen compared to a placebo drink.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/01/2024, The School of Psychology Research Ethics Committee (University of Leeds, Leeds, LS29JT, United Kingdom; +44 (0)113 2431751; psyc-ethicssubmissions@leeds.ac.uk), ref: PSCETHS-808

Study design
Single-centre randomized single-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

Condition
Reduction of blood pressure

Interventions
The study is conducted using a counterbalanced crossover trial method, with each participant acting as their own control. 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 between participants, sessions and visits as a method to minimise practice effects. Participants will attend two separate study visits with at least a 5-day washout between each visit. After completing baseline measurements, participants will consume either a hibiscus concentrate containing 260 mg anthocyanins or a placebo drink containing 0 mg anthocyanins, alongside a high carbohydrate breakfast on each study visit. Blood pressure, blood glucose and cognitive function are measured across a 2.5-hour postprandial period.

Intervention Type
Other

Primary outcome measure
Blood pressure measured using an automatic blood pressure cuff (Omron) at baseline, and every 20 minutes after consumption of the drink and test meal for a 2 ½ hour postprandial period

Secondary outcome measures
1. Interstitial glucose measured using a Continuous Glucose Monitor (Freestyle Libre, Abbott) every 15 minutes.
2. Cognitive function (verbal memory, executive function, pattern separation) measured using a Visual Verbal learning test, Tower of Hanoi and Pattern separation at baseline and then 90 minutes after the consumption of the drink

Overall study start date
01/11/2023

Overall study end date
30/03/2024

Eligibility

Participant inclusion criteria
1. Age 18-56
2. BMI more than 27kg/m2 but less than35kg/m2
3. Male and female, local to the Leeds area
4. Presence of high blood pressure
5. Sufficient knowledge and understanding of the English language (preferably first language)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
56 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Participant exclusion criteria
1. For women – pregnancy, lactation, perimenopause/menopause
2. Food allergy or intolerance to any of the study foods
3. Medical conditions – clinical depression, thyroid diseases, hypertension, type 1 or type 2 diabetes, or blood diseases
4. Using any medication for hypertension or cholesterol-lowering sterols
5. Recent blood donation (<3 months)
6. Participation in simultaneous studies

Recruitment start date
05/01/2024

Recruitment end date

15/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Human Appetite Research Unit
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Sponsor type
University/education

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ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Leeds

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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

Intention to publish date
30/06/2024

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
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			17/06/2024	No	Yes
Statistical Analysis Plan			17/06/2024	No	No
Results article		26/02/2025	03/03/2025	Yes	No