Participant Information Sheet

Effects of blueberry drink consumption on blood glucose and cognition

This participant information sheet contains information about the blueberry study which you have expressed an interest in being a part of.

What is the research about?

You are invited to take part in a blueberry-based drink study based at the Human Appetite Research Unit (HARU) at the University of Leeds. Before you decide to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and do not hesitate to ask further questions or clarification.

The study has been designed to investigate how blueberries can affect blood glucose response and cognition after a meal.

Will I be able to take part in this study?

You will be able to participate in this study if you meet **all** the following criteria:

- Between 18 – 56 years of age
- BMI <27.0 kg/m^2. This will be measured at screening
- Be in general good health (with no known food allergies/intolerances)
- Not taking any medication/s known to affect blood pressure, blood glucose (like diabetic medication) or cholesterol
- Not be pregnant or planning a pregnancy within the next 3 months. Not have been pregnant or lactating within the previous 6 months
- Not menopausal
- Like all the study foods and test products (checked at screening)
- Be a non-smoker (for at least the last 6 months)
- Sufficient fluency of the English language to be able to understand the study instructions and questionnaires
- Willing to visit the HARU for a screening session (1 hour) and 4 test mornings (7.00am – 11.00am).

What will I have to do if I decide to take part?

For this study, you will be required to come to visit the HARU for one screening session, which will last about an hour, and for 4 test mornings (7.00am – 11.00am).

We will provide you with an evening meal (cheese and tomato pizza and a low-calorie drink e.g. diet coke) to be consumed on the evening prior to each test day and ask you to come to the HARU in a fasted state. This means you must not consume any food or drinks, except water, after 9pm on the evening before your test day and the morning of your visit. You must also refrain from alcohol consumption or heavy exercise the day before your visit to the lab and on the test day itself. You must not exercise heavily on the test morning and should attend each test day using the same mode of transport to arrive at the HARU (to keep your morning activity levels constant).

During your visit in the HARU, we will ask you to provide a urine sample when you first arrive. You will then have a baseline set of measurements taken which include fitting a small device called a “Continuous Glucose Monitor”

to your triceps which will measure blood glucose. In addition, a trained phlebotomist will insert a cannula into your arm to be able to take blood samples to measure gastrointestinal hormones associated with appetite. Your blood pressure will be measured by using a standard blood pressure cuff and then you will undergo a series of cognitive tests. Finally, you will be asked to complete several questionnaires which will ask about your appetite, mood, and mental alertness. After these baseline measures have been taken, you will consume a small breakfast and a blueberry beverage. The above measures will be repeated across the test morning for a period of 3 hours. You will be required to stay in the HARU during this time, however you are more than welcome to bring work/reading material with you.

What are the possible disadvantages, risks, and benefits of taking part?

Participating in a research study can be an inconvenience to your daily life. When considering taking part you should think carefully about the time commitments and responsibilities required by the study. For 4 of your visits (study intervention days) you will be asked to attend the HARU for about 3-4 hours and you should consider any other commitments before agreeing to do this. However, we will try to be flexible and accommodate your schedule as far as is possible. You must carefully follow any instructions given to you concerning the study.

No new or experimental foodstuffs are being used in this study so there are no known risks associated with their consumption. You will receive a free evening meal the night before the test day and free breakfast on each study day.

There are no known risks associated with completing any of the questionnaires that will be used in this study. However, it is possible that some of the questions asked may cover topics you find embarrassing or sensitive. You are, therefore, not obliged to provide answers or responses to any questions that are sensitive for you, and you may elect to skip some questions without giving a reason. In addition, if taking part in this study raises any psychological issues for you then please find some useful sources of support at the end of this information sheet.

There are a few small risks associated with the venepuncture for cannulation. This can include feeling dizzy, feeling nauseous and in rare events, vasovagal (fainting). You may also be left with a small bruise from the site of insertion.

There is a small risk of localised inflammation or bruising from the Continuous Glucose Monitor (CGM).

Will I be compensated for my time?

Yes. You will receive an honorarium of £80 (taxable) upon completion of the study, to compensate for the time commitments required for the research. This will be paid via the University payroll system directly into your bank account (please note that this can take up to 2 months to process).

Will my taking part in the study be kept confidential?

All information that is collected from you during the course of the study will be treated in the strictest of confidence at all times and will only be used for the purposes of this research. For additional information, please refer to the 'University of Leeds Privacy Notice for Research Participants' which is provided at the end of this information sheet.

After initially completing the consent form and recruitment questionnaire you will be given a unique study identity code. All data will then be recorded safely using this code and not your name. The link between your name (and other personal data) and your unique study identity code will be maintained and stored securely in the HARU at The University of Leeds and will only be accessible to the University research team. Anything that you say will be treated in confidence and no names will be mentioned in any reports of the study. Some results from the study will be used towards an educational qualification by a member of the research team. Individuals will not be identifiable from any details in reports, presentations or scientific publications based on the results of the study.

What happens if I decide I do not wish to take part?

You are free to decide whether you wish to take part in the study, and participation is entirely voluntary. If you decide not to take part, you will not be required to do anything after reading this form. You will not have to sign anything. Nor will you be expected to state your reason for not wishing to take part. If, during the study, you decide that you no longer wish to take part, you will not be asked to state a reason. However, we would like to use the data you provide, up until the point at which you drop out, but we will give you the opportunity to withdraw your data from the study analysis if you so wish up until the point when the data from all participants (n=24) has been collected and data analysis has begun. We anticipate this point to be reached by 01/07/2023 but the exact deadline for withdrawing your data will be dependent upon the time it takes us to recruit all participants to the study.

What if something goes wrong?

In the unlikely event of a study-related bodily injury or harm, signing the consent form will protect your rights to compensation. If you wish to make a claim for compensation, then please ask the researchers for information on how to proceed. If you are harmed due to someone's negligence you may have grounds for legal action, but you may have to pay for this. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study you should contact the principal investigators (Dr Christine Bosch or Professor Louise Dye) who will investigate your complaint. If you remain unhappy and wish to complain formally, this can be done through the University complaints procedure.

What happens after the end of the study?

The study can be terminated for various reasons: either the study has been completed, or you no longer wish to take part in it, or the investigator has asked you to withdraw from the study. If your safety or wellbeing is in jeopardy, we will terminate the study at once. You will not be exposed to any form of risk if you prematurely withdraw from the study, and you will not have to do anything else once you have withdrawn.

What will happen to the results of the research study?

Once all 24 participants have completed the study, the information obtained will need to be processed and analysed before any results are published. This is likely to take at least one year to be finalised. If you would also like to know the results of the study, the research team will be able to give this information to you when it becomes available. You will not be identified in any report or publication.

Who has reviewed this study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by The School of Psychology Research Ethics Committee at the University of Leeds (Date of approval: 24/03/2023, Reference number: PSYC-855).

Who is organising and funding the research?

The research is a collaboration between the HARU, University of Leeds and colleagues at the Wild Blueberry Association of North America (WBANA). The research will be carried out with financial support from WBANA.

Interested in taking part?

If you want to take part in this study or have any questions, please feel free to contact Lucy Ellis using the email below. Before participating you will be asked to sign a consent form to show that you have read the information above and have agreed to take part.

Contact details:

Lucy Ellis (PhD Student) E-mail: fs15lre@leeds.ac.uk (HARU Telephone - 0113 3435753)

Principal Investigators

Professor Louise Dye (l.dye@leeds.ac.uk; 0113 3435707)

Dr Christine Bosch (c.bosch@leeds.ac.uk)

Sources of Support

If taking part in this study raises any issues for you, the following sources of support may be helpful:

Local (for University students/staff)

Student Counselling & Wellbeing Services:
http://students.leeds.ac.uk/info/100001/counselling_and_wellbeing

Staff Counselling and Psychological Support Services:
https://wsh.leeds.ac.uk/staff-counselling

National:

The Samaritans: https://www.samaritans.org/how-we-can-help/contact-samaritan/ Or call 116 123 (available 24 hours a day)

Thank you for taking the time to read this Participant Information Sheet

UNIVERSITY OF LEEDS RESEARCH PARTICIPANT PRIVACY NOTICE

Purpose of this Notice

This Notice explains how and why the University uses personal data for research; what individual rights are afforded under the Data Protection Act 2018 (DPA) and who to contact with any queries or concerns.
All research projects are different. This information is intended to supplement the specific information you will have been provided with when asked to participate in one of our research projects. The project specify information will provide details on how and why we will process your personal data, who will have access to it, any automated decision-making that affects you and for how long we will retain your personal data.

Why do we process personal data?

As a publicly funded organisation we undertake scientific research which is in the public interest. The DPA requires us to have a legal basis for this processing; we rely upon "the performance of a task carried out in the public interest" as our lawful basis for processing personal data, and on "archiving in the public interest, scientific or historical research purposes, or statistical purposes" as our additional lawful basis for processing special category personal data (that which reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic or biometric data, and data concerning health, sex life or sexual orientation).

How do we follow data protection principles?

- We have lawful bases for processing personal and special category data.
- Data are used fairly and transparently; we will make it clear to individuals what their data will be used for, how it will be handled and what their rights are.
- We only collect and use personal data for our research, for research in the public interest, or to support the work of our organisation.
- We only collect the minimum amount of personal data which we need for our purposes.
- We take steps to ensure that the personal data we hold is accurate.
- We keep your personal data in an identifiable format for the minimum time required.
- We take steps to ensure that your data is held securely.
- We keep a record of our processing activities.

What do we do with personal data?

Research data can be a very valuable resource for improving public services and our understanding of the societies we live in. One way we can get the most benefit from this work is to make the data available, usually when the research has finished, to other researchers. Sometimes these researchers will be based outside the European Union. We will only ever share research data with organisations that can guarantee to store it securely. We will never sell your personal data, and any data shared cannot be used to contact individuals. The project specific information will include more detail about how your data will be used.

Your rights as a data subject

Because we use personals data to support scientific research on the public interest, individuals participating in research do not have the same rights regarding their personal data as they would in other situations. This means that the following rights are limited for individuals who participate, or have participated in, a research project:

- The right to access the data we hold about you.
- The right to rectify the data we hold about you.
- The right to have the data we hold about you erased.
- The right to restrict how we process your data.
- The right to data portability.
- The right to object to us processing the data we hold about you.

Data security

We have put in place security measures to prevent your personal data from being accidentally lost, used or accessed in an unauthorised way and will notify you and any applicable regulator of a suspected breach where we are legally required to do so.

Retention periods

We will only retain your identifiable personal information for as long as necessary to fulfil the purposes we collected it for; we may then retain your data in anonymised or pseudonymised format. To determine the appropriate retention period for personal data we consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorised use or disclosure, the purposes for which we process your personal data and whether we can achieve those purposes through other means, and the applicable legal requirements.

Additional notices and guidance/policies

The University has also published separate policies and guidance which may be applicable to you in addition to other privacy notices:

Current staff privacy notice Current students privacy notice

The Research and Innovation Service website has other relevant policies and guidance.

Communication

In the first instance please contact the researcher who your initial contact was with.

You may also contact the Data Protection Officer for further information (see contact details below). Please see the Information Commissioner's website for further information on the law.

You have a right to complain to the Information Commissioner's Office (ICO) about the way in which we process your personal data. Please see the ICO's website.

Concerns and contact details

If you have any concerns with regard to the way your personal data is being processed or have a query with regard to this Notice, please contact our Data Protection Officer (Alice Temple: A.C.Temple@leeds.ac.uk).

Our general postal address is University of Leeds, Leeds LS2 9JT, UK.

Our postal address for data protection issues is University of Leeds Secretariat, Room 11.72 EC Stoner Building, Leeds, LS2 9JT.

Our telephone number is +44 (0)113 2431751.

Our data controller registration number provided by the Information Commissioner's Office is Z553814X.

This notice was last updated on 20 February 2019.