ISRCTN88119879 https://doi.org/10.1186/ISRCTN88119879

Exploring food choice across the menstrual cycle

Submission date
01/12/2025

Recruitment status
Recruiting

Registration date
02/12/2025

Overall study status
Ongoing

Last Edited
18/12/2025

Condition category
Urological and Genital Diseases

[X] 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
Broadly, the present study seeks to explore food choice in those with heavy menstrual bleeding. Due to the design of the study, full background and study aims will be provided once data collection has finished.

Who can participate?
We are looking to recruit 65 adults who self-report to be experiencing heavy menstrual bleeding (defined in the eligibility criteria). A specific list of inclusion and exclusion criteria have been specified under the 'Eligibility' section.

What does the study involve?
This is a multi-part study online study that is completed over 4 days across the menstrual cycle. Total participation is estimated to be around 2 hours. A full breakdown of the study procedure is outlined in the information sheet. However, in brief, participants will:
- Be asked questions about themselves and their menstrual cycle in an initial pre-study questionnaire
- Have a brief Microsoft Teams call with the researcher to ask any questions and confirm set up of the study
- Each day, answer a brief question that asks if they are currently menstruating
- At two timepoints across the study:
o When notified by the researcher, participants will be asked to complete an at home finger-prick blood test kit in the morning and send it via post to the laboratory
o On the same day, that evening, participants will be asked to complete a 15-minute task consisting of food choice and wellbeing questions
o The following day, in the evening, participants will be asked to complete a further 15-minute task consisting of food choice and wellbeing questions
- After completing a total of 2 finger-prick kits and 4 food choice tasks, participants will be sent a final questionnaire that asks questions about themselves (e.g., age and gender), their menstrual cycle features, and their general food preferences
- At the end of the study, participants will receive a full debrief that outlines the study aims, and will have the opportunity to ask questions before signing the final consent form.

About the finger-prick blood test kits:
Participants will be asked to complete a finger-prick kit at two points in their menstrual cycle: once when menstruating, and once when not menstruating. The finger-prick kits can only be completed Monday to Thursday, and the researcher will always notify participants of when they should be completing the tasks both the day before, and on the morning of testing. Information on the kits we will be using can be found at this link: https://onedaytests.com/pages/home-kit

What are the possible benefits and risks of participating?
Benefits:
Participants will receive a £25 Amazon voucher in exchange for completing the full study. Should a participant only complete part of the study, they will receive a voucher proportionate to the amount of the study they completed. Further to this, there will be a prize draw for one of two additional £50 Amazon vouchers for those who complete the full study.
Participants will also be offered the opportunity to receive the results of their finger-prick kits. These reports will highlight 4 biomarkers of health from the two time-points studied – more information about what this means will be sent after participants complete the study.
Finally, as with most research, the participant will be informed of the full background and aims of the study after they take part (in the debrief) alongside the opportunity to ask any questions. This information may be interesting to the individual, and they could learn more about eating behaviour from taking part.

Risks:
Whilst the risk is low, there is some risk associated with the finger-prick kits such as bruising, prolonged bleeding, and in rare cases, infection. We will provide participants with instructions on using the kits properly to minimise the chance of these outcomes.
Further to this, the study includes measures such as physical and mental wellbeing which may some individuals may feel uncomfortable answering. To mitigate this, we include the option of answering “prefer not to say” where possible. We also have a clear withdrawal procedure outlined in the information sheet should the participant no longer wish to take part.

Where is the study run from?
The research team is based at the University of Bristol. However, the study is run entirely online.

When is the study starting and how long is it expected to run for?
The study is anticipated to begin recruitment in January 2026 and run until September 2026

Who is funding the study?
The study is funded by the Bristol Biomedical Research Center which is part of the National Institute of Health Research.

Who is the main contact?
Jody Salton (jody.salton@bristol.ac.uk)

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Miss Jody Salton

ORCID ID
https://orcid.org/0009-0004-8498-9297

Contact details
12a Priory Road
Bristol
United Kingdom
BS8 1TU
0117 455 8806
jody.salton@bristol.ac.uk

Type(s)
Scientific

Contact name
Prof Jeff Brunstrom

ORCID ID
https://orcid.org/0000-0003-4657-7799

Contact details
12a Priory Road
Bristol
United Kingdom
BS8 1TU
0117 928 8574
jeff.brunstrom@bristol.ac.uk

Type(s)
Scientific

Contact name
Prof Julian Hamilton-Shield

ORCID ID
https://orcid.org/0000-0003-2601-7575

Contact details
Bristol Royal Hospital for Children
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ
07703066901
j.p.h.shield@bristol.ac.uk

Additional identifiers

Study information

Scientific Title
Exploring variation in food choice in heavy menstrual bleeding populations

Study objectives
To be outlined post data collection

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 14/11/2025, University of Bristol Research Ethics Committee (University of Bristol, Beacon House, Queens Road, Bristol, BS8 1QU, United Kingdom; NA; research-governance@bristol.ac.uk), ref: 27342

Primary study design
Observational

Secondary study design
Longitudinal study

Study type(s)

Health condition(s) or problem(s) studied
Individuals who report their menstrual bleeding to meet the criteria specified for heavy menstrual bleeding.

Interventions
This study utilises an observational design to assess food choice across the menstrual cycle, with all participants completing the same study procedure.
Due to the nature of the study, details pertaining to the methodology and analysis will be masked until data collection has been completed. However, a detailed pre-registration will be submitted via the Open Science Framework (OSF) prior to data collection (embargoed until data collection has been completed), which will outline the full aims, hypotheses, list of measures, and analysis plan.

Intervention Type
Other

Primary outcome(s)
1. Food choice measured using food choice tasks at 4 points across the menstrual cycle (detailed outcomes of interest will be revealed when data collection has been completed)

Key secondary outcome(s))

Completion date
07/09/2026

Eligibility

Key inclusion criteria

1. Are aged 18-45
2. Are a UK resident
3. Are familiar with, and willing to consume, the following test foods: steak, lamb, chicken, beef burger, macaroni cheese, pizza, roast beef, battered cod, beef bolognese, pork sausages, gammon steaks, halloumi
4. In line with the above, currently consume meat within the diet
5. Are experiencing heavy menstrual bleeding, defined in this study as experiencing at least two of the following over the past year:
- Flooding through clothes or onto bedding
- A need to change sanitary products every 2 hours or less (or using 12+ sanitary products a day)
- Need for double sanitary protection (e.g., a tampon and sanitary towel)
- Passing large blood clots
6. Have a menstrual cycle that meets the following:
- Have experienced at least 8 menstrual bleeds (periods) in the past year
- Have a menstrual bleed of at least 3 days in duration
- A duration of at least 12 days between menstrual bleeds
- Not experiencing bleeding in between menstrual bleeds
7. Own a smartphone with an internet connection and either Google play or the App store, and be willing to download the Samply research app

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Have a diagnosis of PCOS (polycystic ovary syndrome) or endometriosis
2. Are currently pregnant or trying to conceive
3. Are currently experiencing an eating disorder or disordered eating
4. Due to use of at home finger-prick blood testing kits, have:
- A bleeding disorder or use of medication which increases the risk of bleeding
- A skin disorder or condition that may result in slower healing
- Impaired circulation, particularly in relation to the upper limbs
- A known condition or taking medication that elevates the risk of infection
- A known blood-borne disease (e.g., hepatitis B/C, Human Immunodeficiency Virus)
- A fear of blood
- A history of fainting, an arrhythmia, or any other applicable symptoms

Date of first enrolment
22/12/2025

Date of final enrolment
10/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Bristol Biomedical Research Centre
University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
University of Bristol
Senate House
Tyndall Avenue
Bristol
England
BS8 1TH

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Funder Name
NIHR Bristol Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre Bristol, National Institute for Health Research Bristol Biomedical Research Centre, NIHR Bristol BRC, Bristol BRC, Bristol Biomedical Research Centre

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Following data collection, the anonymised dataset generated during the current study will be stored on the University of Bristol Research Data Repository (data.bris https://data.bris.ac.uk /data/dataset) which is a publicly available repository.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/12/2025	No	Yes