ISRCTN41186851 https://doi.org/10.1186/ISRCTN41186851

Testing how bread with different amounts of fiber affects blood sugar and insulin levels

Submission date	Recruitment status	[X] Prospectively registered
02/12/2024	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/12/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/12/2024	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The significance of dietary fibre in promoting human health has garnered attention, given its association with reducing the risk of cardiovascular disease, type 2 diabetes, and various cancers. Despite established guidelines recommending a daily fibre intake of 30g, UK adults typically consume only 18g per day. Cereals, particularly bread, contribute significantly to daily fibre intake, with much of it derived from low-fibre white bread. Consequently, there's a demand for consumer-accepted, high-fibre bread options. Wheat flour's major fibre components are arabinoxylan (AX) and β-glucan. Genetic variations in AX content have facilitated the production of high-AX bread at Rothamsted Research. The Wheat Study aims to evaluate the impact of bread samples, each varying in fibre content, on blood glucose and insulin metabolism.

Who can participate?
Adults aged 18 to 65 years old who have a BMI of 18-30 kg/m2.

What does the study involve?
Participants will complete a questionnaire and attend a screening visit where they will be seen by a doctor and asked about their medical history, current health, and any medications. Measurements of height, weight, waist and hip circumference, and body composition will be taken, and BMI will be calculated. They will also undergo a full blood test, and all females of childbearing potential will complete a pregnancy test. Following this, a glucose tolerance test will be performed. Participants will be given a large glass of concentrated sugar solution (75g of glucose dissolved in 250ml of water). Two hours after consuming the drink, another blood sample will be taken to measure plasma glucose levels.

Eligible participants will be invited to attend six study visits at the Clinical Research Facility at Hammersmith Hospital. At each visit, all females of childbearing potential will complete a pregnancy test. A small plastic tube (cannula) will be inserted into the participant's arm. During each test, participants will consume either a glucose drink or bread containing varying amounts of fiber. The order in which these foods are consumed will be randomized and not chosen by the participants. Bread samples will be prepared by the researcher following a standard recipe in the Imperial College Research Facility (ICRF) kitchen.

To measure blood sugar, insulin, and C-peptide levels, two fasting blood samples will be taken 10 minutes apart before the start of the study (-10, 0), before consuming any food or drink. Afterward, additional samples will be collected at six time points: 15, 30, 45, 60, 90, and 120 minutes post-consumption. Approximately 5 ml of blood (roughly a teaspoon) will be collected at each time point, amounting to a total of 40 ml of blood per session. These samples will be collected through the cannula. Measurements will continue for two hours after participants consume the test meal. Additionally, participants will be asked to complete a 24-hour food diary the day before each study visit. Participants will be reimbursed £10 for the screening visit and £25 for each study visit, with a total of £160 paid at the end of the study. An additional £15 will be reimbursed for travel expenses for each visit.

What are the possible benefits and risks of participating?
Although taking part in the study will provide no direct benefit to participants, the results will contribute to understanding how bread with varying amounts of fiber affects blood glucose responses. Additionally, if any of the screening questionnaires or blood tests reveal medical issues (e.g., diabetes, kidney, or liver problems), the participant's GP will be informed to coordinate further care, arrange any necessary tests, and refer the participant to a hospital specialist if needed. The insertion of the cannula during each study visit may cause minor discomfort or superficial bruising. However, these procedures will be performed by an experienced healthcare professional under sterile conditions to minimize these risks.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
September 2024 to September 2026

Who is funding the study?
Biotechnology & Biological Sciences Research Council (UK)

Who is the main contact?
Prof Gary Frost, g.frost@imperial.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Gary Frost

ORCID ID
https://orcid.org/0000-0003-0529-6325

Contact details
Commonwealth Building, 6th Floor, Hammersmith Hospital, Hammersmith Campus
London
United Kingdom
W12 0NN
+44 (0)20 7594 0959
g.frost@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
340491

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 64537, Biotechnology and Biological Sciences Research Council grant code: BB/X018849/1

Study information

Scientific Title
Glycemic and insulin metabolism testing of arabinoxylan-enriched bread

Acronym
Wheat Study

Study objectives
The study aims to assess the impact of 10 types of bread, each with different amounts of AX, on blood glucose and insulin metabolism.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/10/2024, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8084; fulham.rec@hra.nhs.uk), ref: 24/LO/0671

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Other disorders of glucose regulation and pancreatic internal secretion

Interventions
During the study visits, participants will be given either bread or a glucose solution. The 10 test breads will vary in fiber content, and each type of bread will be consumed once on separate occasions. Each portion will provide either 25 g or 50 g of available carbohydrates. The reference food will be glucose solution.

Sealed Envelope software will be used to randomise participants to determine which dietary intervention they will be given for the first study period. Each participant will be randomized to 5 of the 10 test breads. Participants will attend a total of six study visits. Blood samples will be collected to assess blood glucose, insulin, and C-peptide levels.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Blood glucose levels measured via the glycaemic response measured in blood samples collected by cannulation at 15, 30, 45, 60, 90, and 120 minutes post-consumption.

Secondary outcome measures
Blood insulin and C-peptide levels measured in blood samples collected by cannulation at 15, 30, 45, 60, 90, and 120 minutes post-consumption.

Overall study start date
01/09/2024

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. Age between 18-65 years (inclusive)
2. Body mass index (BMI) of 18-30 kg/m2
3. Willingness and ability to give written informed consent and willingness and ability to understand, to participate and to comply with the study requirements.

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Key exclusion criteria
1. Screening blood results outside of normal reference values
2. Weight change of > = 5kg in the preceding 2 months
3. Current smokers
4. History of substance abuse and/or excess alcohol intake
5. Pregnancy
6. Diabetes
7. Cardiovascular disease
8. Cancer
9. Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
11. Kidney disease
12. Liver disease
13. Pancreatitis
14. Having polycystic ovary syndrome (PCOS)
15. Started new medication within the last 3 months likely to interfere with energy metabolism, appetite regulation and hormonal balance, including anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones.
16. Subjects who are currently participating in other clinical trials
17. Any blood donation within the 12 week period prior to entering this study
18. Subjects who are unable to give informed consent by themselves

Date of first enrolment
02/01/2025

Date of final enrolment
05/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

NIHR Imperial Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
Shepherd's Bush
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College London

Sponsor details
c/o Mr Cheuk Fung Wong
Joint Research Compliance Office, 5th Floor, Sherfield Building, South Kensington Campus
London
England
United Kingdom
SW7 2BB
+44 207 594 9832
cheuk-fung.wong@imperial.ac.uk

Sponsor type
University/education

Website
https://www.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Biotechnology and Biological Sciences Research Council

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal within 12 months of the overall trial end date

Intention to publish date
01/10/2026

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