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Clinical trial to evaluate Reducose® mulberry leaf extract as a functional food ingredient to improve metabolic health

Submission date
09/10/2024

Recruitment status
No longer recruiting

Registration date
16/10/2024

Overall study status
Completed

Last Edited
11/09/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study is investigating whether a mulberry leaf extract called Reducose® can help improve health indicators like blood sugar levels, body weight, and gut health. The goal is to see if Reducose® can reduce blood sugar spikes after eating by slowing down the absorption of sugars in the gut. The study will test the supplement over 12 weeks in healthy, overweight individuals.

Who can participate?
Healthy, overweight individuals with a body mass index (BMI) between 25 and 29.9 kg/m² and body fat percentages of at least 20% for males and 30% for females can participate.

What does the study involve?
Participants will be randomly assigned to take either Reducose® or a placebo. They will visit the Oxford Brookes Centre for Nutrition and Health three times for various tests, including blood tests and body measurements. Participants will also wear a small device to monitor blood sugar levels and collect stool samples at home to check gut health. They will complete questionnaires about their feelings of fullness after meals.

What are the possible benefits and risks of participating?
Participants might experience mild side effects like stomach discomfort if they are sensitive to mulberry leaf extract. The risks of the study are minimal and similar to routine medical tests. Benefits include receiving Amazon vouchers for participation and getting detailed information about their body composition and blood pressure.

Where is the study run from?
The study is conducted at the Oxford Brookes Centre for Nutrition and Health in Headington, Oxford, UK.

When is the study starting and how long is it expected to run for?
September 2023 to March 2026

Who is funding the study?
The study is funded by Innovate UK and Phynova Group Limited, the company that makes Reducose®. Innovate UK is also funding the Oxford Brookes Centre for Nutrition and Health.

Who is the main contact?
Dr Sangeetha Thondre, pthondre@brookes.ac.uk
Dr Jonathan Tammam
Andrew Gallagher, agallagher@phynova.com

Contact information

Type(s)
Public, Scientific

Contact name
Mr Andrew Gallagher

ORCID ID
https://orcid.org/0000-0002-5974-4093

Contact details
Office 3 at Magenta
2 Brookhill Way
Banbury
United Kingdom
OX16 3ED
+44 (0) 1993 880700
agallagher@phynova.com

Type(s)
Principal investigator

Contact name
Dr Sangeetha Thondre

ORCID ID
https://orcid.org/0000-0003-2065-8443

Contact details
Oxford Brookes Centre for Nutrition and Health
Faculty of Health and Life Sciences
Oxford Brookes University Headington Campus
Oxford
United Kingdom
OX3 0BP
+44 (0) 1865 483988
pthondre@brookes.ac.uk

Additional identifiers

Protocol serial number
PYN-CT-008

Study information

Scientific Title
A twelve-week randomised, placebo-controlled study on the effect of Reducose® on glucose, insulin, haemoglobin A1c, satiety, body composition, lipid profile, inflammatory markers and changes in gut microbiome in an overweight population. REMET (Reducose Metabolic Trial)

Acronym
REMET

Study objectives
The aim of this placebo-controlled study is to examine the effect of mulberry leaf-derived food ingredient (Reducose®) on glucose levels, insulin, HbA1c, weight, body composition, satiety, lipid profile, blood pressure, inflammatory markers, and beneficial changes in gut microbiome and microbiome metabolites in overweight individuals.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/02/2024, Oxford Brookes University Health & Social Care Research Ethics Sub-Committee (Gipsy Lane and Headington Hill Sites, Oxford Brookes University, Headington, Oxford, OX3 0BP, United Kingdom; +44 (0) 1865 483297; ethics@brookes.ac.uk), ref: 231762

Primary study design
Interventional

Study design
Single-centre randomized placebo-controlled parallel group design trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Overweight

Interventions
Prior to the start of the intervention, participants will be randomly assigned to one of the two parallel groups using block randomisation with randomly permuted blocks (2, 4, 6, or 8 block size).

1. Three grams of food-grade beadlets containing 250mg Reducose mulberry leaf extract (standardised to contain 12.5mg 1-deoxynojirimycin) taken immediately before dinner and the next largest meal of the day.
2. Matched 3g placebo beadlets (cellulose).

Participants to take interventions twice daily for 12-weeks.

Intervention Type
Supplement

Primary outcome(s)
Blood glucose concentrations measured via venipuncture and CGM. Venipuncture measurements are collected at clinic visits at week 1, week 6, and week 12, and by CGMs used during weeks 1-2, and weeks 11-12.

Key secondary outcome(s)
1. Body weight measured using a body composition analyser at week 1, week 6, and week 12.
2. Body composition measured through bioimpedance using a body composition analyser at week 1, week 6, and week 12.
3. Height measured using a stadiometer at week 1, week 6, and week 12.
4. Waist and hip circumference measured using a standard non-stretch tape at week 1, week 6, and week 12.
5. Systolic and diastolic blood pressure measured using a digital blood pressure monitor at week 1, week 6, and week 12.
6. Intraday glucose variability measured for 14 days from week 1 and week 10 using continuous glucose monitors.
7. 14-day food records collected from week 1 and week 10 using the Nutritics Libro App.
8. Satiety outcomes (hunger, fullness, desire to eat, and prospective food consumption) measured over 8 hours during week 1, week 6, and week 12 using an online visual analogue scale (VAS).
9. Microbiome functional data (measurement of acetate, propionate, SCFA ratio, iso-butyrate, iso-valerate) and compositional data (total bacteria, firmicutes, bacteriodetes, lactobacillus, bifidobacterium) measured using NeoVos Advanced Gut Test at week 1 and week 12.
10. Clinical biochemistry outcomes insulin, HbA1c, blood lipids, adiponectin, leptin, inflammatory markers (CRP, TNF-a, IL-6) measured via venipuncture. Measurements are collected at clinic visits at week 1, week 6, and week 12.

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Body mass index (BMI) ≥25 kg/m² or ≤29.9 kg/m²
2. Body fat percentages ≥20% for males, ≥30% for females

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Aged <18 or >60 years
2. Body mass index (BMI) <25 kg/m² or >29.9 kg/m²
3. Body fat percentages < 20% for males, <30% for females
4. HbA1c >6.5%
5. Any known food allergy or intolerance to the placebo or test product
6. Medical condition(s) or medication(s) known to affect glucose regulation or appetite and/or which influence digestion and absorption of nutrients
7. Known history of diabetes mellitus or the use of antihyperglycaemic drugs or insulin to treat diabetes and related conditions
8. Major medical or surgical event requiring hospitalization within the preceding 3 months
9. Use of steroids, protease inhibitors or antipsychotics (all of which have major effects on glucose metabolism and body fat distribution)
10. Volunteers self-reporting as currently dieting (including ketogenic) or having lost >5% body weight in the previous year
11. Volunteers who have significantly changed their physical activity in the past 2-4 weeks or who intend to change during the study
12. Participation in another experimental study or receipt of an investigational drug/product within 30 days of the screening visit
13. Participants with restricted or abnormal eating behaviour
14. Regular intake of a food supplement with effects on glucose metabolism and satiety (e.g. prebiotics, proteins, chromium, cinnamon, berberine, biotin)
15. Smoker in the last 3 months
16. Heavy alcohol consumers, more than 14 units per week (14 units is equivalent to 6 pints of average-strength beer or 10 small glasses of low-strength wine)

Date of first enrolment
28/10/2024

Date of final enrolment
22/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Oxford Brookes Centre for Nutrition and Health (OxBCNH)
Faculty of Health and Life Sciences
Oxford Brookes University Gipsy Lane Campus Headington
Oxford
England
OX3 0BP

Sponsor information

Organisation
Phynova Group Ltd

Organisation
Oxford Brookes University

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Andrew Gallagher, agallagher@phynova.com after publication of the results.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			11/09/2026	No	No
Plain English results			11/09/2026	No	Yes
Protocol file	version 2024	04/11/2024	11/09/2026	No	No