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Effects of Reducose®, a mulberry leaf extract formulation, on post-meal glycaemic control, insulin response, satiety, and appetite regulation in healthy adults (SATISPHY)

Submission date
16/03/2026

Recruitment status
Recruiting

Registration date
18/03/2026

Overall study status
Ongoing

Last Edited
28/04/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
This study will examine the effects of two dietary supplements containing mulberry leaf extract compared with placebo on their ability to reduce the rise in blood sugar and plasma insulin and increase the levels of hormones that regulate appetite after eating a complete meal. The study will further investigate whether the supplements change feelings of satiety (fullness and hunger) throughout the day.

Who can participate?
Healthy men and women aged 18 years or older without diabetes and with normal fasting blood glucose.

What does the study involve?
Participants will attend three morning visits after fasting overnight. At each visit, they will take either Reducose® mulberry leaf extract, an exploratory botanical formulation containing Reducose®, or a matched placebo capsule containing inert ingredients before consuming a standardised breakfast meal. Blood samples will be taken over 3 hours taken at 0, 15, 30, 45, 60, 90, 120 and 180. Throughout the visit, participants will complete short questionnaires about hunger, fullness, meal palatability and food noise, and they will also complete a 24-hour dietary recall before and after each visit. Each visit lasts around four hours and is separated by at least two days.

What are the possible benefits and risks of participating?
Participants may gain general insight into their own body composition and some of their blood measurements collected during the study. However, these results are for research purposes only and will not be interpreted as medical information, diagnosis, or health advice. The study itself may help researchers understand how natural supplements influence appetite and post-meal glucose responses, which could support the development of non-invasive approaches to appetite and glucose regulation in the future.

Risks are minimal but may include:
1. Mild discomfort or bruising from blood sampling
2. Temporary soreness at the cannula site
The study team is trained in first aid and phlebotomy, and all procedures follow University safety guidelines. If any unexpected findings occur (e.g., unusual glucose levels), participants will be advised to contact their GP.

Where is the study run from?
University of Westminster (UK)

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

Who is funding the study?
Phynova Group Limited (UK)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
A double-blind, placebo-controlled, randomised, single-centre, three-arm crossover study to evaluate the effects of Reducose® mulberry leaf extract and a mulberry extract based botanical formula versus placebo on postprandial glucose, insulin, GLP1, PYY and appetite responses in healthy adults (SATISPHY)

Acronym
SATISPHY

Study objectives
1. To determine whether 250 mg Reducose® mulberry leaf extract decreases incremental area under the curve (iAUC) for blood glucose following a mixed macronutrient meal compared with placebo.
2. To determine whether a proprietary dietary supplement formulation decreases incremental area under the curve (iAUC) for blood glucose following a mixed macronutrient meal compared with placebo.
3. To evaluate the effects of each active independently versus placebo on plasma insulin, GLP-1 and PYY.

4. To assess peak concentration (Cmax) for glucose, insulin, GLP-1 and PYY for each intervention independently versus placebo
5. To evaluate appetite perception using validated visual analogue scale (VAS) questionnaires for each intervention independently vs placebo
6. To evaluate 24-hour appetite, hunger and food noise for each intervention independently versus placebo.
7. The study is powered for placebo-controlled comparisons only and no formal statistical comparison between the two active interventions is prespecified.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/12/2025, College Research and Knowledge Exchange Ethics Committees (CRECs) (Liberal Arts and Sciences (LAS) University of Westminster 309 Regent Street, London, W1B 2HW, United Kingdom; +44 (0)20 7911 5000; A.Voiculescu@westminster.ac.uk), ref: ETH2526-0070

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Crossover

Purpose
Dietary supplement

Study type(s)

Health condition(s) or problem(s) studied
Postprandial glycaemic control and appetite regulation in healthy adults

Interventions
This is a double blind, randomised, placebo controlled, three arm crossover study conducted at the Centre for Nutraceuticals, University of Westminster. Each participant completes three intervention visits, receiving all treatments in a randomised sequence with a minimum 48hour washout between visits.

Participants will be randomised using a Williams design with six balanced sequences (ABC, ACB, BAC, BCA, CAB, CBA) to ensure equal distribution of treatment order and control for firstorder carryover effects.

The three interventions are:
Arm 1: Reducose® – 250 mg mulberry leaf extract (equivalent to 12.5 mg DNJ)
Arm 2: Exploratory Proprietary botanical formulation – containing 250 mg mulberry leaf extract plus additional citrus bioactives
Arm3: Placebo – microcrystalline cellulose, matched in appearance to active capsules

At each visit, participants consume two capsule (active or placebo) immediately before eating a standardised mixed macronutrient test meal. The meal must be consumed within 10 minutes.

A venous cannula is inserted on arrival, and blood samples are collected over a 3-hour period to measure glucose, insulin, GLP1 and PYY. Participants also complete validated Visual Analogue Scale (VAS) questionnaires assessing hunger, fullness, satisfaction, and palatability at repeated time points. A 24 hour dietary recall and Food Noise Questionnaire (FNQ) are completed before and after each visit to assess extended appetite effects.

The crossover design allows each participant to act as their own control. Treatments are compared independently against placebo; no head to head comparison between the two active interventions is prespecified.

Intervention Type
Supplement

Primary outcome(s)
1. Incremental area under the curve (iAUC) for postprandial blood glucose measured using venous whole glucose concentrations collected via an indwelling cannula. iAUC will be calculated using the trapezoidal method, subtracting baseline values to quantify the incremental glucose response. Measured at 0 to 120 minutes following consumption of the standardised test meal, with repeated sampling across the 2hour postprandial period.

Key secondary outcome(s))
1. Incremental area under the curve (iAUC) for postprandial glucose measured using venous whole blood glucose concentrations with iAUC calculated via the trapezoidal method after baseline subtraction at 0–180 minutes following consumption of the standardised test meal

2. Incremental area under the curve (iAUC) for plasma insulin measured using plasma insulin concentrations analysed via appropriate assay with iAUC calculated using the trapezoidal method after baseline subtraction at 0–180 minutes following consumption of the standardised test meal

3. Incremental area under the curve (iAUC) for GLP1 measured using plasma GLP-1 concentrations analysed via appropriate assay with iAUC calculated using the trapezoidal method after baseline subtraction at 0–180 minutes following consumption of the standardised test meal

4. Incremental area under the curve (iAUC) for PYY measured using plasma PYY concentrations analysed via appropriate assay with iAUC calculated using the trapezoidal method after baseline subtraction at 0–180 minutes following consumption of the standardised test meal

5. Peak postprandial concentration (Cmax) for glucose, insulin, GLP1 and PYY measured using the highest venous plasma concentration observed during the sampling period at any timepoint within 0–180 minutes postmeal

6. Time to peak concentration (Tmax) for glucose, insulin, GLP1 and PYY measured using the timepoint at which the maximum venous plasma concentration occurs, at any time within the 0–180 minute sampling window

7. Subjective appetite and satiety ratings measured using validated Visual Analogue Scale (VAS) questionnaires assessing hunger, fullness, satisfaction and prospective food intake, at at baseline and repeated intervals across the 0–180 minute postprandial period

8. Intrusive foodrelated thoughts measured using the Food Noise Questionnaire (FNQ) at 24 hours before each intervention visit and 24 hours after each visit

9. Energy intake and dietary composition over 24 hours measured using a structured 24hour dietary recall completed before and after each intervention visit at the 24hour previsit and 24hour postvisit timepoints

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Male and female participants aged 18 years and over
2. BMI between 18.5 and 30 kg/m² (lean and overweight individuals)
3. Generally healthy, with no clinically significant medical conditions as determined by screening
4. Stable use of permitted medications, including:
4.1. Oral contraceptives
4.2. Acetylsalicylic acid (aspirin)
4.3. Thyroxine
4.4. Vitamin and mineral supplements
4.5. Medications for hypertension or osteoporosis
5. Willing and able to comply with all study procedures
6. Able to provide written informed consent

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Fasting blood glucose >6.9 mmol/L
2. Body mass index (BMI) >30 kg/m²
3. Known food allergies or intolerances, including lactose intolerance
4. Use of anti-hyperglycaemic medications or insulin
5. Major medical or surgical event requiring hospitalisation within the past 3 months
6. Presence of diseases or use of medications that affect digestion or nutrient absorption
7. Use of steroids, protease inhibitors, or antipsychotics (due to their effects on glucose metabolism and body fat distribution)
8. Use of medications known to affect glucose tolerance (excluding oral contraceptives)
9. Current participation in dieting or intentional weightloss programmes
10. Consumption of >14 units of alcohol per week
11. Use of implanted medical devices such as pacemakers
12. Current smokers or users of nicotine products
13. Clinically significant depression or other mental health conditions that may interfere with study participation
14. Inability or unwillingness to provide informed consent

Date of first enrolment
16/03/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre of Nutraceuticals
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Sponsor information

Organisation
Phynova Group Limited

Funder(s)

Funder type

Funder Name
Phynova Group Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available