

How a combination of mulberry leaf, berberine, and chromium impacts weight and sugar metabolism in adults

Submission date 11/07/2026	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 15/07/2026	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/07/2026	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Obesity can increase the risk of health problems such as type 2 diabetes and heart disease. Researchers wanted to find out whether a supplement containing three ingredients, berberine, white mulberry leaf extract, and chromium, could help adults with obesity reduce body fat and improve the way their bodies process sugar. The study compared this supplement with a placebo (a dummy treatment that contains no active ingredients).

Who can participate?

Adults aged 18 to 65 years with obesity (body mass index (BMI) of at least 30 kg/m²) and no other diagnosed chronic diseases could take part. Participants had to be willing to give written informed consent before joining the study.

People could not take part if they were pregnant or breastfeeding, planned to become pregnant during the study, had diabetes treated with insulin or diabetes medicines, had significant liver or kidney problems, had previous or planned weight-loss surgery, were allergic to any of the study ingredients, were taking certain medicines such as anticoagulants, were using other weight-loss or blood sugar supplements, had recently taken part in another clinical trial, or had another diagnosed chronic disease.

What does the study involve?

Participants were randomly assigned to receive either the active supplement or a placebo. Neither the participants nor the researchers knew which treatment each person received until the study had finished.

The active supplement contained berberine, white mulberry leaf extract, and chromium. Participants took the study treatment twice a day before their main meals for 12 weeks.

Participants were asked to keep their usual diet and physical activity levels unchanged during the study. Researchers monitored this using food diaries, diet questionnaires, physical activity questionnaires, and weekly compliance forms.

At the start of the study and again after 12 weeks, participants had measurements of their BMI, body fat, and visceral fat (fat around the internal organs). They also completed a glucose tolerance test, which involved drinking a glucose solution and having blood samples taken over the following 2 hours to measure blood sugar and insulin levels.

What are the possible benefits and risks of participating?

Participants receiving the supplement experienced greater reductions in weight, total body fat, and visceral fat, and showed improvements in measures of blood sugar control compared with participants receiving the placebo.

The reported side effects were generally mild and mainly involved stomach discomfort. As with any research study, participants may also have experienced inconvenience from attending study visits, completing questionnaires, and having blood tests.

Where is the study run from?

The study was carried out at Athens Euroclinic Hospital in Athens, Greece.

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

The first participant joined the study on 19 November 2024. Recruitment finished on 10 December 2024. Each participant took part in the study for 12 weeks. The study was completed on 8 April 2025.

Who is funding the study?

The study is funded by the Hellenic Institute of Nutrition.

Who is the main contact?

Dr Konstantinos Xenos
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Contact information

Type(s)

Scientific, Principal investigator, Public

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Study information

Scientific Title

Effects of berberine, white mulberry leaf extract and chromium picolinate on body composition and insulin resistance in adults with obesity: a randomized controlled trial

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/11/2024, Ethics Committee of Athens Euroclinic Hospital (Athanasiadou 7-9, Athens, 11521, Greece; +30 21 0641 6600; kxenos@euroclinic.gr), ref: 5/12.11.2024

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Obesity, Insulin Resistance

Interventions

Study design

A 12-week, randomized, double-blind, placebo-controlled, parallel-group trial conducted at a single center (Athens Euroclinic Hospital), approved by the hospital's Ethics Committee.

Interventions

Active: a fixed-dose combination taken in two divided doses before main meals:

Berberine hydrochloride 1000 mg (≈970 mg pure berberine)

White mulberry (*Morus alba*) leaf extract 400 mg, standardized to 5% DNJ (1-deoxynojirimycin), providing 20 mg DNJ

Chromium picolinate 0.644 mg

Comparator: matched placebo

Dosing was based on prior clinical literature for each ingredient rather than a dose-finding step in this trial

Randomization and blinding

1:1 allocation via a computer-generated sequence created by an independent statistician; the code stayed masked to investigators and participants until database lock.

Controlling for lifestyle confounds

Participants were instructed to hold their baseline diet and activity constant, monitored via:

3-day food diaries at weeks 0, 6, 12

A semi-quantitative Food Frequency Questionnaire at weeks 0 and 12

IPAQ physical activity questionnaire at weeks 0, 6, 12

Weekly compliance forms for supplement adherence and habit stability

Intervention Type

Supplement

Primary outcome(s)

1. Insulin sensitivity measured using the Matsuda Composite Insulin Sensitivity Index (ISI-Matsuda), derived from a 75g oral glucose tolerance test (glucose/insulin at 0, 60, 120 min). Calculated from a 75g oral glucose tolerance test (OGTT), using glucose and insulin concentrations sampled at 0 (fasting), 60, and 120 minutes, applying the modified three-time-point Matsuda formula. Analyzed on the log-transformed scale due to positive skew; results back-transformed to geometric mean ratios (GMR). at baseline (week 0) and week 12

Key secondary outcome(s)

1. BMI Metric: kg/m² measured using Standard calculation from measured height and weight at baseline (week 0) and week 12

2. Visceral fat rating measured using Bioimpedance analysis (BIA) at baseline (week 0) and week 12

3. Total body fat mass measured using Bioimpedance analysis (BIA) at baseline (week 0) and week 12

Completion date

08/04/2025

Eligibility

Key inclusion criteria

1. Adults with obesity — BMI $\geq$ 30 kg/m²
2. Otherwise healthy — free of any other diagnosed chronic disease
3. Willing and able to provide written informed consent prior to enrolment
4. Recruited via advertisements at Athens Euroclinic Hospital

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

104

Key exclusion criteria

1. Pregnancy, breastfeeding, or plans to become pregnant during the study period
2. Diagnosed type 1 or type 2 diabetes mellitus currently treated with insulin or oral hypoglycaemic agents
3. Significant hepatic impairment or renal insufficiency
4. Prior bariatric surgery or planned bariatric surgery during the study period
5. Known hypersensitivity or allergy to berberine, mulberry, or chromium-containing compounds
6. Current use of anticoagulant or antiplatelet therapy
7. Use of any other weight-loss, glucose-lowering, or insulin-sensitizing nutritional supplement within 4 weeks prior to screening
8. Participation in another interventional clinical trial within 3 months prior to enrolment
9. Presence of any other diagnosed chronic disease

Date of first enrolment

19/11/2024

Date of final enrolment

10/12/2024

Locations**Countries of recruitment**

Greece

Sponsor information**Organisation**

Hellenic Institute of Nutrition

Funder(s)

Funder type

Funder Name

Hellenic Institute of Nutrition

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available