ISRCTN72565988 https://doi.org/10.1186/ISRCTN72565988

Effects of plant-based probiotic supplementation on health

Submission date
06/03/2026

Recruitment status
No longer recruiting

Registration date
10/03/2026

Overall study status
Completed

Last Edited
09/03/2026

Condition category
Other

[_] 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 looked at whether taking a daily plant-based probiotic supplement called SlimBiotics could help improve weight loss and general health in adults who were also taking part in a walking and weight loss programme. The researchers wanted to see if the probiotic could help people lose weight in a healthier way, support good gut health, and improve measures such as body fat, waist size, energy use, fitness, and quality of life.

Who can participate?
Adults aged 18 years to 65 years could take part if they were generally healthy, living independently, and had a body mass index between 25 and 32 kilograms per square metre or a body fat level above 30 per cent. Participants also needed to be willing to join a walking-based fitness programme. People were not able to take part if they had certain medical conditions, recent major lifestyle changes, recent weight loss, or if they were pregnant.

What does the study involve?
Participants were randomly assigned to take either the SlimBiotics probiotic or a placebo capsule every day for 12 weeks. They also followed a walking and weight loss programme. Measurements such as weight, body fat, waist and hip size, energy use, fitness level, quality of life, blood sugar markers, and any side effects were checked at the start, after six weeks, and after 12 weeks. The study was double blinded, meaning neither the participants nor the researchers knew who was taking the probiotic or the placebo.

What are the possible benefits and risks of participating?
Taking part may have helped participants improve their health through weight loss, increased fitness, and possibly benefits from the probiotic supplement. There may also have been no direct benefit. Risks were expected to be low and similar to those of other probiotic supplements and gentle exercise programmes, though some people may have experienced mild digestive symptoms or other side effects. All participants were monitored throughout the study.

Where is the study run from?
The study was carried out in the United States of America and was run from Texas A\&M University in College Station, Texas (USA).

When is the study starting and how long is it expected to run for?
Participants were first enrolled on 23 August 2023, and the final participant was enrolled on 6 November 2024. The study finished on 23 January 2025.

Who is funding the study?
The study is funded by SlimBiotics GmbH (Germany), the company that produces the SlimBiotics probiotic supplement.

Who is the main contact?
Dr Richard Kreider, based at Texas A\&M University, College Station, USA
rbkreider@tamu.edu

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Richard Kreider

ORCID ID
https://orcid.org/0000-0002-3906-1658

Contact details
675 John Kimbrough Blvd.
Suite #118
College Station
United States of America
77843-4253
+1 9794581498
rbkreider@tamu.edu

Type(s)
Public

Contact name
Mr Christopher Rasmussen

ORCID ID
https://orcid.org/0009-0005-8941-3067

Contact details
675 John Kimbrough Blvd.
Suite #206F
College Station
United States of America
77843-4253
+1 9794581741
crasmussen@tamu.edu

Additional identifiers

Study information

Scientific Title
Effects of plant-based probiotic supplementation on weight loss and markers of health

Study objectives
To determine whether daily ingestion of a plant-based probiotic (SlimBiotics) while participating in a weight loss and fitness program helps preserve loss in fat free mass and/or improves markers of health in overweight men and women.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/06/2023, Texas A&M Institutional Review Board (IRB) (301 Old Main Drive, Suite 3104, College Station, 77843, United States of America; +1 9794584067; irb@tamu.edu), ref: IRB2023-0472F

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Effects of plant-based probiotic supplementation on health

Interventions
- Placebo (~ 350mg microcrystalline cellulose + ~10mg magnesium stearate + ~10mg silicon dioxide)

- Active Treatment (150mg of SlimBiotics 4-strain probiotic formula (Limosilactobacillus fermentum K7-Lb1 2B CFU, Limosilactobacillus fermentum K8-Lb1 2B CFU, Limosilactobacillus fermentum K11-Lb3 2B CFU, and/or Lactiplantibacillus plantarum K4-Lb6 2B CFU probiotic

strains) + ~ 200mg microcrystalline cellulose + ~10mg magnesium stearate + ~10mg silicon dioxide).

Supplements will be prepared in capsules and coded for double-blind administration by the sponsor.

Participants will be instructed to take their assigned supplement for the entire duration of the study, 12 weeks.

Block randomization using sealed envelopes was used for this clinical trial.

Intervention Type
Supplement

Primary outcome(s)
1. Body weight in pounds measured using a calibrated digital scale at baseline, six weeks, and 12 weeks

2. Body fat mass in pounds measured using a calibrated Dual Energy X-Ray Absorptiometry (DXA) at baseline, six weeks, and 12 weeks

3. Waist to Hip circumference measured using a tension regulated tape measure at baseline, six weeks, and 12 weeks

Key secondary outcome(s)
1. Resting Energy Expenditure (REE) measured using a calibrated Parvo Medics TrueOne 2400 Metabolic Cart at baseline, six weeks, and 12 weeks

2. Maximal aerobic exercise capacity measured using a calibrated Parvo Medics TrueOne 2400 Metabolic Cart at baseline, six weeks, and 12 weeks

3. Quality of Life (QOL) measured using a SF-36 validated questionnaire at baseline, six weeks, and 12 weeks

4. Side effects measured using a side effects questionnaire at baseline, six weeks, and 12 weeks

5. Hemoglobin A1c measured using turbidimetric inhibition immunoassay (tinia) at baseline, six weeks, and 12 weeks

Completion date
23/01/2025

Eligibility

Key inclusion criteria
1. Have the ability to comply with the study procedures and consume the investigational product daily for the duration of the study
2. Have a willingness to provide voluntary, written, informed consent to participate in the study
3. Have the ability to complete the study based on the durations of individual visits and scheduling requirements
4. Have the ability to be free-living (living in a private home and able to maintain your health and

hygiene without assistance)
5. Are in generally good health and willing to participate in a fitness program that includes aerobic walking
6. Have a Body Mass Index (BMI) between 25 and 32 kg/m² and/or a body fat > 30% (preferred BMI between 25 and 29.9 kg/m² with a desire to lose weight and participate in a walking program)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
160

Key exclusion criteria
1. Have plans for a major change in your lifestyle (i.e., diet, dieting, exercise level, travel, etc.) during the study
2. Have a history (< 3 months) of exercise training or weight loss (> 5%)
3. Have an orthopedic limitation that would prevent participation in a general fitness program
4. Have uncontrolled heart disease, hypertension, diabetes, thyroid disease, cancer, neurological disease, or untreated psychotic or major depressive disorder in which participation in a general fitness program is contraindicated
5. Have taken weight loss dietary supplements or medications during the last four weeks
6. Have a history of chronic use of oral or injectable corticosteroids
7. Have a history within the previous 12 months of alcohol or substance abuse
8. Are a heavy smoker (>1 pack/day within the past 3 months)
9. Are pregnant or have a desire for pregnancy during the study
10. Have a known allergy to any of the ingredients in the supplement product (Probiotics) or placebo (Maltodextrin)

Date of first enrolment
23/08/2023

Date of final enrolment
06/11/2024

Locations

Countries of recruitment

United States of America

Sponsor information

Organisation
Slimbiotics GmbH

Funder(s)

Funder type

Funder Name
Slimbiotics GmbH

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available