Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effects of Akkermansia muciniphilia postbiotic , Lactobacillus rhamnosus postbiotic and green tea extract on body composition, anthropometric and biochemical indices, appetite, and depression scores in overweight or obese adults: a Randomized, double-blind, controlled clinical trial

Protocol summary

Study aim

Comparing the effect of capsule containing Akkermansia muciniphila postbiotic Lactobacillus rhamnosus postbiotic and green tea extracts on body composition, anthropometric and biochemical indices in obese and overweight adults

Design

This study is a randomized, double- blinded, phase 3 controlled clinical trial with four parallel groups (3 intervention and one control groups). 108 individuals (27 in each group) were randomized into groups with balanced- blocked randomization.

Settings and conduct

108 eligible individuals referred to Imam Reza clinic, after becoming informed and obtaining informed consent, are randomly assigned into 4 study groups. They receive group samples, which are named the same as the groups with the letters A, B, C and D to blind the participant and the researcher and they take it daily before meals for 12 weeks. Body composition, anthropometric and biochemical indices and appetite and depression scores will be assessed before and after the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Overweight or obese age 20 to 50 years • Not being menopause for females •Not suffering from metabolic, endocrine, chronic diseases or any kind of infection •Not hospitalized, did not use antibiotics, probiotic or prebiotic supplements or any medication for 3 months before the study Exclusion criteria: • Pregnancy and lactation

Intervention groups

The study groups, including intervention and control groups, included the first group, which included postbiotic Akkremancia muciniphila and green tea extract, the second group, which included postbiotic Lactobacillus rhamnosus and green tea extract, the third group, which included postbiotics and green tea , and the fourth group, which included the control group. The control group was used capsules containing fillers such as Avicel or croscarmellose.

Main outcome variables

Body weight, WC, BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241014063363N1**
Registration date: **2025-04-10, 1404/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-10, 1404/01/21**
Update count: **0**

Registration date

2025-04-10, 1404/01/21

Registrant information

Name

Sanaz Rowshanzadeh

Name of organization / entity

Shiraz university

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-02-19, 1403/12/01
Expected recruitment end date
2025-05-22, 1404/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of Akkermansia muciniphilia postbiotic , Lactobacillus rhamnosus postbiotic and green tea extract on body composition, anthropometric and biochemical indices, appetite, and depression scores in overweight or obese adults: a Randomized, double-blind, controlled clinical trial

Public title
Studying the the effects of Akkermansia Muciniphilia postbiotic , Lactobacillus rhamnosus postbiotic and green tea extract on overweight and obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Not obese or overweight (body mass index above 25 kg/m2) Not obese due to known hormonal disorders Not intolerant to IBS IBD neuropathy, gastroparesis and gastrointestinal motility disorder No thyroid disorders, diabetes, kidney disease, rheumatoid arthritis, or migraine No antibiotics for 2 months prior to study entry No nutritional supplements, prebiotics, probiotics, and omega-3 for one month prior to study entry No planning for pregnancy within the next 6 months and no breastfeeding No history of hospitalization, surgery, or bariatric surgery from 3 months before the study to 6 months after entering the study. No weight change of more than 6 kg in the past 3 months
Exclusion criteria:
Planning for pregnancy for 6 months after the study Not having breast-feeding heavy alcohol use
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will perform using the random block method (1:1:1 ratio) for four groups (one control and three intervention groups). In this method, blocks of four with rotation will be created by an out-of-study person. Then, a block will be randomly selected to determine the groups assigned to the first four participants. The random- blocks selection process will be repeated to determine the random allocation for the entire sample size. For allocation concealment, after determining the random sequence, these sequences will be placed in numbered sealed opaque envelopes for each participant. An out of study person familiar with randomization will perform this process. During the study, by entering any participant in this study, based on the sequence, an envelope will be opened and the allocated group will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, for building the intervention, supplements (including three types) and placebo are the same in terms of color and odor of capsules and will be named A, B, C and D. The process of producing capsules and naming them will be done by an out-of -study person. Therefore, in this study, the researcher team and the participants of different groups will be blinded to the type of the interventions or placebo consumed by each participant in order to observe the principles of blinding.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Schools of Health and Nutrition-Shiraz University of Medical Sciences
Street address
School of Health and Nutrition, Razi Blvd., Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2025-02-26, 1403/12/08
Ethics committee reference number
IR.SUMS.REC.1403.577

Health conditions studied

1

Description of health condition studied
Overweight and obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
body weight
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Scale

2

Description
Waist circumference
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Stadiometer

Secondary outcomes

1

Description
Percent of body fat
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Body composition analyzer

2

Description
Lipopolysacchride (LPS)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Enzyme-linked immuno-sorbent (ELISA) assay

3

Description
High- sensitivity C-reactive Protein (hs-CRP)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Enzyme-linked immuno-sorbent (ELISA) assay

4

Description
Interleukin 6 (IL-6)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Enzyme-linked immuno-sorbent (ELISA) assay

5

Description
Interleukin 1-B (IL-1 B)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Enzyme-linked immuno-sorbent (ELISA) assay

6

Description
Leptin
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Enzyme-linked immuno-sorbent (ELISA) assay

7

Description
GLP-1
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Enzyme-linked immuno-sorbent (ELISA) assay

8

Description
Waist to hip ratio
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Flexible meter

9

Description
Visceral body fat
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Body composition analyzer

10

Description
Lean body mass

Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Body composition analyzer

11

Description
Malondialdehyde (MDA)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Spectrophotometry

12

Description
Total antioxidant capacity (TAC)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

13

Description
Waist circumference to height
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Flexible meter

14

Description
Appetite score
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
VAS questionnaire

15

Description
Depression score
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Beck questionnaire

16

Description
Triglyceride
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

17

Description
Total cholesterol
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

18

Description
LDL (Low- density lipoprotein)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

19

Description
HDL (High- density lipoprotein)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

20

Description
Fasting blood sugar (FBS)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

21

Description
Aspartate transaminase (AST)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

22

Description
Physical activity
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
met questionnaire

23

Description
Food intake
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
24- hour dietary recall (24hr)

24

Description
Alanine transaminase (ALT)
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Colorimetric method

25

Description
Adiponectin
Timepoint
At the beginning of the study (before the intervention) and the end of study (12 weeks after the intervention)
Method of measurement
Enzyme-linked immuno-sorbent (ELISA) assay

Intervention groups

1

Description
Intervention group1: Consume 3 capsules of Akkermansia muciniphila postbiotic supplement with count of 3×10^10 cell count daily for 12 weeks
Category
Treatment - Other

2

Description
Intervention group 2: Consume 3 capsules of Lactobacillus rhamnosus postbiotic supplement with count of 3×10^10 cell count daily for 12 weeks
Category
Treatment - Other

3

Description
Intervention group 3: Consume 3 capsules of Akkermansia muciniphila postbiotic and Lactobacillus rhamnosus supplement with count of 3×10^10 cell count daily for 12 weeks
Category
Treatment - Other

4

Description
Control group: Consume placebo daily for 12 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza clinic
Full name of responsible person
Zahra Shrabi
Street address
Imam Reza clinic, Zand Street, Namazi square, Shiraz
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7134814734
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University
Full name of responsible person
Dr. Mohammad Hadi Eskandari
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Food science department- Agriculture collage-Shiraz Bajgah
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Postal code
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Phone
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Email
eskandar@shirazu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research contract
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University

Full name of responsible person

Sanaz Rowshanzadeh

Position

Ph.D Candidate

Latest degree

Master

Other areas of specialty/work

Food Technology and Quality Control

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Zahra Shrabi

Position

Associate professor

Latest degree

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Full name of responsible person

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Position

Ph.D Candidate

Latest degree

Master

Other areas of specialty/work

Food Technology and Quality Control

Street address

Food science department- Agriculture collage- Bajgah

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available