Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

investigating the effect of synbiotic supplementation on anthropometric indices and body composition in overweight or obese adults: A randomized, triple-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Determining and comparing the effect of synbiotic beverage powder supplementation (containing pasteurized Akkermansia muciniphila, green tea extract, and glucomannan konjac gum) on changes in anthropometric indices (weight, waist circumference, waist-to-hip circumference, and body mass index), body composition (fat percentage, fat mass, fat-free mass, etc.), metabolic indices (lipid profile and fasting blood sugar), appetite, and blood pressure (SBP-DBP) in the intervention and control groups.

Design

A triple-blind randomized clinical trial with two parallel groups (intervention and control) will be conducted on 72 overweight or obese participants.

Settings and conduct

Among the clients in the nutrition clinic, 72 overweight or obese individuals will be randomly assigned to the intervention or control group after reviewing the inclusion and exclusion criteria. The participants will be given either a supplement or a placebo. Outcomes will be assessed at the beginning, middle, and end of the study.

Participants/Inclusion and exclusion criteria

Adults between 18 and 45 years of age who are overweight or obese without a specific medical condition, with no history of taking medications or supplements that affect the study outcomes or medications that interfere with green tea consumption, without a routine intake of high amounts of caffeine or fiber, or routine intake of dairy products and probiotic supplements, without a history of bariatric surgery, meal skipping, or a calorie-restricted diet, without a known allergy to the supplement components, and in a breastfeeding, pregnancy, or menopause state.

Intervention groups

The intervention group will receive three sachets of synbiotic beverage powder daily before every meal for two months.

Main outcome variables

Anthropometric indices and body composition

General information

Reason for update

"The placebo was mistakenly listed as maltodextrin, but this was corrected and changed to crystalline microcellulose."

Acronym

IRCT registration information

IRCT registration number: **IRCT20250222064807N2**
Registration date: **2025-03-26, 1404/01/06**
Registration timing: **prospective**

Last update: **2025-09-05, 1404/06/14**
Update count: **3**

Registration date

2025-03-26, 1404/01/06

Registrant information

Name

Parastoo Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2000

Email address

asgharip4022@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date
2025-10-23, 1404/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
investigating the effect of synbiotic supplementation on anthropometric indices and body composition in overweight or obese adults: A randomized, triple-blind, placebo-controlled clinical trial

Public title
Investigating the effect of synbiotic supplement (containing pasteurized Akkermansia muciniphila, green tea extract and glucomannan konjac gum) on overweight or obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged 18 to 45 years Body mass index in the overweight or obese range (27-34.9) Waist circumference greater than 88 cm in women and greater than 102 cm in men Maintaining a stable weight (no weight gain or loss of more than 5% in the past 3 months) With informed consent
Exclusion criteria:
Pregnant, lactating and postmenopausal women Confirmed or clinical history of eating disorders, gastrointestinal diseases, cardiovascular, hepatic, renal, pulmonary, endocrine diseases (thyroid, diabetes, etc.), cancer or any serious acute or chronic disease Current addiction to cigarettes, drugs or alcohol Presence of known allergies or sensitivities to supplement and placebo components History of bariatric surgery People who skip at least one of their meals Following a special diet, such as a vegetarian diet Regular consumption of more than 300 mg of caffeine or more than 30 g of fiber per day Regular consumption of Pro-, Pre-, and Synbiotic Food products Following a calorie-restricted diet for three months prior to the start of the study Taking probiotics, prebiotics, synbiotics or antibiotics within one month before the start of the study Consuming medications including cholesterol and lipid lowering drugs (statins, etc.), blood sugar lowering drugs (insulin, metformin, liraglutide, etc.), blood pressure lowering drugs (angiotensin II receptor blockers, beta blockers, calcium channel blockers, alpha blockers), drugs affecting weight and body composition, appetite such as antipsychotic drugs, corticosteroids, anti-obesity drugs, drugs affecting GI function Consuming weight loss supplements (including supplements affecting appetite, metabolism, food absorption) such as orlistat Consuming medications that interact with green tea: anisindione, atorvastatin, bortezomib, dicoumarol, digoxin, fusolent, lisinopril, nadolol, rosuvastatin, simvastatin, tacrolimus, tamoxifen, tirzepatide, warfarin professional athletes or those experiencing variations in the intensity and quantity of physical activity over the past four weeks

Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Using random allocation software, a list of random blocks of 6 blocks of 6 is designed and a number is assigned to each block. The order of the contents of each block ensures a balanced allocation of individuals in the study groups. With each patient's visit, one of the blocks is randomly selected and the patient is assigned to one of the groups according to the order of its contents.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this triple-blind study, participants, main researchers, physicians, observers, data collection officials, evaluators, as well as data analyzers are unaware that each person participating in the study group is in the main intervention group (supplementation of the synbiotic) or placebo. For blinding, symbiotic supplements and placebo will be similar in appearance, packaging and labeling. The process of packing and coding of the supplement and placebo will be carried out by the manufacturer (Parsi Lact company).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Working Group/Committee, Faculty of Medicine, Mashhad University of Medical Sciences
Street address
Faculty of Medicine, Eastern Gate of the University Campus, Azadi Square, Mashhad, Razavi Khorasan
City
Mashhad

Province
Razavi Khorasan
Postal code
9177948564
Approval date
2025-02-04, 1403/11/16
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1403.491

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
Anthropometric parameters: weight - waist and hip circumference - waist-to-hip ratio - body mass index
Timepoint
Before, in the middle and at the end of the study
Method of measurement
Scale (with an accuracy of 0.1 kg) - meter

2

Description
Body composition: body fat percentage, fat mass, fat free mass, etc.
Timepoint
Before, in the middle and at the end of the study
Method of measurement
BIA

Secondary outcomes

1

Description
Metabolic parameters (fasting blood sugar, lipid profile: TC-TG-HDL-LDL)
Timepoint
Before and at the end of the study
Method of measurement
Laboratory methods

2

Description
Appetite sensation
Timepoint
Before, in the middle and at the end of the study
Method of measurement
visual analog scale

3

Description
Physical activity
Timepoint
Before, middle and at the end of the study
Method of measurement
International physical activity questionnaire

4

Description
dietary intake
Timepoint
Before, middle and at the end of the study
Method of measurement
24 hour dietary recall

5

Description
gastrointestinal symptoms
Timepoint
Before, middle and at the end of the study
Method of measurement
Gastrointestinal symptom rating scale

6

Description
Blood pressure
Timepoint
Before and at the end of the study
Method of measurement
Electric blood pressure monitor

Intervention groups

1

Description
Intervention group: Weight loss program (diet + physical activity recommendations) + daily consumption of synbiotic beverage powder supplement containing pasteurized Akkermansia muciniphila, green tea extract, and konjac glucomannan gum (provided by Parsi Lact Company) (one sachet half an hour before every meal with sufficient amounts of water) for two months.
Category
Treatment - Other

2

Description
Control group: Weight loss program (diet + physical activity recommendations) + daily consumption of placebo (Microcrystalline cellulose) (with the same color, taste, and appearance) (provided by Parsi Lact Company) (one sachet half an hour before every meal with sufficient amounts of water) for two months
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
nutriton clinic
Full name of responsible person
Dr Mohsen Nematy
Street address
Top Floor of Dr. Moayed Laboratory, Corner of Parastar Street (Ahmadabad 2), Ahmadabad, Mashhad Boulevard, Razavi Khorasan
City
Mashhad
Province
Razavi Khorasan
Postal code
9176698664
Phone
+98 51 3846 0320
Email
NematyM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaqodi
Street address
Vice Chancellor for Research; Mashhad University of Medical Sciences; Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Parastoo Asghari
Position
M.Sc. student of clinical nutrition
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Faculty of Medicine, Eastern Gate of the University Campus, Azadi Square, Mashhad, Razavi Khorasan
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
Fax
Email
AsghariP4022@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Parastoo Asghari
Position
M.Sc. student of clinical nutrition
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Phone
+98 51 3800 2000
Fax
Email
AsghariP4022@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Parastoo Asghari

Position
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Latest degree
Bachelor

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9177948564

Phone
+98 51 3800 2000

Fax

Email
AsghariP4022@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Non-identifiable personal information of participants in this study will be shared. The protocol, results, and statistical analysis of the study will also be published in relevant articles.

When the data will become available and for how long
Access to data will begin 6 months after the results are published.

To whom data/document is available
Participants' non-identifiable personal information will then be made available to other researchers at academic institutions.

Under which criteria data/document could be used
Participants' non-identifiable personal information can only be used for research aspects.

From where data/document is obtainable
Non-identifiable information about participants can be obtained by sending an email to Dr. Saeideh Talebi (talebis@mums.ac.ir).

What processes are involved for a request to access data/document
Other researchers at academic institutions can send their requests via email to Dr. Saeideh Talebi. The data will be sent to them after consultation and approval by the research team.

Comments