Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparing the effects of yogurt containing Akkermansia Muciniphilia postbiotic with yogurt containing Lactobacillus Rhamnosus postbiotic 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 yogurt containing Akk.muciniphila postbiotic with yogurt containing Lactobacillus rhamnosus postbiotic on body composition, anthropometric, and biochemical indices in obese or overweight adults

Design

This study is a randomized, double-blinded, phase 3 controlled clinical trial with three parallel groups (2 intervention and one control groups). 66 individuals (22 in each group) were randomized into groups with balanced-blocked randomization.

Settings and conduct

66 eligible individuals referred to Imam Reza clinic,Shiraz, after becoming informed and obtaining informed consent, are randomly assigned into 3 study groups.They receive group yogurts, which are named the same as the groups with the letters A, B and C to blind the participant and the researcher and they take it daily before meals for 8weeks. Body composition, anthropometric and biochemichal indices and appetite and depression scores will be assessed before and after the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: overweight or obese individuals aged 20-50 and Not being menopause for females. Not suffering from metabolic,endocrine,chronic diseases, Covid-19, or any kind of infection; Not hospitalized, didn't use antibiotics, prebiotic and probiotic supplements or any medication or supplement for 3 months before the study.Not following special diets for 1 month before the study Exclusion criteria:Pregnancy and lactation

Intervention groups

Intervention group1:22 participants will consume 120cc of yogurt containing 10^10 TFU Akkermansia muciniphila postbiotic 30min befor meal daily for 8 weeks Intervention group2: 22 participants will consume 120cc of yogurt containing 10^10TFU Lactobacillus rhamnosus postbiotic 30min befor meal daily for 8weeks Control group:22 participants will consume 120cc of low fat yogurt 30min befor meal daily for 8weeks

Main outcome variables

WC,weight,BMI

General information

Reason for update

Due to the lack of access to the probiotic Lactobacillus Acidophilus as one of the interventions of the study, Lactobacillus rhamnosus is replaced and because effects of Ackermansia muciniphila postbiotic are safer and more than its probiotic, therefore we decide to use the postbiotic instead of probiotic in the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230522058257N1**
Registration date: **2023-11-04, 1402/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-22, 1403/08/01**
Update count: **1**

Registration date

2023-11-04, 1402/08/13

Registrant information

Name

Erfaneh Aalipanah

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-09-23, 1402/07/01
Expected recruitment end date
2024-01-20, 1402/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of yogurt containing Akkermansia Muciniphilia postbiotic with yogurt containing Lactobacillus Rhamnosus postbiotic 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
Comparing the effects of yogurt containing Akkermansia Muciniphilia postbiotic with yogurt containing Lactobacillus Rhamnosus postbiotic on body composition, anthropometric and biochemical indices, appetite, and depression scores in overweight or obese adults
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 20 - 50 years and not being menopause for females Being overweight or obese (Body mass index higher than 25) Not allergic to milk protein and Not lactose intolerant,not being gluten-intolerant Not suffering from known endocrine-related obesity, Inflammatory bowel disease, Irritable bowel syndrome, nouropathy, gastroparesis and gastrointestinal disorders at the beginning of the study Not suffering from thyroid diseases, diabetes, kidney disease, rheumatic diseases and migraine headache at the baseline did not use antibiotics for 2 months before the beginning of the study didn't take probiotic, prebiotic, and omega 3 supplements for 1month before the study Not taking part in other studies for 6 months before the study No weight reduction over 6 Kg in the last 3 months prior to the study no history of hospitalization or any surgery and bariateric surgery for 3 months before the study and 6 months after entering the study Not following special diets such as vegetarian or gluten free or weight-reducing diets Not infected with Covid-19 or any other infections or any hospitalization for 1 month before the study
Exclusion criteria:
planning for pregnancy for 6 months after the study and 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: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will perform using the random block method (1: 1: 1 ratio) for three groups (one control and two intervention groups). In this method, blocks of three 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 three 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 opaqued envelopes for each participant. An out-of-study person familiar with randomization will perform this process. During the study, by entering any participant in the 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 blinding the interventions, enriched yogurts (including two types of yogurts) and placebo are the same in terms of color, odor, and taste and will be named A, B, and C. The process of filling yogurt containers and naming them will be done by an out-of-study person. Therefore, in this study, the research 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
2023-05-21, 1402/02/31
Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1402.073

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
waist circumference
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
stadiometer

2

Description
body weight
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
scale

3

Description
body mass index
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
By calculating using the formula with using height and weight

Secondary outcomes

1

Description
percent of body fat
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Body composition analyzer

2

Description
Lipopolysaccharide (LPS)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Enzyme-linked immuno_sorbent assay (ELISA) kit

3

Description
High-sensitivity C-reactive Protein (hs-CRP) blood level
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Enzyme-linked immuno_sorbent assay (ELISA) kit

4

Description
visceral body fat
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Body composition analyzer

5

Description
Lean body mass
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Body composition analyzer

6

Description
waist to hip ratio
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
flexible meter

7

Description
malondialdehyde (MDA)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
spectrophotometry

8

Description
Appetite score
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
VAS questionnaire

9

Description
depression score
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
beck questionnaire

10

Description
total antioxidant capacity (TAC)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

11

Description
waist circumference to height
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
flexible meter

12

Description
triglyceride
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

13

Description
total cholestrol
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

14

Description
LDL (low-density lipoprotein)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

15

Description
HDL (high-density lipoprotein)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

16

Description
fasting blood sugar (FBS)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

17

Description
Alanine transaminase (ALT)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

18

Description
Aspartate transaminase (AST)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
colorimetric method

19

Description
Physical activity
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)

Method of measurement
met questionnaire

20

Description
food intake
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
24-hour dietary recall (24hr)

Intervention groups

1

Description
Intervention group 1: consume 120 cc of yogurt containing 10^10 TFU Ackermansia muciniphila postbiotic befor meal daily for 8 weeks.
Category
Treatment - Other

2

Description
Intervention group 2: consume 120 cc of yogurt containing 10^10 TFU Lactobacillus Rhamnosus postbiotic befor meal daily for 8 weeks.
Category
Treatment - Other

3

Description
Control group: consume 120 cc of low fat yogurt befor meal daily for 8 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza clinic
Full name of responsible person
Zahra Sohrabi
Street address
Imam Reza clinic, Zand St., Namazi Sq., Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
Sohrabi@sums.ac.ir
Grant name
Grant code / Reference number
27971
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Erfaneh Aalipanah
Position
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Latest degree
Master
Other areas of specialty/work
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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