

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparing the effects of yogurt containing Akkermansia Muciniphila 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 Akkermansia 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 8 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 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 before meal daily for 8 weeks. Intervention group2: 22 participants will consume 120cc of yogurt containing  $10^{10}$  TFU Lactobacillus rhamnosus postbiotic 30min before meal daily for 8 weeks. Control group: 22 participants will consume 120cc of low fat yogurt 30min before meal daily for 8 weeks

##### 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 Akkermansia 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

##### Country

Iran (Islamic Republic of)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <b>Phone</b><br>+98 71 3638 4944                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | planning for pregnancy for 6 months after the study and not having breast-feeding heavy alcohol use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Email address</b><br>aalipanah@sums.ac.ir                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Age</b><br>From <b>20 years</b> old to <b>50 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Recruitment status</b><br><b>Recruitment complete</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Gender</b><br>Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Funding source</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Phase</b><br>3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Expected recruitment start date</b><br>2023-09-23, 1402/07/01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Groups that have been masked</b><br><ul style="list-style-type: none"> <li>• Participant</li> <li>• Investigator</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Expected recruitment end date</b><br>2024-01-20, 1402/10/30                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Sample size</b><br>Target sample size: <b>66</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Actual recruitment start date</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Actual recruitment end date</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Randomization description</b><br>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. |
| <b>Trial completion date</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Blinding (investigator's opinion)</b><br>Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Scientific title</b><br>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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Blinding description</b><br>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.                                                                                                                                                                                                                                                                                                                                          |
| <b>Public title</b><br>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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Placebo</b><br>Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Purpose</b><br>Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>Aged 20 - 50 years and not being menopause for females<br>Being overweight or obese (Body mass index higher than 25)<br>Not allergic to milk protein and Not lactose intolerant, not being gluten-intolerant<br>Not suffering from known endocrine-related obesity, Inflammatory bowel disease, Irritable bowel syndrome, neuropathy, gastroparesis and gastrointestinal disorders at the beginning of the study<br>Not suffering from thyroid diseases, diabetes, kidney disease, rheumatic diseases and migraine headache at the baseline<br>did not use antibiotics for 2 months before the beginning of the study<br>didn't take probiotic, prebiotic, and omega 3 supplements for 1 month before the study<br>Not taking part in other studies for 6 months before the study<br>No weight reduction over 6 Kg in the last 3 months prior to the study<br>no history of hospitalization or any surgery and bariatric surgery for 3 months before the study and 6 months after entering the study<br>Not following special diets such as vegetarian or gluten free or weight-reducing diets<br>Not infected with Covid-19 or any other infections or any hospitalization for 1 month before the study | <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Ethics committees</b><br><br><b>1</b><br><b>Ethics committee</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

**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 cholesterol

## **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 before 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 before meal daily for 8 weeks.

#### Category

Treatment - Other

### 3

#### Description

Control group: consume 120 cc of low fat yogurt before  
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

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814734

##### Phone

+98 71 3725 1002

##### Email

Zahra\_2043@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Zahra Sohrabi

##### Street address

Shiraz University of Medical Sciences, Zand St., Shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3235 7282

##### 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

Ph.D. Candidate

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

##### Street address

School of Nutrition and Food Sciences, Razi Blvd.,  
Shiraz

##### City

Shiraz

##### Province

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7134814336

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Zahra Sohrabi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Erfaneh Alipanah

**Position**

Ph.D. Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

School of Nutrition and Food Sciences, Razi Blvd.,  
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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