

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of probiotic yogurt and exercise on the muscle mass, muscle strength, anthropometry and biochemical parameters and depression score in post-bariatric surgery patients

Protocol summary

Study aim

Determining the effect of yogurt containing probiotics and exercise on muscle mass, muscle strength, anthropometric and biochemical indices and depression score in patients after bariatric surgery.

Design

This study is a randomized, double-blinded, controlled clinical trial with four parallel groups (3 intervention and one control groups). 52 individuals (13 in each group) were randomized into groups with balanced-blocked randomization.

Settings and conduct

52 eligible individuals referred to Hafez and Ghadir hospital, Shiraz, after becoming informed and obtaining informed consent, will be randomly assigned into 4 study groups. They receive yogurt and exercise program according to their group. The yogurt bottles named the same as the groups with the letters A, B to blind the participant and the researcher and they take it daily for 12 weeks. Body composition, muscle strength, anthropometric and biochemical indices and depression score will be assessed before and after the study

Participants/Inclusion and exclusion criteria

Inclusion: Age over 18 years and post-bariatric surgery patients, absence of disease or special sensitivity

Exclusion: unwillingness to continue cooperation for any reason or any complications after the operation, not following interventions and suffering from disease or infection

Intervention groups

1. Receiving 120 cc of low-fat yogurt containing *Bacillus coagulans* + *Lactobacillus plantarum* probiotics in the amount of 10¹⁰ bacteria per day for 12 weeks along with resistance training program
2. Receiving 120 cc of yogurt containing the desired probiotics for a period of 12 weeks
3. Receive 120 cc of plain low-fat yogurt for 12 weeks along with resistance training program
4. Receiving 120

cc of plain low-fat yogurt for 12 weeks as a control group

Main outcome variables

muscle mass , muscle strength

General information

Reason for update

Change in the type of questionnaire in the title due to the greater importance of depression factor in these people based on studies/Editing inclusion and exclusion criteria/

Acronym

IRCT registration information

IRCT registration number: **IRCT20231231060581N1**

Registration date: **2024-01-08, 1402/10/18**

Registration timing: **prospective**

Last update: **2026-02-11, 1404/11/22**

Update count: **1**

Registration date

2024-01-08, 1402/10/18

Registrant information

Name

Shirin Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3636 3326

Email address

sh_rajabi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic yogurt and exercise on the muscle mass, muscle strength, anthropometry and biochemical parameters and depression score in post-bariatric surgery patients

Public title

Investigating the effect of probiotics and exercise in patients after bariatric surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

post-bariatric surgery patients Age above 18

Exclusion criteria:

Having cardiovascular disorders, systolic or diastolic blood pressure, uncontrolled metabolic disorders, neuromuscular or rheumatological disorders, acute pulmonary embolism, chronic symptomatic heart failure, mental or physical disabilities Sensitivity to milk protein and lactose Sensitivity to gluten Taking prebiotics and probiotics since 1 month before entering the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will perform using the random block method (1: 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 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 and placebo are the same in terms of color, odor, and taste and will be named A and B. 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. For the exercise intervention group, the program is designed individually and home-based and the participants are not aware about each other's intervention.

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

2023-12-31, 1402/10/10

Ethics committee reference number

IR.SUMS.MED.REC.1402.421

Health conditions studied**1****Description of health condition studied**

obesity, bariatric surgery

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

muscle 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 Analyzer

2

Description

muscle strength

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

handgrip, sit to stand test

3

Description

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

4

Description

BMI

Timepoint

At the beginning of the study (before the intervention)
and the end of the study (8 weeks after the intervention)

Method of measurement

formula

5

Description

body fat percent

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 analyzer

6

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

flexible meter

7

Description

hip 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

flexible meter

8

Description

waist/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

formula

9

Description

waist/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

formula

10

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

11

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

12

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

13

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

14**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

15**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

16**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

17**Description**

GGT(Gammaglutamyl transferase)

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**

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

19**Description**

Insulin

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

20**Description**

cortisol

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

21**Description**

hs-CRP(C-reactive Protein)

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

22**Description**

Adiponectin

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

23**Description**

vitamin d3

Timepoint

At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)

Method of measurement

HPLC

24**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

questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving 120 cc of low-fat yogurt containing Bacillus coagulans + Lactobacillus plantarum probiotics in the amount of 10¹⁰ bacteria per day for 12 weeks along with a resistance training program

Category

Treatment - Other

2**Description**

Intervention group: Receiving 120 cc of yogurt containing the desired probiotics for a period of 12 weeks

Category

Treatment - Other

3**Description**

Intervention group: Receive 120 cc of plain low-fat yogurt for 12 weeks along with a resistance training program

Category

Treatment - Other

4**Description**

Control group: Receive 120 cc of plain low-fat yogurt for 12 weeks

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hafez Hospital

Full name of responsible person

Siavash Babajafari

Street address

Chamran Blvd

City

Shiraz

Province

Fars

Postal code

۳۴۷۸۶-۷۱۹۴۶

Phone

+98 71 3647 9531

Email

jafaris@sums.ac.ir

2**Recruitment center****Name of recruitment center**

Ghadir Mother and Child Hospital

Full name of responsible person

Siavash Babajafari

Street address

Gloshan Town

City

Shiraz

Province

Fars

Postal code

۷۱۴۴۹۹۵۳۷۷

Phone

+98 71 3227 9701

Email

jafaris@sums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Siavash Babajafari

Street address

Shiraz University of Medical Sciences, Zand St., Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3235 7282

Email

jafaris@sums.ac.ir

Grant name**Grant code / Reference number****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

Shirin Rajabi

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
Fars
Postal code
7134814336
Phone
+98 71 3725 8099
Email
shirin_r69@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
siavash babajafari
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Nutrition and Food Sciences, Razi Blvd.,
Shiraz
City
shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3725 8099
Email
jafaris@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person

Shirin Rajabi
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
Fars
Postal code
7134814336
Phone
+98 71 3481 4336
Email
shirin_r69@yahoo.com

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