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 strenght, anthropometric and biochemichal 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)

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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 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

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
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۳۴۷۸۶-۷۱۹۴۶
Phone
+98 71 3647 9531
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2

Recruitment center
Name of recruitment center
Ghadir Mother and Child Hospital
Full name of responsible person
Siavash Babajafari
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Gloshan Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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