Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Effects of probiotic supplementation with weight reducing plan on anthropometric measures, body composition, eating behavior, and related hormone levels in patients with food addiction and weight regain after bariatric surgery: A randomized clinical trial

Protocol summary

Study aim
Determining the effect of probiotic supplementation with weight loss diet and psychotherapy intervention on the improvement of food addiction and anthropometric indices in people with food addiction and weight regain after bariatric surgery

Design
A randomized, blinded, controlled clinical trial with a parallel group design of 50 patients, enrolled between may 2022 and September 2022

Settings and conduct
The study site is in the obesity clinic of Sina Hospital and the National Nutrition Research Institute. Study participants, researchers, intervention partners, data collectors, and data analysts are blind in this study. All subjects received a diet and three sessions of psychotherapy intervention for three months, and two probiotic capsules per day in the intervention group and two placebo capsules per day in the control group

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being in the age range of 18-50 years; At least 18 months have elapsed since the date of bariatric surgery and have a weight regain of at least 10% of the minimum weight gained; Confirmation of food addiction after obtaining the required score from the relevant questionnaire (YFAS) Criteria for non-inclusion in the study: Pregnancy, lactation; professional athlete; Use of any antibiotics in the last three weeks; Use of any probiotic product or protein supplement in a recent month; Diseases of the liver (other than fatty liver), kidney, cancer and thyroid disease; Use of weight loss and appetite suppressants

Intervention groups
In this study, multi-strain probiotics were used for the intervention group and the control group receive a placebo capsule containing 300 mg of starch. The capsules are exactly the same in shape, size and color

Main outcome variables
Anthropometric indexes; Eating behavior; Food addiction; hormone levels of leptin; serotonin; oxytocin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220406054437N1**
Registration date: **2022-06-01, 1401/03/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-01, 1401/03/11**
Update count: **0**

Registration date
2022-06-01, 1401/03/11

Registrant information

Name
fateme ghafouri-taleghani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2235 7484

Email address
fatima.ghafouri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-15, 1401/02/25

Expected recruitment end date

2022-09-16, 1401/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of probiotic supplementation with weight reducing plan on anthropometric measures, body composition, eating behavior, and related hormone levels in patients with food addiction and weight regain after bariatric surgery: A randomized clinical trial

Public title

effect of probiotic on food addiction and weight regain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Being in the age range of 18-50 years At least 18 months have passed since the date of bariatric surgery and have a weight regain of at least 10% of the minimum weight gained Confirmation of food addiction after obtaining the necessary points from the relevant questionnaire (YFAS)

Exclusion criteria:

Reluctance to cooperate in the study Pregnancy, breastfeeding professional athlete Use of any antibiotics in the last three weeks Use any probiotic product or protein supplement in a recent month Liver disease (other than fatty liver), kidney, cancer and thyroid disease Use of weight loss and appetite suppressants

Age

From **18 years** old to **50 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: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a Triple-blind Randomized Controlled Clinical Trial. A simple method has been used for randomization. Randomization unit is Individual. Excel software has been used for randomization.Using unique codes as ID numbers, using random numbers generated by the software, participants were randomly assigned to the same volume in the intervention and placebo groups. (Description of randomization by Excel software: In the first step, we generated 50 random numbers according to the sample size, in the next step, we obtained the rank of these numbers obtained in the first step, in the third step, we divided these numbers by 25, in the fourth step, the numbers that fell between zero and one were in the intervention group and the rest in the placebo group) The central service method was used for allocation concealment and someone outside our study performed allocation concealment and labeling of supplements.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Study participants, main study researchers, intervention and treatment partners, data collectors, and data analyzers were blinded in this study, and someone outside the study was used for randomization and labeling of probiotic and placebo supplements.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Science

Street address

Next to Ayatollah Taleghani Hospital, Arabi Street, Yemen Street, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2022-02-19, 1400/11/30

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1400.099

Health conditions studied

1

Description of health condition studied

Food addiction, Weight regain after bariatric surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Weight changes

Timepoint
At the beginning of the study and three months after the intervention
Method of measurement
Digital scale with an accuracy of 0.1 kg

2

Description
Food addiction
Timepoint
At the beginning of the study and three months after the intervention
Method of measurement
Yale Food Addiction Scale; YFAS

3

Description
Levels of the hormones leptin, serotonin and oxytocin
Timepoint
At the beginning of the study and three months after the intervention
Method of measurement
By ELISA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Multi-strain probiotics were used. Each probiotic capsule contains Lactobacillus acidophilus (1.8 × 109 CFU / capsule), Bifidobacterium bifidum (1.8 × 109 CFU / capsule), Bifidobacterium lactis (1.8 × 109 CFU / capsule), Bifidobacterium longul / C, 1.8 (1 × 109 CFU / capsule), Lactobacillus reuteri (1 × 109 CFU / capsule), magnesium stearate and maltodextrin. participants take 2 capsules daily (after breakfast and after lunch) for 12 weeks. Prepared by Tach Gene Zist Company. All individuals are given a hypocaloric (-300 to 500 kcal/day), high-protein (25% of energy) diet based on basal metabolism rate (using indirect calorimetry) and level of physical activity (using metabolic equivalents task: MET). For all individuals, ten sessions (Once a week individually) of congenital behavioral therapy (CBT) intervention will be performed online based on the Michael Frey protocol.
Category
Treatment - Other

2

Description
Control group: participants in the control group take two placebo capsules (after breakfast and lunch) daily for 12 weeks, containing 300 mg of starch. The capsules are completely similar in shape, size and color to the intervention capsules and are prepared by Tach Gene Zist Company. All individuals are given a hypocaloric (-300 to 500 kcal/day), high-protein (25% of energy) diet based on basal metabolism rate (using indirect calorimetry) and level of physical activity (using metabolic equivalents task: MET). For all individuals, ten sessions (Once a week individually) of congenital behavioral therapy (CBT) intervention will be performed online based on the Michael Frey protocol.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Country Nutrition Research Institute
Full name of responsible person
Atoosa Saidpour
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2207 7425
Email
atoosa.saidpour@gmail.com

2

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Atoosa Saidpour
Street address
Emam Khomeini Street
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
atoosa.saidpour@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Atoosa Saidpour

Street address
Next to Taleghani Hospital; Yemen Street; Shahid Chamran Highway

City
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1985717443

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Email
Atoosa.Saidpour@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Atoosa Saidpour

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fateme Ghafouri-Taleghani

Position
phd candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Email
fatima.ghafouri@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Academic researchers and people working in industry

Under which criteria data/document could be used

In order to do research work or make medical products

From where data/document is obtainable

Send email to the Atoosa Saidpour (Atoosa Saidpour@gmail.com)

What processes are involved for a request to access data/document

After sending the necessary documents to confirm the research or industrial project

Comments