

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 (1.8×10^9 CFU / capsule), Bifidobacterium bifidum (1.8×10^9 CFU / capsule), Bifidobacterium lactis (1.8×10^9 CFU / capsule), Bifidobacterium longum / C, 1.8 (1×10^9 CFU / capsule), Lactobacillus reuteri (1×10^9 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

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Province

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Postal code

1981619573

Phone

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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

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Province

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Postal code

1136746911

Phone

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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

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Province

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Postal code

1985717443

Phone

+98 21 2387 1021

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

Atoosa Saidpour

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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Phone

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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