Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Effect of probiotic supplementation on gut microbiota in patients with food addiction and weight regain after bariatric surgery

Protocol summary

Study aim
Investigating the effect of probiotic supplementation on the change of intestinal microflora

Design
This study is a Triple-blind Randomized Controlled Clinical Trial with a parallel group design of 50 patients. A simple method has been used for randomization. Randomization unit is Individual. Excel software has been used for randomization. The central service method was used for allocation concealment.

Settings and conduct
The intervention site is Clinic of National Nutrition Research Institute. 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.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age18-50 years, weight regain after bariatric surgery , food addiction Exclusion criteria: Pregnancy, lactation, use of any antibiotics, probiotic product or protein supplement, liver disease, kidney, cancer and thyroid disease, use of weight loss and appetite suppressants

Intervention groups
Intervention group: for 12 weeks, 2 Multi-strain probiotic capsules daily (after breakfast and after lunch) with hypocaloric (-300 to 500 kcal/day), high-protein (25% of energy) diet and ten sessions (Once a week individually) of cognitive behavioral therapy (CBT) intervention (online based). Control group: for 12 weeks, 2 placebo capsules daily (after breakfast and after lunch) with hypocaloric (-300 to 500 kcal/day), high-protein (25% of energy) diet and ten sessions (Once a week individually) of cognitive behavioral therapy (CBT) intervention (online based). Supplements are provided by Tekgen Zist company.

Main outcome variables
Abundance of Eubacterium ؛ Akkermansia ؛ Megamonas ؛ Bifidobacterium ؛ Lactobacillus ؛ Bacteroides

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220406054437N2**
Registration date: **2022-11-14, 1401/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-14, 1401/08/23**
Update count: **0**

Registration date
2022-11-14, 1401/08/23

Registrant information

Name
fateme ghafouri-taleghani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2235 7484

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fatima.ghafouri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of probiotic supplementation on gut microbiota in patients with food addiction and weight regain after bariatric surgery

Public title
The effect of probiotics on intestinal microbiota

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
At least 18 months have passed since the date of bariatric surgery and having weight regain of at least 10% of the lowest weight gained Confirmation of food addiction with yale food addiction scale (YFAS) Being in the age range of 18-50 years

Exclusion criteria:
Pregnancy, lactation, menopause professional athlete Use of any type of antibiotic in the last three weeks Using any type of probiotic product or protein supplement in the last month Having liver diseases (other than fatty liver), kidney, cancer and thyroid diseases 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, and using random numbers generated by the software, participants were randomly assigned to the equal sample size 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. A person outside the research team allocated unique codes A and B to the supplements, none of the research team members knew which code belonged to the intervention or placebo group

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. The list of random numbers was generated by a statistics professor. It was delivered confidentially to the research team of Tachgen Zist company in Excel form. An unknown person from the research team of Tachgen Zist company was chosen by the company manager as the person responsible for blinding the supplements. Probiotic and placebo supplements were given to the research team in a completely similar shape with Numeric and A/B codes. none of the research team members knew which code belonged to the intervention or placebo group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of national nutrition and food thechnology research institute

Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City
Tehran

Province
Tehran

Postal code
1981619573

Approval date
2022-03-14, 1400/12/23

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.024

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
Bacteroides Abundance in the stool sample
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
Polymerase chain reaction (PCR) in stool samples

2

Description
Lactobacillus Abundance in the stool sample
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
Polymerase chain reaction (PCR) in stool samples

3

Description
Bifidobacterium Abundance in the stool sample
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
Polymerase chain reaction (PCR) in stool samples

4

Description
Megamonas Abundance in the stool sample
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
Polymerase chain reaction (PCR) in stool samples

5

Description
Eubacterium Abundance in the stool sample
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
Polymerase chain reaction (PCR) in stool samples

6

Description
Akkermansia Abundance in the stool sample
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
Polymerase chain reaction (PCR) in stool samples

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants take 2 Multi-strain probiotic capsules daily (after breakfast and after lunch) for 12 weeks. 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 Cognitive behavioral therapy (CBT) intervention will be performed online based on the Michael Frey protocol. 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, produced by Tach Gene Zist Company.
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 produced 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 Cognitive 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
National Nutrition and Food Technology Research Institute
Full name of responsible person
Atoosa Saidpour
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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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Email
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2

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Atoosa Saidpour
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Emam Khomeini street, near Hasan Abad square
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Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Next to Taleghani Hospital; Yemen Street; Shahid Chamran Highway
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Province
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1985717443
Phone
+98 21 2387 1021
Email
Zarghi@sbmu.ac.ir
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
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Other areas of specialty/work
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Person responsible for updating data

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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