

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of Probiotic Supplementation on Anthropometric, Body composition, Appetite, Eating Behavior, plasma level of Leptin , Neuropeptide Y and Oxytocin in Obese Women with Food addiction

Protocol summary

Study aim

Determination of the effect of probiotic supplementation on anthropometric measurement, appetite, leptin and neuropeptide Y levels in obese women with food addiction

Design

In this study, participants first divided into two groups based on Body Mass Index grade-1 obesity BMI=(29.9-34.9) and grade-2 obesity BMI= (34.9-39.9), then individuals in each The group is assigned to the probiotic supplement group and the placebo group by randomized blocking method.

Settings and conduct

The population of this study was obese women referred to the obesity clinic of Rasool Akram Hospital. Sample size: 60 subjects (30 in the intervention group and 30 in the control group). Intervention: Individuals will take 2 capsules containing probiotics (every 12 hours) or 2 capsules per day for 12 weeks a week. In addition, participants in both groups will receive weight loss during the study period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI between 30 and 39.99 The desire to participate in the study Confirmation of food addiction through the relevant questionnaire Being in the age range of 20-50 years Exclusion criteria: - Weight loss diets - Pregnancy, lactation Menopause - Continuous use of vitamin and mineral supplements - Use of any type of antibiotic - Use of weight loss and appetite suppressants - Sports activity - Cancer, Cardiovascular disease, Diabetes mellitus, Acute gastrointestinal diseases, Chronic kidney or liver disease

Intervention groups

People randomly receive a weight loss program, a probiotic supplement, or a weight loss and placebo (starch) regimen for 12 weeks, depending on the group they are in.

Main outcome variables

Weight, Body composition, Waist circumferences, Appetite, Eating behaviour, Plasma level of leptin, Neuropeptide Y and Oxytocin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131228015968N5**
Registration date: **2019-05-03, 1398/02/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-03, 1398/02/13**

Update count: **0**

Registration date

2019-05-03, 1398/02/13

Registrant information

Name

Atoosa Saidpour

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
School of nutrition

Country

Iran (Islamic Republic of)

Phone

-

Email address

a.saidpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-09-21, 1398/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Effect of Probiotic Supplementation on Anthropometric, Body composition, Appetite, Eating Behavior, plasma level of Leptin , Neuropeptide Y and Oxytocin in Obese Women with Food addiction
Public title
The effect of probiotic supplementation on obesity
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Body Mass Index 30-39.99 The desire to participate in the study Confirmation of food addiction after obtaining the necessary points from the relevant questionnaire Being in the age range of 20-50 years
Exclusion criteria:
Having a Weight loss diet in the last two months Pregnancy or lactation Menopause Continuous use (more than once a week) of vitamin and mineral supplements in the past month Use of any type of antibiotic in the last three weeks Use of weight loss and appetite suppressants Sports activity that lasted more than three weeks from the start Cancer, cardiovascular disease, diabetes Acute gastrointestinal disease Chronic kidney or liver disease, with the exception of non-alcoholic fatty liver Infectious diseases up to 1 month before the start of the study
Age
From **20 years** old to **50 years** old
Gender
Female
Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participants were classified into two groups with obesity grade A (30-34.9) and obesity grade 2 (34.9-39.9) by stratified blocked randomization method and based on BMI and randomly assigned to One of the groups receiving the supplement is a probiotic or placebo group. Separate randomization is done within each group. The size of the blocks is 4, with two assignments to the intervention group (A) and two allocations to the placebo group (B). There are 6 different permutations of AABB, ABAB, BBAA, BABA, ABBA, BAAB.
Blinding (investigator's opinion)

Double blinded
Blinding description
Prior to the beginning of the study, the canisters containing the capsules are coded by individuals other than the research team, A and B, so that the knowledge of the type of capsules received by each group is not known to the researcher. Since this study is double blind, the subjects , the researchers have no information about the individuals located in the studied and control groups.
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 sciences
Street address
No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran
City
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Province
Tehran
Postal code
1981619573
Approval date
2018-12-31, 1397/10/10
Ethics committee reference number
IR.sbmu.nnftri.Rec.1397.029
2
Ethics committee
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Ethics committee of Shahid Beheshti University of Medical sciences
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Postal code
1981619573
Approval date
2018-12-31, 1397/10/10
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1398.002

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Weight

Timepoint

Before intervention, after 6 Weeks of intervention and after 12 Weeks of intervention

Method of measurement

Seca scale

2

Description

Body Mass Index

Timepoint

Before intervention, after 6 Weeks of intervention and after 12 Weeks of intervention

Method of measurement

Calculation (kg/m²)

3

Description

Waist circumference

Timepoint

Before intervention, after 6 Weeks of intervention and after 12 Weeks of intervention

Method of measurement

Meter strip

4

Description

Fat Mass

Timepoint

Before intervention, after 6 Weeks of intervention and after 12 Weeks of intervention

Method of measurement

Bio Impedance Analyzer

5

Description

Fat Free Mass

Timepoint

Before intervention, after 6 Weeks of intervention and after 12 Weeks of intervention

Method of measurement

Bio Impedance Analyzer

Secondary outcomes

1

Description

Serum level of Leptin

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

Elisa

2

Description

Serum Neuropeptide Y

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

Elisa

3

Description

Appetite

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

Simple appetite questionnaire

4

Description

Serum level of Oxytocin

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

Elisa

5

Description

Eating behavior

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

The Three-Factor Eating Questionnaire

Intervention groups

1

Description

Intervention group received daily two probiotic capsules containing (Lactobacillus acidophilus, Bifidobacterium bifidum, Bifidobacterium lactis, Bifidobacterium langum, Lactobacillus ruminosus and Lactobacillus rotiria (every 12 hours) with microbial load 2×10^9 for 12 weeks manufactured in Tak Gene, Iran

Category

Treatment - Drugs

2

Description

Control group: received daily two placebo capsules containing 300 mg of starch every 12 hours for 12 weeks. manufactured in Zahravi Pharmaceutical Company. The placebo is completely similar to the probiotic supplement in terms of its appearance

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity clinic of Hazrat-e-Rasool Akram hospital

Full name of responsible person

Elham Narmaki

Street address

Rasoul-e-Akram Hospital-Corner of Mansouri Street --
Nyayesh Avenue- Sattar Khan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical sciences- School of Nutrition

Full name of responsible person

Dr.Esmat Nasserri

Street address

No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave.,
Shahrake Qods(Gharb) town, Tehran, Iran

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Email

Nasserri_esm@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University
of Medical sciences- School of Nutrition

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

Elham Narmaki

Position

PhD. student of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable