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 mearsurment, 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, NeuropeptideY 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

Tehran

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

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical sciences

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

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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 rhominosus 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 Nasseri
Street address
No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran
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Nasseri_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
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Nutrition
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
Nutrition

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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