

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of co-supplementation with probiotic and magnesium on components of microbiota-gut-brain axis including mood, intestinal barrier function and stool microbial populations in obese subjects with metabolic mood syndrome

Protocol summary

Study aim

Evaluating effects of probiotic and magnesium co-supplementation on mood, intestinal barrier function and stool microbial populations in obese subjects with metabolic mood syndrome

Design

A two-arm, parallel double blind controlled randomized clinical trial

Settings and conduct

Recruitment will take place in Imama Reza Clinic, Shiraz,Iran. Two assessors will collect data and conduct random allocation according to the orders already provided by a statistician. Intervention and placebo capsules will be in same containers with labels "A" or"B" provided by a non involved faculty, so both subjects and assessors will be blinded to the intervention type.

Participants/Inclusion and exclusion criteria

men and women with age range of 18 to 50 years old willing to participate in the study, with Body Mass Index \geq 30 and waist circumference \geq 85cm and 102 cm in women and men, respectively. Beck Depression Inventory scores ranging from 17 to 40. No history of chronic diseases. Not using probiotics in the last 2 months, or antibiotic in the last 3 months. Pregnancy, breast feeding, menopause, regular smoking or alcohol use, addiction, regular intake of anti-inflammatory drugs and using magnesium, omega-3, and anti-oxidants in the previous month will also make subjects un-eligible for the study Exclusion Criteria: pregnancy, significant change in diet or physical activity, starting new drugs or antibiotics, and not intending to continue study protocols.

Intervention groups

One capsule containing probiotic species of Lactobacillus and Bifidobacteria + a capsule containing magnesium chloride. Control group will receive identical capsules containing maltodextrin

Main outcome variables

Glucose, insulin, insulin resistance markers,cortisol, Zonulin, Endotoxin, CRP, Beck,MoCA & DASS scores,, quality of life, stool population of Bacteroidetes, Firmicutes, Akkermensia Muciniphila,anthropometric measures

General information

Reason for update

After we reviewed the evidence and based on consultation with our statistician our team decided to decrease the intervention period from 12 to 9 weeks. Furthermore, a number of outcome variables has been added to the previously recorded variables including: serum levels of cortisol, insulin, fasting glucose, C-reactive protein, as well as markers of insulin resistance (QUICKI,HOMAIR), DASS anxiety, stress and depression scores, Quality of life, and percent of fat-free mass and fat mass.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045525N1**
Registration date: **2020-04-07, 1399/01/19**
Registration timing: **prospective**

Last update: **2021-09-12, 1400/06/21**

Update count: **1**

Registration date

2020-04-07, 1399/01/19

Registrant information

Name

Sepideh Mahboobi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3832 3281

Email address

sepidmahboobi@gmail.com

Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2020-04-20, 1399/02/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of co-supplementation with probiotic and magnesium on components of microbiota-gut-brain axis including mood, intestinal barrier function and stool microbial populations in obese subjects with metabolic mood syndrome

Public title

Probiotic applications in obesity and related mood disorders

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Willing to participate in the study Age range of 18 to 50 years Body Mass Index (BMI) ≥ 30 and waist circumference (WC) more than 85cm in women and 102 cm in men Beck Depression Inventory (BDI) scores ranging between 17 to 40 Not taking probiotic supplements in the last 2 months and antibiotics in the last 3 months Absence of chronic liver, kidney, cardiovascular, GI and infectious diseases as well as diabetes, and severe neurological and psychiatric disorders. Not using anti-depressants Not using antioxidants, omega-3 and magnesium supplements less than one month prior to study commencement Not regular use of steroid and non-steroid anti-inflammatory drugs No regular alcohol drinking or smoking, No opioid addiction No history of heart attack, not being pregnant or intending pregnancy, not being in breastfeeding or menopausal states.

Exclusion criteria:

pregnancy, any significant change in diet or physical activity, starting new drugs or antibiotics, and not intending to continue study protocols.

Age

From 18 years old to 50 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

By implementing block randomization method using blocks of four, eligible subjects will be randomly allocated to either intervention or control group. Allocation concealment will be conducted by application of sealed envelopes containing active or placebo, created by a colleague that is not involved with data gathering and participant evaluation.

Blinding (investigator's opinion)

Double blinded

Blinding description

All active capsules and placebo will be the same in size, color, odor, taste and other related characteristics. Furthermore, the packaging will be the same so neither data collectors and outcome assessors (that are the same in the present study) nor participants will be aware of the intervention type.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

71345-1978

Approval date

2020-03-03, 1398/12/13

Ethics committee reference number

IR.SUMS.REC.1398.1375

2**Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

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Postal code

71345-1978

Approval date

2020-05-30, 1399/03/10

Ethics committee reference number

IR.SUMS.REC.1399.212

Health conditions studied

1

Description of health condition studied

Obesity with mood disorders

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Beck Depression Inventory (BDI) score

Timepoint

Before commencement and after 12 weeks of intervention

Method of measurement

Beck Depression Questionnaire

Secondary outcomes

1

Description

Beck Anxiety Inventory (BAI) score

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Beck anxiety questionnaire

2

Description

Plasma Zonulin Levels

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

ELIZA

3

Description

Plasma Endotoxin

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

ELIZA

4

Description

Some Stool Bacterial populations

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Real time PCR

5

Description

Waist

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Tape meter

6

Description

Weight

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Body analyzer (Inbody)

7

Description

Body mass index

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Body analyzer (Inbody)

8

Description

fat mass

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Body analyzer (Inbody)

9

Description

fat free mass

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Body analyzer (Inbody)

10

Description

Quality of life

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

qol-12 questionnaire

11

Description

depression . stress and anxiety scores

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

DASS anxiety, stress & depression questionnaire

12

Description

Fasting serum cortisol

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

ELIZA

13

Description

Fasting blood glucose

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Autoanalyzer

14

Description

Fasting serum insulin

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

ELIZA

15

Description

Homeostatic Model Assessment for Insulin Resistance (HOMAIR)

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

FORMULA

16

Description

quantitative insulin-sensitivity check index (QUICKI)

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

FORMULA

17

Description

C-reactive protein

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

ELIZA

18

Description

Serum magnesium

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Autoanalyzer

19

Description

Montreal Cognitive Assessment score (MoCA)

Timepoint

Before commencement and 9 weeks after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group will receive 1 gram Capsule containing lactobacillus and bifidobacteria at dose of 3×10^9 CFU + one capsule containing 1 gram magnesium chloride providing 250 milligrams of elemental magnesium on a daily basis after one of main meals (preferably dinner)

Category

Other

2

Description

Control group will receive two 1-gram capsules containing maldodextrin similar to those with active components based on color, shape, odor, weight, and packaging, on a daily basis after a main meal (preferably dinner).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Professor Mohammad Hassan Eftekhari

Street address

Namazi Square

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7134814336

Phone

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Email

sepidmahboobi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

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1433671348

Phone

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ghasemiy@sums.ac.ir

Grant name

Razi Festival

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

60

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**

Shiraz University of Medical Sciences

Full name of responsible person

Sepideh Mahboobi

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Sepideh Mahboobi

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Latest degree

Master

Other areas of specialty/work

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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