Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of a weight loss diet with or without prebiotic supplementation on anthropometric measures, metabolic and inflammatory status, gut permeability, endotoxemia and depression status in obese women with major depression disorder

Protocol summary

Study aim

The aim of the present study is to investigate the effects of a weight loss diet with or without prebiotic supplementation on anthropometric measures, metabolic and inflammatory status, gut permeability, endotoxemia and depression status in obese women with major depression disorder.

Design

Randomized double-blind clinical trial with two arm parallel groups

Settings and conduct

The study will be conducted in the psychiatry clinic of Tabriz University of Medical Sciences, and supplementation duration will be 8 weeks. The prebiotic and placebo sachets will be coded by the person responsible for preparing them, and the main investigators and the patients will be blinded to the type of the supplement each group receives.

Participants/Inclusion and exclusion criteria

48 patients with mild to moderate depression and BMI of 30-40 Kg/m2 will be included in the study. Pregnancy, lactation, and co-morbidity of other psychological or neurological diseases are among the exclusion criteria of the study.

Intervention groups

The subjects in both groups will receive a weight loss diet considering their dietary habits. Patients in the prebiotic group will use a 10 gram inulin sachet with their lunch, daily. In the placebo group, the sachet will contain 10 grams of maltodextrin.

Main outcome variables

State-trait anxiety inventory (STAI-Y), Beck depression inventory (BDI-II), Hamilton depression rating scale (HDRS), well-being (WHO-5); anthropometric measures and body composition; Resting metabolic rate (RMR); blood pressure; serum levels of lipopolysaccharide (LPS), Zonulin, insulin, glucose, lipid profile (TG, HDL-C, LDL-C, TC), inflammatory biomarkers (IL-10, TNF-a, hs-CRP, MCP-1, TLR-4), and brain-derived neurotrophic factor (BDNF), tryptophan and Kynurenine

General information

Reason for update

Additional biomarkers will be assayed in the serum samples of the patients, as the assessed outcomes of two new Masters' theses. Information about these biomarkers as well as ethics codes for these theses are added to this project.

Acronym

IRCT registration information

IRCT registration number: **IRCT20100209003320N15**
Registration date: **2018-08-02, 1397/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-26, 1398/09/05**
Update count: **1**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 1113

Email address

ebrahimimamagani@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-09-22, 1397/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of a weight loss diet with or without prebiotic supplementation on anthropometric measures, metabolic and inflammatory status, gut permeability, endotoxemia and depression status in obese women with major depression disorder

Public title
Effects of prebiotic supplementation and calorie restriction in major depressive disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Non-menopausal women aged 20-50 years Body Mass Index (BMI) range: 30-40 Kg/m2 Suffering from mild to moderate depression based on DSM-V (Diagnostic and Statistical Manual of Mental Disorders, 5th Edition) criteria, as diagnosed by a psychiatrist willingness to participate in the study

Exclusion criteria:
Pregnancy or lactation Co-morbidity with other major psychological or neurological diseases including psychosis, multiple sclerosis (MS), bipolar disorder Suffering from thyroid dysfunctions Drug abuse Smoking A history of following particular diets Using synthetic or herbal drugs for weight loss Changes in type or dosage of any other medications or nutritional supplements, during the study Using fiber supplements or taking more than 25 grams of dietary fiber per day Regular use of prebiotic or probiotic products or supplements, or antibiotic drugs during 2 months prior to the study or during the study Any significant events during the study, which might affect the patient's psychological health

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
From among the patients who volunteer to participate in the study, 48 individuals will be selected by simple randomization. Then by using the Random Allocation Software, the subjects will be allocated into either prebiotic or placebo group, stratified by depression severity and BMI.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the main investigators (including the student, and her supervisor and adviser professors) as well as the patients will be blinded to the type of the supplement (prebiotic or placebo) received by each group. The person responsible for preparing the supplement sachets (who is completely unrelated to the study) will be asked to assign a three digit code to each of the two powders (prebiotic and placebo), and keep the codes for himself until the end of the study and data analyses.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Research Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166/1573113

Approval date
2018-05-21, 1397/02/31

Ethics committee reference number
IR.TBZMED.REC.1397.189

2

Ethics committee

Name of ethics committee
The Research Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

City
Tabriz

Province
East Azarbaijan
Postal code
5166/1573113
Approval date
2019-10-14, 1398/07/22
Ethics committee reference number
IR.TBZMED.REC.1398.718

3

Ethics committee
Name of ethics committee
The Research Ethics Committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166/1573113
Approval date
2019-11-11, 1398/08/20
Ethics committee reference number
IR.TBZMED.REC.1398.813

Health conditions studied

1

Description of health condition studied
Major depressive disorder, mild
ICD-10 code
F33.0
ICD-10 code description
Major depressive disorder, recurrent, mild

2

Description of health condition studied
Major depressive disorder, moderate
ICD-10 code
F33.1
ICD-10 code description
Major depressive disorder, recurrent, moderate

Primary outcomes

1

Description
Anthropometric measures
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of height and weight without shoes and with minimum clothes on, by Seca stadiometer and scale, respectively. Measurement of waist and hip circumferences by a tape measure. Calculation of waist to hip ratio (WHR) by dividing waist circumference by hip circumference, and body mass index (BMI) by dividing weight (Kg) by height squared (m2)

2

Description
Body composition
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Bioelectrical Impedance Analysis (BIA) to determine Fat mass (FM), Fat free mass (FFM), and Body water (BW)

3

Description
Resting metabolic rate
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Indirect calorimetry

4

Description
Gut permeability
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of Serum Zonulin by ELISA method

5

Description
Endotoxemia
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Measurement of serum lipopolysaccharide (LPS) by ELISA

6

Description
Blood pressure
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
stethoscope

7

Description
Blood glucose
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

8

Description
Lipid profile
Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of total cholesterol, HDL-cholesterol and triglyceride through enzymatic methods and calculation of LDL-cholesterol by Friedewald equation

9

Description

Inflammatory indices

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Measurement of serum hs-CRP by immunoturbidimetry, and serum TNF-a and IL-10 by ELISA

10

Description

State-trait anxiety

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI-Y)

11

Description

Depression severity

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Beck Depression Inventory (BDI-II)

12

Description

Depression remission

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Hamilton Depression Rating Scale (HDRS)

13

Description

Psychological well-being

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

WHO-5 questionnaire

14

Description

Serum brain-derived neurotrophic factor (BDNF)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA

15

Description

Serum Monocyte Chemoattractant Protein-1 (MCP-1)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA

16

Description

Serum Toll-like receptor 4 (TLR_4)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA

17

Description

Serum Tryptophan

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA

18

Description

Serum kynurenine

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will receive weight loss diet and prebiotic supplements for 8 weeks. Prebiotic supplement is a sachet containing 10 grams of inulin (a product by Sensus Co.and made in The Netherlands) which will be dissolved in a glass of water and used once a day with lunch.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive weight loss diet and placebo for 8 weeks.Placebo is a sachet containing 10 grams of maltodextrin (a product by FIC Co. and made in China)which will be dissolved in a glass of water and used once a day with lunch.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bozorghmehr Psychology Center, Tabriz University of Medical Sciences

Full name of responsible person
Dr. Fatemeh Ranjbar

Street address
Across from Post Office, Artesh Jonoubi St.

City
Tabriz

Province
East Azarbaijan

Postal code
5138634348

Phone
+98 41 3540 3562

Email
fk_ranjbar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Alireza Ostad Rahimi

Street address
Faculty of Nutrition and Food Sciences

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 2292

Email
nut-rc@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Elnaz Vaghef-Mehrabany

Position
Ph.D. candidate in Nutritional Sciences

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
Faculty of Nutrition and Food Sciences, Attar Neyshabouri Av., Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 7582

Email
elnaz.vaghef@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mehrangiz Ebrahimi Mamagani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Faculty of Nutrition and Food Sciences, Attar Neyshabouri Av., Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3335 7582

Email
ebrahimimamagani@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Elnaz Vaghef-Mehrabany

Position

Ph.D. candidate in Nutritional Sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Faculty of Nutrition and Food Sciences, Attar Neyshabouri Av., Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7582

Email

elnaz.vaghef@gmail.com

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

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

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

Title and more details about the data/document

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

access starting 12 months after publication

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta-analysis.

From where data/document is obtainable

To access the required data, the researchers can contact Ms. Elnaz Vaghef-Mehrabany: email address: elnaz.vaghef@gmail.com cellphone number: 0098 9143044360

What processes are involved for a request to access data/document

The applicant should provide a brief description of the aims and methods of his Meta-analysis. His request will be assessed by the researchers, and if all of them agree to the request, the requested data will be emailed to the applicant in an Excel file format. All these procedures will take no longer than 15 days.

Comments