

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effects of anti-inflammatory diet on inflammatory biomarkers, gut microbiome and disease severity in clinically-diagnosed women with depression

Protocol summary

Study aim

Determining the effect of anti-inflammatory diet on some inflammatory indicators, gut microbiome composition, and symptoms and disease severity in patients with depression.

Design

A clinical trial with a control group, with two parallel groups, without blinding, randomized, and on 60 patients who were randomly assigned in a pot.

Settings and conduct

Intervention in the hospital and in parallel and without blinding

Participants/Inclusion and exclusion criteria

1. Taking antibiotics 2. Taking probiotic supplements 3. Vigorous physical activity 4. Changing the type or dose of medication used for mental disorders 5. Hospitalization due to severe depression 6. Getting pregnant 7. Smoking 8. Getting infected with the coronavirus 9. The occurrence of unpleasant events such as the death of loved ones or close relatives 10. Body mass index more than 35 or less than 20 kg/m².

Intervention groups

the intervention group in this study will receive an anti-inflammatory diet. first, using the age, sex, height, and current weight of the patients in the Harris-Benedict formula, the basal metabolic rate (BMR) of the patients will be calculated. Then the daily energy requirement of each person is calculated based on his physical activity and taking into account the thermogenic effect of food (TEF), then based on the person's current BMI, the energy intake of overweight and obese people is limited to 500 calories. will be done. The food plan of these people will be adjusted in such a way that macronutrients will be distributed as follows: carbohydrates 50-55% of energy, fat 25-30% of energy, and protein 15-20% of energy. Based on this division, the required amounts of each food group will be calculated.

People in the control group will receive their usual dietary intake for 8 weeks

Main outcome variables

Inflammatory biomarkers, gut microbiome, and severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230107057069N1**

Registration date: **2023-05-04, 1402/02/14**

Registration timing: **prospective**

Last update: **2023-05-04, 1402/02/14**

Update count: **0**

Registration date

2023-05-04, 1402/02/14

Registrant information

Name

Mohammad Reza Mazandarani Fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5531 4405

Email address

r.mazandarani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of anti-inflammatory diet on inflammatory biomarkers, gut microbiome and disease severity in clinically-diagnosed women with depression

Public title

Effects of anti-inflammatory diet in depression

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Female gender Being between the ages of 20 and 60 Suffering from clinical depression with moderate or greater severity and diagnosed by a psychiatrist.

Exclusion criteria:

Pregnant or lactating Decision to get pregnant in the future Being a smoker or addicted to other tobacco products Having intense physical activity as a professional athlete There has been a change in the type and dose of medication used for mental disorders during the last two months All types of antibiotics have been used during the two have consumed in the last month Have consumed any amount of probiotic supplements during the last two months Have been exposed to the coronavirus All types of cancer, heart, and brain strokes, and multiple, CKD, have been affected in The last month, as well as diseases such as diabetes Sclerosis or other autoimmune diseases in the last three months Taking omega 3 supplements and Suffering from various eating disorders are also part of the criteria.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

People will be placed in blocks of two according to their age (20 to 40 and 40 to 60 years) and body mass index (20 to 25, 25 to 30 and 30 kg/m2 and above). Then, the people placed in each two-person block will be randomly assigned to intervention and non-intervention groups. To randomly assign people to groups, each person is assigned a code and these codes are poured into a pot. A person outside the study is then asked to draw codes from the pot using a lottery. The first code will be assigned to the intervention group, the second code will be assigned to the control group, and the rest of the people will be randomly assigned to two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of School of Medicine- Tehran University of Medical Sciences

Street address

Intervention in the hospital and in parallel and without blinding

City

Tehran

Province

Tehran

Postal code

1416643931

Approval date

2023-01-21, 1401/11/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.690

Health conditions studied**1****Description of health condition studied**

depression

ICD-10 code

F33.9

ICD-10 code description

Major depressive disorder, recurrent, unspecified

Primary outcomes**1****Description**

moderate depression score based on Hamilton's 17-item questionnaire (score 14 to 17)

Timepoint

At the beginning and 8 weeks after the start of the intervention

Method of measurement

Hamilton's 17-item questionnaire

Secondary outcomes

1

Description

gut microbiota

Timepoint

At the beginning and 8 weeks after the start of the intervention

Method of measurement

real-time PCR

2

Description

inflammatory biomarkers

Timepoint

At the beginning and 8 weeks after the start of the intervention

Method of measurement

Elisa

Intervention groups

1

Description

Intervention group: Anti-inflammatory diet

Category

Lifestyle

2

Description

Control group: Normal diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Kargar Nejad Hospital

Full name of responsible person

Mohammad Reza Mazandaranian Fard

Street address

Kargar Nejad Hospital, Qutb Rawandi Blvd, Kashan, Isfahan province

City

Kashan

Province

Isfahan

Postal code

7344687159

Phone

+98 31 5554 9111

Email

r.mazandaranian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

ahmad esmaillzadeh

Street address

No. 44, Keshavarz Boulevard, Naderi St., Hojat Dost St

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 21 8895 5975

Email

a.esmaillzadeh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

ahmad esmaillzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Email

a.esmaillzadeh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

ahmad esmaillzadeh

Position

Professor

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Other areas of specialty/work

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Phone

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Email

a.esmaillzadeh@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad reza Mazandarani Fard

Position

Student

Latest degree

Master

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

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