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 Mazandaranian Fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5531 4405

Email address

r.mazandaranian@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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
ahmad esmaillzadeh
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No. 44, Keshavarz Boulevard, Naderi St., Hojat Dost St
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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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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