Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effect of flaxseed oil supplementation on severity of depression and serum level of BDNF- α in depressed women: a randomized, double blind clinical trial

Protocol summary

Study aim

1-Comparison of Depression Severity Changes in Depressed Women Before and After Intervention (flaxseed oil Supplementation) in Treatment and Control group. 2-Comparison of serum level of BDNF changes in Depressed Women Before and After Intervention (flaxseed oil Supplementation) in Treatment and Control group.

Design

This study is a double blind randomized clinical trial in which 60 depressed women will be enrolled to study according to DSM-IV criteria. Then, participants will be divided equally into intervention and control groups using permuted block randomization

Settings and conduct

60 women referred to Imam Khomeini clinic will be randomly divided to intervention and control groups. The intervention group will receive flaxseed oil supplementation for 10 weeks, 1000 mg, 2 time per day and the control group will receive placebo. At the beginning and end of the study 3 ml of venous blood (for assessment of BDNF) is taken from all patients and Beck's questionnaire will be completed to assess the severity of depression

Participants/Inclusion and exclusion criteria

1-Ages 18 to 45 years old 2-having depression confirmed by a Psychiatrist according to DSM-IV criteria and being treated with antidepressant medications 3-Willingness to cooperate in the project exclusion criteria: 1-having cardiovascular disease and hypertension 2-having kidney, liver, cancer, diabetes and inflammatory diseases 3-having addiction and taking any drugs, tobacco or alcohol 4-taking any multivitamin and omega-3 supplements 3 months before the study 5-having cysts in the breast and ovary or having family history of cysts

Intervention groups

intervention group: participants will receive flaxseed oil supplementation 100 milligram, twice daily control group: participants will receive placebo contained paraffin twice daily

Main outcome variables

1-depression severity 2- serum level of BDNF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130903014551N3**
Registration date: **2019-10-07, 1398/07/15**
Registration timing: **prospective**

Last update: **2019-10-07, 1398/07/15**
Update count: **0**

Registration date

2019-10-07, 1398/07/15

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3792 3183

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s_m_rouhani2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-14, 1398/07/22

Expected recruitment end date

2020-01-22, 1398/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of flaxseed oil supplementation on severity of depression and serum level of BDNF- α in depressed women: a randomized, double blind clinical trial

Public title

Effect of flaxseed oil supplementation on severity of depression and serum level of BDNF- α in depressed women: a randomized, double blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 45 years old Having Depression confirmed by a Psychiatrist according to DSM-IV criteria and being treated with antidepressant medications Willingness to cooperate in the project

Exclusion criteria:

Having cardiovascular disease and hypertension Having kidney, liver, cancer, diabetes and inflammatory diseases Having addiction and taking any drugs, tobacco or alcohol Taking any multivitamin and omega-3 supplements 3 months before the study Having cysts in the breast and ovary or having family history of cysts

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through block randomization method (permuted blocked randomization). depending on the sample size , each block includes 4 characters and will be used AABB combination. In the following, all possible modes from the combination will be listed and a code will be allocated to each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

For double blinding of this study, at the beginning, cans contained flaxseed supplement and placebo were coded as A and B by person other than researcher to ensure researcher and participants were not informed about types of supplement received by participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jerib street, Esfahan, Iran

City

Esfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-05-28, 1398/03/07

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.134

Health conditions studied

1

Description of health condition studied

Depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Severity of depression

Timepoint

Before and after intervention

Method of measurement

Beck questionnaire

2

Description

Serum level of BDNF

Timepoint

Before and after intervention

Method of measurement

ELISA method

Secondary outcomes

1

Description
Physical activity
Timepoint
At the beginning and end of the intervention
Method of measurement
Physical activity record questionnaire

2

Description
Dietary intake
Timepoint
At the beginning the intervention, In the fifth week and end of the intervention
Method of measurement
Two day food record

Intervention groups

1

Description
Intervention group: Patients in this group will receive flaxseed oil supplementation, 1000 mg, made by Barijessence company twice a day for 10 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will receive a paraffin-containing placebo made by Barijessence company, 2 times daily for 10 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Clinic
Full name of responsible person
Dr.Maryam Poorbafrani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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http://research.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
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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