

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Evaluating effects of omega-3 supplementation on weight and depression among overweight or obese women with depression compared to placebo

Protocol summary

Summary

Objective: To determine the effects of omega-3 supplementation on weight and depression among overweight or obese women with depression compared with the control group. Main inclusion criteria: Age 18 to 50 years, female gender, body mass index above 25, the diagnosis of depression. Main exclusion criteria: Taking drugs that affect on depression and weight, hormonal and metabolic disorders - Study population: The 18-50 years women with depression who are overweight or obese - Sample size: 50 - Intervention Study: omega-3 - Intervention duration: 12 weeks - Primary outcome or outcomes studied: Depression, weight, body mass index - Design of the study: fifty patients with mild depression (based on a semi-structured diagnostic interview and the Hamilton depression scale test) who are overweight or obese will participate in this double-blind, 12-week, placebo-controlled study. Participants will sign the informed consent form and then they will be randomly assigned to one of two groups receiving daily 3 gr omega-3 capsules or placebo. The groups will be blinded by placebo to participants and will be blinded to researcher by coding. At the end, hypothesis of the study will be tested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014053016465N3**

Registration date: **2014-06-16, 1393/03/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-06-16, 1393/03/26

Registrant information

Name

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Name of organization / entity

Psychiatry Research Center/ Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-05-06, 1394/02/16

Expected recruitment end date

2016-05-06, 1395/02/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating effects of omega-3 supplementation on weight and depression among overweight or obese women with depression compared to placebo

Public title

Evaluating the effects of omega-3 on weight and depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 50 years; females; Body Mass Index above 25; patients with mild (minor)

depression based on semi- structured diagnostic interview by a psychiatrist; to sign a consent form
 Exclusion Criteria: Those who are taking antidepressants; severe (major) depression; psychotic depression or have suicidal thoughts; use of anti-inflammatory glucocorticoids, and steroids; those who take medicines to reduce appetite or weight; those with diabetes who are taking medications or insulin; those with heart disease or hypercholesterolemia who are taking medication (statins, fibrates, diuretics); those how are taking oral anti-inflammatory drugs corticosteroids or any drug that causes weight loss or gain; taking hormonal contraceptives; pregnancy and lactation; menopause; severe mental disorder; schizophrenia and bipolar; hypothyroidism; exercise professionals; allergic to fish (due to Omega-3 supplements); those with special diets such as the diets for kidney disorders.

Age

From **18 years** old to **57 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Committee on Ethics in Medical Research, Research Council, Central Building of Tehran University of Medical Sciences, Keshavarz Blvd Tehran, Iran

City

Tehran

Postal code

Approval date

2013-12-05, 1392/09/14

Ethics committee reference number

130/2045/92/3

Health conditions studied

1

Description of health condition studied

Mild Depression

ICD-10 code

F32.0

ICD-10 code description

Mild depressive episode Two or three of the above symptoms are usually present. The patient is usually distressed by these but will probably be able to continue with most activities.

2

Description of health condition studied

Moderate depression

ICD-10 code

F32.1

ICD-10 code description

Moderate depressive episode Four or more of the above symptoms are usually present and the patient is likely to have great difficulty in continuing with ordinary activities.

3

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Weight

Timepoint

At baseline and at weeks 2, 4, 8 and 12 after the beginning of the study

Method of measurement

Standard scales Seca

2

Description

Body Mass Index

Timepoint

At baseline and at weeks 2, 4, 8 and 12 after the beginning of the study

Method of measurement

kg/(m)²

3

Description

Depression

Timepoint

At baseline and at weeks 2, 4, 8 and 12 after the beginning

of the study
Method of measurement
Hamilton rating scale for depression

Secondary outcomes

1
Description
Central fat mass
Timepoint
At baseline and at weeks 2, 4, 8 and 12 after the beginning
Method of measurement
Bioelectrical impedance

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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Intervention groups

1
Description
3 gram omega-3 (2 capsules with each meal) for 12 weeks
Category
Treatment - Drugs

2
Description
2 placebo capsules with each meal for 12 weeks
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Private weight loss clinic
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Harati-Zadeh
Street address
No. 608, Research Coordination Centre Office, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Boulevard, Tehran, Iran
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Grant name
Grant code / Reference number

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty