

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of olive oil consumption on anthropometric indices, blood pressure, inflammatory status and oxidative stress in patients with depression

Protocol summary

Summary

The aim of this study was to determine the effect of olive oil consumption on anthropometric indices, blood pressure, inflammatory status and oxidative stress in patients with depression. The study design was a double-blind randomized controlled clinical trial that was conducted on 73 patients with major depression and age range of 18 to 65 years old. Patients were chosen by convenience sampling and assigned into intervention and control groups using block stratified random allocation. Stratification in groups was performed according to the severity of depression (mild, moderate and severe) and taking antidepressant medications or not. For a period of 52 days, the intervention group was given 25 milliliters per day of extra virgin olive oil and the control group was given 25 milliliters per day of sunflower oil for oral administration. At the beginning, middle and end of the study, patients' blood pressure and anthropometric indices were measured by means of standard equipments. Serum levels of malondialdehyde and high-sensitivity C-reactive protein were assessed at the beginning and end of the study. In order to monitoring confounding factors, the diet, physical activity and sleep pattern were evaluated by 24-hour dietary recall, International Physical Activity Questionnaire and Pittsburgh Sleep Quality Index during the study, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041820140N3**

Registration date: **2016-05-14, 1395/02/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-14, 1395/02/25

Registrant information

Name

Sahar Foshati

Name of organization / entity

Shiraz University of Medical Sciences

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+98 71372510015

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of olive oil consumption on anthropometric indices, blood pressure, inflammatory status and oxidative stress in patients with depression

Public title

The effect of consuming olive oil in patients with depression

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion criteria: Suffering from major depression based on criteria of Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; aged 18 to 65 years old; routine consumption of sunflower oil; without allergy to olive or sunflower or their products; without fat malabsorption; a score of less than or equal to 7 in 14-item questionnaire of Mediterranean diet adherence and ability and willingness to participate in the study. Main exclusion criteria: Use of lipid lowering medications; use of corticosteroid medications; suffering from a concurrent serious mental disorder such as schizophrenia; suffering from severe or unstable medical conditions; alcohol or drug dependence; pregnancy; lactation; serious risk of homicide or suicide; the need for hospitalization; change in medications or treatments used for depression; change in diet or physical activity; consumption of less than 70% of the recommended oil and loss of any of the inclusion criteria.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **73**

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 Shiraz University of Medical Sciences

Street address

Central Building of Medical Sciences University, Zand Avenue

City

Shiraz

Postal code

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

IR.SUMS.REC.1394.149

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Anthropometric indices (body mass index, waist-to-height ratio)

Timepoint

The beginning, middle and end of the study

Method of measurement

Using the weighing scale with the accuracy of 0.1 kg and measuring tapes with the accuracy of 0.1 cm

2

Description

Blood pressure

Timepoint

The beginning, middle and end of the study

Method of measurement

In millimeters of mercury using the mercury sphygmomanometer

3

Description

Serum high-sensitivity C-reactive protein

Timepoint

The beginning and end of the study

Method of measurement

In milligrams per liter using the assay kit

4

Description

Serum malondialdehyde

Timepoint

The beginning and end of the study

Method of measurement

In micromolars using the assay kit

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: Daily consumption of 25 milliliters extra virgin olive oil for duration of 52 days

Category

Lifestyle

2

Description

The control group: Daily consumption of 25 milliliters sunflower oil for duration of 52 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Advertising in newspapers and placing local announcements

Full name of responsible person

Sahar Foshati

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Emam Reza clinic

Full name of responsible person

Sahar Foshati

Street address

Namazi Square

City

Shiraz

3

Recruitment center

Name of recruitment center

Psychiatric clinic of Hafez hospital

Full name of responsible person

Sahar Foshati

Street address

Chamran Blvd

City

Shiraz

4

Recruitment center

Name of recruitment center

Clinic of Ebne Sina psychiatric hospital

Full name of responsible person

Sahar Foshati

Street address

Hafez Street

City

Shiraz

5

Recruitment center

Name of recruitment center

Health center of Javadieh

Full name of responsible person

Sahar Foshati

Street address

Edalat Blvd

City

Shiraz

6

Recruitment center

Name of recruitment center

Shahid Motahari clinic

Full name of responsible person

Sahar Foshati

Street address

Namazi Square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person

Ms. Zahra Pandkhahi

Street address

Central Building of Medical Sciences University, Zand Avenue

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Shiraz 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

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sahar Foshati

Position

Postgraduate student of nutrition sciences

Other areas of specialty/work

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School of Nutrition and Food Sciences, Razi Blvd

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Akhlaghi

Position

Assistant professor - Faculty member

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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