Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of consuming olive oil on depression, lipid profile, salivary cortisol and brain derived neurotrophic factor in patients with depression

Protocol summary

Summary

The aim of this study was to determine the effect of olive oil consumption on depression, lipid profile, salivary cortisol and brain derived neurotrophic factor 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, depression was evaluated using two questionnaires of Beck Depression Inventory II and Hamilton Depression Rating Scale, 7 item version. Levels of salivary cortisol and serum lipid profile and brain derived neurotrophic factor were measured at the beginning and end of the study. It must be noted that cortisol levels were measured in saliva samples obtained immediately and 30 minutes after awakening in the morning and used to calculate cortisol awakening response. In order to monitoring confounding factors, the diet, physical activity and sleep pattern were assessed 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: **IRCT2016041720140N2**
Registration date: **2016-06-03, 1395/03/14**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-06-03, 1395/03/14

Registrant information

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Sahar Foshati
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Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of 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 consuming olive oil on depression, lipid profile, salivary cortisol and brain derived neurotrophic factor in patients with depression

Public title

The effect of consuming olive oil in patients with depression

Purpose
Treatment
Inclusion/Exclusion criteria
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. 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
N/A
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
Patients were assigned into intervention and control groups using block stratified random allocation.

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.1394.154

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Depression
Timepoint
The beginning, middle and end of the study
Method of measurement
Using two questionnaires of Beck Depression Inventory II and Hamilton Depression Rating Scale, 7 item version

2

Description
Serum lipid profile (triglycerides, total cholesterol, high density lipoprotein cholesterol, low density lipoprotein cholesterol, very low density lipoprotein cholesterol)
Timepoint
The beginning and end of the study
Method of measurement
In milligrams per deciliter using laboratory kits

3

Description
Salivary cortisol
Timepoint
The beginning and end of the study
Method of measurement
In nanogram per milliliter using the assay kit

4

Description
Serum brain derived neurotrophic factor
Timepoint
The beginning and end of the study
Method of measurement
In nanogram per milliliter 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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Person responsible for scientific inquiries

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Assistant professor and faculty member

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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