

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effects of Mediterranean diet instruction on anthropometric indices, depression, anxiety and stress disorders and their relationship with healthy lifestyle score: A randomized double-blind controlled clinical trial

Protocol summary

Study aim

To determine the effect of Mediterranean diet instruction on anthropometric indices, stress, anxiety and depression disorders

Design

Parallel, double blind, randomized controlled trial. Randomization was done using random table of numbers.

Settings and conduct

Sixty participants suffering from stress, anxiety and depression will be randomly assigned to intervention or placebo groups. Intervention group will receive Mediterranean diet instructions and control group will receive usual nutritional instructions. Investigator and participants will be blinded to randomization and allocation till the end of the study

Participants/Inclusion and exclusion criteria

Participants aged 18-60 years, with diagnosed stress, anxiety or depression by a physician for at least one month will be enrolled in the study. Participants will be excluded if: questionnaires were not completed properly, the instructions were not followed during intervention, dietary intake was miss reported (<800 or >4200 Kcal/day), stresses like divorce or emotional break up in the last 6 months was present, Body mass index was <18.5 or >40, there was a history of death of relatives or close friends in the last 6 months, Drug or alcohol abuse was present at least once a week, participants suffered from chronic diseases such as diabetes, cardiovascular, cancer, blood pressure, Pregnancy and lactating

Intervention groups

Intervention: Participants will be informed and instructed regarding the Mediterranean diet and its characteristics. Placebo: Participants will receive usual nutritional instruction

Main outcome variables

Anthropometric indices; Score for stress, anxiety and

depression; healthy lifestyle score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180201038585N8**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Karim Parastouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 3516

Email address

parastouei@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-03, 1399/07/12

Expected recruitment end date

2020-11-05, 1399/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Mediterranean diet instruction on anthropometric indices, depression, anxiety and stress disorders and their relationship with healthy lifestyle score: A randomized double-blind controlled clinical trial

Public title

Effect of Mediterranean diet on weight and psychological disorders

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20-59 years Suffering from depression, anxiety or stress disorders for more than one month

Exclusion criteria:

If questionnaires were not completed properly If the instructions were not followed during intervention If dietary intake was miss reported (<800 or >4200 Kcal/day) Presence of stresses like divorce or emotional break up in the last 6 months Body mass index <18.5 or >40 History of death of relatives or close friends in the last 6 months Drug or alcohol abuse at least once a week Suffering from chronic diseases such as diabetes, cardiovascular, cancer, blood pressure Pregnancy and lactating

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed by block randomization method. Random sequence generation was done using table of random numbers by a third trained person. Allocation concealment was performed using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Intervention and assignment was performed by a third trained non-investigator person. The investigator and the participants were not aware of the allocation and will remain unaware till the end of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Molla Sadra Ave., Vannak Sq.

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-09-20, 1399/06/30

Ethics committee reference number

IR.BMSU.REC.1399.370

Health conditions studied**1****Description of health condition studied**

Mental disorders

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

2**Description of health condition studied**

Mental disorders

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Weight

Timepoint

At the beginning and end (12 weeks) of the study

Method of measurement

Scale, kg

2**Description**

Body Mass Index

Timepoint

At the beginning and end (12 weeks) of the study

Method of measurement

Equation, $\text{Weight(kg)/[height(m)]}^2$, kg/m²

3

Description

Score of stress

Timepoint

At the beginning and end (12 weeks) of the study

Method of measurement

DASS-21 questionnaire

4

Description

Anxiety score

Timepoint

At the beginning and end (12 weeks) of the study

Method of measurement

DASS-21 questionnaire

5

Description

Depression score

Timepoint

At the beginning and end (12 weeks) of the study

Method of measurement

DASS-21 questionnaire

Secondary outcomes

1

Description

Healthy lifestyle score

Timepoint

At the end of the study

Method of measurement

HLS questionnaire

2

Description

Food intake frequency

Timepoint

At the beginning and end (12 weeks) of the study

Method of measurement

Food Frequency questionnaire - 168 items

3

Description

Physical activity

Timepoint

At the beginning and end (12 weeks) of the study

Method of measurement

IPAQ questionnaire

Intervention groups

1

Description

Intervention group: Mediterranean diet instructions. Participants will be asked to follow the instructions during the 12 weeks of interventions. The details of Mediterranean diet instructions are as follows: 1- Change your protein type. Use more vegetable proteins such as beans, peas and nuts. Eat fish at least 2-3 times a week. Use oily fish such as salmon. Try not to cook fish fried. Use white meats such as chicken and turkey every 2-3 days. Limit the consumption of red meat such as beef and veal to once a week. Avoid processed meats such as sausages. 2- Modify your cooking oils. Use olive oil. Remove hydrogenized oils. Reduce your butter consumption and replace it with healthy oils. If you do not have access to olive oil, use canola oil 3- Increase consumption of vegetables. Eat at least 3 glasses of different vegetables with different colors daily. 4- Eat more fruits. Eat at least two seasonal fruits daily. 5- If possible, consume 30 grams of raw nuts every other day, such as: pistachios, walnuts, almonds and Hazelnuts 6- Choose all your bread from whole grain breads. Whole grain breads are darker in color than non-whole grain breads. Limit rice consumption to twice a week. 7- Consume simple sugars such as sweets, cakes. Completely limit candy, desserts and soft drinks. Patients' follow-up status will be monitored by telephone during the intervention.

Category

Lifestyle

2

Description

Control group: Usual healthy nutrition instructions. Participants in the intervention group will be asked to follow the instructions for 12 weeks. The healthy eating instructions for the control group are as follows: 1. Remove hydrogenized and saturated fats. Use liquid oils 2- Reduce the consumption of animal fats 3- Reduce your salt intake and eliminate table salt 4- Eat at least 2 glasses of milk daily 5- Try to have 3 times of physical activity during the week such as walking 6- Reduce the consumption of fatty foods 7- Avoid consuming large amounts of food per meal 8- Do not skip any meals 9- Eat breakfast always 10- Have 3 main meals and 3 snacks every day 11- Consume tea and coffee at least 2 hours after meals. Patients' follow-up status will be monitored by telephone during the intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mahallati Hospital

Full name of responsible person

Meisam Zarezade

Street address

Shahid Mahallati St., 22 Bahman Blvd.
City
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East Azarbaijan
Postal code
5169648549
Phone
+98 41 3449 5336
Email
mahallati.hosp@gmail.com
Web page address
<http://www.shahidmahallati.com/Login>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ali Shiri
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Mollasadra Ave, Vanak Sq,
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1435915371
Phone
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Email
shira.reza@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Karim Parastouei
Position

Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available