Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 21 8248 3516

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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, 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
Tabriz
Province
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
Street address
Mollasadra Ave, Vanak Sq,
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1435915371
Phone
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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
Latest degree
Ph.D.
Other areas of specialty/work
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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