Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Investigating the effect of MIND diet on cognitive performance and metabolic responses in obese adults along with the control of BDNF Val66Met and COMT Val158Met polymorphisms

Protocol summary

Study aim
The effect of MIND pattern on cognitive functions and metabolic responses in obese women aged 40-60
Design
Two arm parallel group randomized trial
Settings and conduct
At initial visit subjects signed a consent form and then subsequently underwent a standardized medical interview as well as a neurological examination. Demographic and anthropometric data, as well as, details on dietary compliance have been gathered. Before ad after of study all of the participants were tested on a complex battery of neurocognitive tests to examine their cognitive performance and also biochemical test to evaluate metabolic responses.
Participants/Inclusion and exclusion criteria
Middle aged 40-65 women, Body Mass Index(BMI 25-35 kg/m2), lack of history of severe untreated medical, neurological, and psychiatric diseases, used weight loss drug in the last 3 months and also used of multivitamins and minerals that affect cognitive performance over the last 6 months
Intervention groups
Subjects were randomly allocated to control calorie restricted diet and calorie restricted plus MIND diet group.
Main outcome variables
The effect of MIND pattern on cognitive functions and metabolic responses

General information

Reason for update
Acronym
MIND diet
IRCT registration information
IRCT registration number: **IRCT20190427043387N1**
Registration date: **2019-06-24, 1398/04/03**
Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**
Update count: **0**
Registration date
2019-06-24, 1398/04/03

Registrant information
Name
Golnaz Arjmand
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-10-24, 1397/08/02
Expected recruitment end date
2019-06-18, 1398/03/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of MIND diet on cognitive performance and metabolic responses in obese adults along with the control of BDNF Val66Met and COMT Val158Met polymorphisms

Public title
MIND diet and cognitive function
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
40-60 years old Obese women (Body Mass Index=30-35 kg/m2) Educated subjects normal cognitive function (Mini Mental State examination of survey ≥ 24) People's participation in study
Exclusion criteria:
History of severe untreated medical, neurological, and psychiatric diseases which may interfere with the study intervention. Gastrointestinal problems Participated in weight loss program or used weight loss drug in the last 3 months used of multivitamins and minerals that affect cognitive performance over the last 6 months
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized will be done using a random number table method. In this way, using Randomization.com, random numbers and blocks are prepared and the numbers are placed inside the envelope, then each participant chooses an envelope after accepting the terms and it is determined by its contents. Which group will be.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Shiraz university of medical science
Street address
School of nutrition and food sience
City
Shiraz
Province
Fars
Postal code
7153675541
Approval date
2018-10-26, 1397/08/04
Ethics committee reference number
IR.SUMS.REC.1397.759

Health conditions studied

1

Description of health condition studied
Neuronal system function
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cognitive performance score
Timepoint
Cognitive performance score at the beginning of the study and after the end of the 3 month study period.
Method of measurement
PCAP (Persia paper and pencil cognitive assessment package) questioner

Secondary outcomes

1

Description
Metabolic responces
Timepoint
The beginning and the end of the 3 month study period.
Method of measurement
Biochemical tests

Intervention groups

1

Description
Intervention group: Participants in the MIND diet group received instruction in modifying the content of their diet to meet MIND pattern guidelines. This pattern emphasizes natural, plant-based foods, specifically promoting an increase in consumption of berries and green leafy vegetables, with limited intakes of animal based and high saturated fat foods.
Category
Treatment - Other

2

Description
Control group: This group is told not to change their eating habits during the course of a three-month period.

Also, in order to comply with ethical principles and motivate behavior for joining the study, they will give general advice on choosing healthy foods for this group. At the end of the study, the study regime will also be available for control group.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic, Nutrition Clinic
Full name of responsible person
Golnaz Arjmand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Golnaz Arjmand
Position
PhD student
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Contact

Name of organization / entity
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Full name of responsible person
Golnaz Arjmand

Position
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Latest degree
Master

Other areas of specialty/work
Nutrition

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Fax

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available