

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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 and 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/m<sup>2</sup>), 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)

###### Phone

+98 71 3725 1007

###### Email address

g.arjmand989@gmail.com

##### 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/m<sup>2</sup>) Educated subjects normal cognitive function (Mini Mental State examination of survey  $\geq$  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 science

##### 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 responses

#### 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

**Street address**

Namazi Square, Imam Reza Clinic, Nutrition Clinic

**City**

Shiraz

**Province**

Fars

**Postal code**

7153675541

**Phone**

+98 71 3725 1001

**Email**

g.arjmand989@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

younes ghaemi

**Street address**

Shiraz university of medical science, Zand street

**City**

Shiraz

**Province**

Fars

**Postal code**

713451978

**Phone**

+98 71 3235 7282

**Email**

g.arjmand989@gmail.com

**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**

Nutrition

**Street address**

School of nutrition and food science

**City**

Shiraz

**Province**

Fars

**Postal code**

7153675541

**Phone**

+98 71 3725 1001

**Email**

g.arjmand989@gmail.com

**Person responsible for scientific 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**

Nutrition

**Street address**

Razi Blvd, school of nutrition and diet therapy

**City**

Shiraz

**Province**

Fars

**Postal code**

7153675541

**Phone**

+98 71 3725 1007

**Fax****Email**

g.arjmand989@gmail.com

## Person responsible for updating data

g.arjmand989@gmail.com

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Phone**

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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