

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### The effect of Mediterranean diet on on Cognitive performances in patient with Parkinson's disease

#### Protocol summary

##### Study aim

The aim of this study was to determine the effect of the Mediterranean diet on cognitive function in patients with Parkinson's disease

##### Design

Clinical trial, randomized, parallel study

##### Settings and conduct

80 patients with Parkinson's disease referred to Neurology clinic of Al-Zahara hospital in Isfahan were selected and randomly assigned to two experimental and control groups. Patients in the experimental group receive Mediterranean diet for 10 weeks the control group received no intervention

##### Participants/Inclusion and exclusion criteria

idiopathic Parkinson's disease (based on the criterion (Hoehn and Yahr); ages 40 and older. Exclusion criteria: psychological problems (cognitive problems); failure to complete the consent form before study

##### Intervention groups

Patients with Parkinson's disease are randomly assigned to experimental and control groups. Patients in the experimental group receive the Mediterranean diet for 10 weeks. There is no intervention in the control group.

##### Main outcome variables

The effect of the Mediterranean diet on cognitive function in patients with Parkinson's disease is assessed using the Montreal Cognitive Assessment Questionnaire.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141108019853N5**

Registration date: **2019-01-28, 1397/11/08**

Registration timing: **retrospective**

Last update: **2019-01-28, 1397/11/08**

Update count: **0**

##### Registration date

2019-01-28, 1397/11/08

##### Registrant information

###### Name

Zamzam Paknahad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3792 3166

###### Email address

paknahad@hlth.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-30, 1396/02/10

##### Expected recruitment end date

2017-05-20, 1396/02/30

##### Actual recruitment start date

2017-04-30, 1396/02/10

##### Actual recruitment end date

2017-05-20, 1396/02/30

##### Trial completion date

2017-07-19, 1396/04/28

##### Scientific title

The effect of Mediterranean diet on on Cognitive performances in patient with Parkinson's disease

##### Public title

Effect of Mediterranean diet in Parkinson disease

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Cases of idiopathic Parkinson's disease (based on criteria (H & Y) Age of illness over 40 years

**Exclusion criteria:**

Mental illness (cognitive problems) Failure to complete the consent form before study

**Age**

From **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization with random numbers extracted from the statistical software excel. A number is determined between two ranges.. In this case, we use the RandBetween function. This function has two parameters: the first parameter represents the start of the range, and the second parameter represents the end of the range.

**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**

Ethics committee of esfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib, Isfahan, Iran

**City**

esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2017-02-19, 1395/12/01

**Ethics committee reference number**

IR.MUI.REC.1395.2.282

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

Parkinson disease

**ICD-10 code**

G20

**ICD-10 code description**

G20 Hemiparkinsonism Paralysis agitans Parkinsonism or Parkinson disease: NOS idiopathic primary

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

Montreal Cognitive Assessment Questionnaire

**Timepoint**

Before and after intervention

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Patients in the experimental group receive Mediterranean diet for 10 weeks.

**Category**

Lifestyle

**2****Description**

Control group: : In the control group received no intervention.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Neurology clinic of Al-Zahara hospital in Isfahan

**Full name of responsible person**

Dr Ahmad Chitsaz

**Street address**

Safeh Boulevard - Al-Zahra Educational Center

**City**

esfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 1668 5555

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+98 31 1668 4510  
**Email**  
alzahra@mui.ac.ir  
**Web page address**  
<http://alzahra.mui.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr. Shaghayegh Haghjoo Javanmard  
**Street address**  
Deputy of Research & Technology of Isfahan  
University of Medical Sciences, Hezar Jarib Street,  
Isfahan, Iran  
**City**  
esfahan  
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+98 31 3668 8138  
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+98 31 3668 7898  
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sh\_haghjoo@med.mui.ac.ir  
**Web page address**  
<http://research.mui.ac.ir>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Esfahan 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**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Zamzam Paknahad  
**Position**  
Ph.D of Nutrition Sciences

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

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## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Dr. Zamzam Paknahad

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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**

No more 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