Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Zamzam Paknahad

Name of organization / entity

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Iran (Islamic Republic of)

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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
Isfehan

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

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Safeh Boulevard - Al-Zahra Educational Center

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Shaghayegh Haghjoo Javanmard
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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
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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