Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Sep 2026

Effect of the dietary modification on the body mass index, body fat percent and clinical manifestations in patients with multiple sclerosis (MS).

Protocol summary

Study aim

Determine the effect of dietary modification on body mass index, body weight, body fat percent, quality of life, disease activity, number of attacks and fatigue severity in patients with multiple sclerosis (MS) with controlling type and dose, calorie intake, age, Sex, educational level, duration of MS and family history of MS.

Design

A randomized, controlled clinical trial in 180 MS patients that were selected by stratified blocked randomization (based on MS type), followed for 6 months.

Settings and conduct

This study was done in MS Isfahan clinic. After placement of subjects into intervention and control groups, the intervention group undergoes a modified Mediterranean-like diet. Four sessions were formed for training each subject. The variables were measured three times.

Participants/Inclusion and exclusion criteria

The inclusion criteria were: aged between 20-60 years, basic literacy, writing ability and memory strength, and favorable mental condition for continuing study. The exclusion criteria were: participation in other clinical trials, having other acute diseases, waiting for abdominal surgery, receiving supplements or corticosteroid therapy, and cigarette smoking, regularly.

Intervention groups

Intervention group: Education of Mediterranean-like diet, in four sessions for each subject by a skilled nutritionist and following-up diet adherence by a trained researcher, monthly. Control group: Continuing usual diet without any intervention.

Main outcome variables

Quality of life; fatigue severity; disease activity; relapse rate; energy intake; family history of multiple sclerosis; duration of multiple sclerosis; height; weight; Body Mass Index (BMI); body fat; age; gender; education level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041641N1**
Registration date: **2018-11-16, 1397/08/25**
Registration timing: **retrospective**

Last update: **2021-04-10, 1400/01/21**
Update count: **1**

Registration date

2018-11-16, 1397/08/25

Registrant information

Name

Amir Reza Moravejolahkami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

2018-01-20, 1396/10/30

Actual recruitment end date

2018-07-21, 1397/04/30

Trial completion date

2018-10-22, 1397/07/30

Scientific title
Effect of the dietary modification on the body mass index, body fat percent and clinical manifestations in patients with multiple sclerosis (MS).

Public title
The effect of dietary modification on multiple sclerosis.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-60 years Having basic literacy. Writing ability and memory strength Good mental conditions for the continuation of the study
Exclusion criteria:
Participating in other interventional studies at the same time. Having the other acute and severe illness Regular and periodic consumption of special dietary supplement or sport-specific diets The full-dose intake of oral corticosteroides Continues and daily cigarette smoking People who are waiting for abdominal surgery
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **160**
Actual sample size reached: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized allocation was done by Stratified Blocked Randomization method. At first, participants (n=180) were classified into four categories according to the type of MS (relapsing-remitting, primary-progressive, secondary-progressive, progressive-relapsing). Subjects were then assigned to intervention and control groups - each one 90 patients - with blocked randomization.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University Of Medical Sciences, Hezar Jerib Ave
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2018-10-03, 1397/07/11
Ethics committee reference number
IR.MUI.RESEARCH.REC.1397.287

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Quality of life
Timepoint
At first, three months and six months later (end of intervention)
Method of measurement
Multiple Sclerosis Quality Of Life-54 items (MSQOL-54)

2

Description
Fatigue severity
Timepoint
At first, three months and six months later (end of intervention)
Method of measurement
Fatigue Severity Scale-9 items (FSS-9)

3

Description
Disease activity
Timepoint
At first, three months and six months later (end of intervention)
Method of measurement
Extended Disability Status Scale (EDSS)

4

Description
Number of attacks (Relapse rate)

Timepoint
At first, three months and six months later (end of intervention)
Method of measurement
Asking the patient by a neurologist

5

Description
Body Mass Index (BMI)
Timepoint
At first, three months and six months later (end of intervention)
Method of measurement
The equation of weight (in kilograms) divided by the square of height (in square meter)

6

Description
Weight
Timepoint
At first, three months and six months later (end of intervention)
Method of measurement
Digital scale

7

Description
Body fat percentage
Timepoint
At first, three months and six months later (end of intervention)
Method of measurement
Deurenberg Equation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Following a Mediterranean-like diet consist of 17-15% protein with an emphasis on the consumption of fish and seafood, 45-47% carbohydrates with an emphasis on the consumption of whole grains and legumes, 35-32% total fat that only 9-10% of which contains saturated fat and most of it contains PUFA (especially omega-3) with an emphasis on oatmeal oil and flaxseed oil, and fiber (27-38 gr per day) for 6 months
Category
Behavior

2

Description
Control group: They continued their usual diet.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
M.S Isfahan Center
Full name of responsible person
Ahmad Chitsaz
Street address
Hedayat St, Bahonar St, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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sh_haghjoo@med.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
70
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
Amir Reza Moravejolahkami
Position
M. Sc student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The obtained information from the study is presented to participants and other researchers as the best diet recommended by the researcher.
When the data will become available and for how long
Access to data takes place 10 months after the publication of results.
To whom data/document is available
Other researchers at universities and research institutes
Under which criteria data/document could be used
Data should only be used to advance the design of appropriate diets for MS.
From where data/document is obtainable
Corresponding author: a.moravej@mail.mui.ac.ir
What processes are involved for a request to access data/document
10 months after the publication of the related article, individuals can email their requests for the corresponding author. a.moravej@mail.mui.ac.ir
Comments

Trial results

Please tick if results have been published

Yes

Summary result posting date

2021-04-10, 1400/01/21

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

empty

Abstract of published paper

ietary modification may improve quality of life and fatigue severity in Multiple Sclerosis (MS) patients. Given this, there is a growing interest in healthy diets, especially Mediterranean based. The goal of this study was to explore the effects of a modified Mediterranean (mMeD) dietary intervention in Quality Of Life (QOL), and severity of fatigue in MS participants. About 180 Relapsing-Remitting MS patients randomly assigned to follow/not follow the mMeD for 6 months. Primary endpoints were related to dietary adherence and study completion. Clinical endpoints were evaluated Multiple Sclerosis Quality Of Life-54 items, Fatigue Severity Scale (FSS-9), and Visual Analog Fatigue Scale. Data were analyzed by SPSS 24. Of 261 screened patients (July 2018–February 2019), 180 were eligible and willing to commit. 68/90 as mMeD and 79/90 as control group completed the study. Self-reported adherence was excellent (95%). The majority of mean changes for QOL were statistically significant ($P < .001$). As well, Mean change on the FSS-9 was -9.8 ± 11.5 compared to $+0.3 \pm 4.2$ for controls ($P < .001$). This regimen improved fatigue and some components of QOL in RRMS patients. Larger scale and longer duration trials to assess the role of diet as a disease modifier in MS should be conducted.