

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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)

##### Phone

+98 31 3335 4453

##### Email address

a.moravej@mail.mui.ac.ir

##### 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

Isfahan

#### 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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Isfahan

**Province**

Isfahan

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81386-13691

**Phone**

+98 31 3345 8887

**Email**

chitsaz@med.mui.ac.ir

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooy Javanmard

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Isfahan University of Medical Sciences, Hezar Jerib Ave

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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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No. 16, 27 st Stop street, Khademi St

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

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## Person responsible for updating data

### Contact

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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  $-9.8 \pm 11.5$  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.