Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Evaluation of the effect of the nutritional recommendations based on Mediterranean diet and the traditional food recommendation to reduce the fatigue severity and depressive symptoms in patients with multiple sclerosis

Protocol summary

Study aim
Evaluation of the effect of the nutritional recommendations based on Mediterranean diet and the traditional food recommendation to reduce the fatigue severity and depressive symptoms in patients with multiple sclerosis

Design
A concealed, randomized, blinded controlled clinical trial with a parallel group design of 90 patients, enrolled between February 2023 till July 2023

Settings and conduct
Patients with multiple sclerosis who visit Imam Reza Specialized Clinic, Shiraz, during the study will be enrolled and randomly assigned to intervention or control groups using the random block method. This will be a double-blind study, which means that neither the patients nor the doctor examining them, nor the data analyst, will be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of multiple sclerosis; Expanded Disability Status Scale should be less than 6; patients aged 16 to 55 years; Exclusion criteria: Patients with secondary or primary progressive multiple sclerosis, pregnancy, cardiovascular diseases

Intervention groups
The first intervention group receives 20-minute face-to-face educational counseling twice a month for two months in order to increase adherence to the Mediterranean diet, as well as an educational pamphlet. The second intervention group received 20-minute face-to-face educational counseling over two months to increase adherence to four nutritional recommendations based on nutritional principles of traditional Iranian medicine (the nature of food in Sharifi et al.'s research). Patients in the third group (control group) receive healthy general nutritional advice during two months of face-to-face educational counseling for 20 minutes. Patients in all groups receive their standard drug treatment.

Main outcome variables
Fatigue and depression score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220920055995N1**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date
2023-06-27, 1402/04/06

Registrant information

Name
Mohammad Hossein Sharifi

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
2023-02-20, 1401/12/01

Expected recruitment end date
2023-07-24, 1402/05/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of the nutritional recommendations based on Mediterranean diet and the traditional food recommendation to reduce the fatigue severity and depressive symptoms in patients with multiple sclerosis

Public title
The effect of Mediterranean diet and the traditional food recommendation on fatigue and depression in multiple sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with definite diagnosis of multiple sclerosis Kurtzke Extended disability status score < 6 Complete the consent form for the research survey
Exclusion criteria:
Patients with secondary or primary progressive multiple sclerosis Patient with pregnancy Patient receives corticosteroid drug. Patient has cardiovascular disease. Patient has malignant tumors.
Age
From **16 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
A randomized block design will be used. The random sequence will be generated using the online software (Create a blocked randomization list | Sealed Envelope). We will use blocks with sizes of 3, 6, and 12. In addition, a fully sealed envelope covered with carbon paper will be used to conceal the allocation. The statistics specialist will prepare the concealment envelopes, which will remain hidden until the grouping training course is held.
Blinding (investigator's opinion)
Double blinded
Blinding description
Stages of study blinding: Both participants and researchers or outcome assessors in this study are unaware of study group allocation. Everyone involved in the study assumed that all three groups of participants would receive the educational intervention. The clinical caregiver will conduct educational sessions for all patients, introduce the study groups in general, and explain the study's objectives to the patients. The patient-educator and the duration-place will be the same. The educational counseling structure will be the same for all patients, but educational clauses corresponding to the intervention group will be added to the educational structure in the first, second, and third intervention groups. The clinical caregiver is unaware of the patient grouping. The neurologist introduces the patients to the research group after assessing their eligibility for participation in the study. The neurologist has no concept which patients belong to which groups. Based on the block randomization, the clinical supervisor of the study will assign patients to the first, second, and third groups, and then complete fatigue and depression assessment questionnaires for all patients. In the first group, a clinical caregiver will assess patients' adherence to the Mediterranean diet, and then the patient will receive specialized training in the field of increasing adherence to the Mediterranean diet. The patient will also be given an educational pamphlet. This group's clinical caregiver is unaware of the second and third groups. In the second intervention group, a clinical caregiver will first complete the three-day food record questionnaire before providing patients with dietary recommendations based on food traditional medicine (nature of food).This group's clinical caregiver is unaware of the first and third groups. The final group (control group) receives general healthy nutritional advice from a clinical caregiver. This group's clinical caregiver is unaware of the first and second groups. After 8 weeks, the second researcher will complete the main outcome of the study, the fatigue and depression assessment questionnaire for all patients, without knowing the grouping of the participants, and enter the data into the software. A statistician will analyze the data. The statistician is unaware of the study's grouping. Based on the analysis, the primary researcher of the study will draft the article. The primary researcher is aware of the grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical

Sciences

Street address

Shiraz School of Medicine, Imam Hossein Square Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2022-11-09, 1401/08/18

Ethics committee reference number

IR.SUMS.REC.1401.525

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

Fatigue score in Krupp Fatigue Severity Questionnaire

Timepoint

At the beginning of the study and then 60 days after the intervention

Method of measurement

Fatigue Severity Scale Krupp

2

Description

Depression score from Beck depression questionnaire - short form

Timepoint

At the beginning of the study and then 60 days after the intervention

Method of measurement

Beck depression questionaire -short form

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: During two months, patients participate twice in a 20-minute consultation program with the content of the principles of the Mediterranean diet. It will be taught using the Mediterranean diet questionnaire, a 13-question universal questionnaire. The Mediterranean diet emphasizes daily consumption of olives and olive oil, nuts, a high intake of legumes, grains including potatoes and bread, fruits and vegetables, a low consumption of red meat and meat products, and a moderate consumption of milk and dairy products. Patients will be educated on the 13 recommendations and given an educational pamphlet. It is recommended, for example, how many olives to eat per day, how many fruits to eat, and which foods to avoid. At first, the study will use a questionnaire to determine adherence to the Mediterranean diet.

Category

Lifestyle

2

Description

The second intervention group: During two months, patients participate twice in a 20-minute consultation program with the content of the principles of traditional medicine's food pattern (hot and cold foods). 4 Dietary recommendations will be given to patients based on the findings of Sharifi et al.'s study of the dietary pattern in MS patients in Shiraz and the Rezapour study in Tehran. The four important dietary recommendations are as follows: consume two units of nuts per day, only one unit of sweets per day, four units of hot fruits per day, and avoid flavors such as vinegar and pickles. Patients will be given an educational pamphlet

Category

Lifestyle

3

Description

The control group: During a two-month period, patients participate twice in a 20-minute counseling program with the content of healthy eating principles. All patients in this group will receive routine general nutrition education. For example, less salt and low-fat food consumption, less fast food consumption, and a regular physical activity program.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Specialized Clinic

Full name of responsible person

Mohammad Hossein Sharifi

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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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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
Mohammad Hossein Sharifi
Position
Assistant Professor
Latest degree
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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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The title of the proposal and the working method can be published
When the data will become available and for how long
Access to data is possible after 6 months from the publication of the article.
To whom data/document is available
Researchers in the field of medical sciences are allowed access
Under which criteria data/document could be used
If a scientific paper is going to be published using the data of this research, it is necessary to mention the name of the researchers of this project.
From where data/document is obtainable
To get information, it is necessary to refer to the first researcher: • Mohammad Hossein Sharifi, Assistant Professor, MD and Ph.D in nutrition, Shiraz University of Medical Sciences, Shiraz, Iran. sharifimh@sums.ac.ir
What processes are involved for a request to access data/document
After receiving the request email, the cooperation form is signed between the two parties. Then the data will be sent within 10 working days
Comments