Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effects of gain-versus-loss messages following adherence to the Dietary Approaches to Stop Hypertension (DASH) diet and a low-glycemic index diet on stress, anxiety, depression and fatigue in multiple sclerosis patients: a randomized controlled clinical trial

Protocol summary

Study aim
Investigating the effects of gain-versus-loss messages following the DASH diet and low-glycemic index diet on stress, anxiety, depression, and fatigue in people with multiple sclerosis:a randomized controlled clinical trial

Design
Open-label, parallel controlled randomized trial

Settings and conduct
Multiple sclerosis diagnosed by a neurologist from Ahvaz MS Association, divided into 3 groups of 32, receives Gain-loss framed messages (DASH and low glycemic index diet). control receive routine care, for 12 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having multiple sclerosis, the age range of 18 to 55 years, willing to participate in the study (filling in the informed consent form), stable in disease-modifying treatment for 6 months, no relapse in the last 30 days, reliable access through Computer or smartphone to the Internet, Extended Disability Status Scale (EDSS) less than 4.5, literate people Exclusion criteria: Suffering from other types of multiple sclerosis, suffering from any other neurological disease, Suffering from various malignancies, other autoimmune and infectious diseases, kidney and liver diseases, metabolic disorders, using insulin to control diabetes, menopause, in the previous 5 years, if simultaneously participating in another study, illiterate or unwilling to read, Unwillingness to continue participating in the study

Intervention groups
Patients are randomly divided into three groups of 32 people who receive health messages of gain and loss and a control group receives a routine health program. In this study, gain-framed and loss-framed health messages are given to two groups of intervention respectively for 12 weeks.

Main outcome variables
Fatigue

General information

Reason for update

Acronym
Dietary Approaches to Stop Hypertension (DASH)

IRCT registration information
IRCT registration number: **IRCT20220902055853N3**
Registration date: **2023-10-21, 1402/07/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-21, 1402/07/29**
Update count: **0**

Registration date
2023-10-21, 1402/07/29

Registrant information

Name
fatemeh borazjani

Name of organization / entity

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Iran (Islamic Republic of)

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+98 61 3321 9570

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fa.borazjani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-11, 1402/06/20

Expected recruitment end date
2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of gain-versus-loss messages following adherence to the Dietary Approaches to Stop Hypertension (DASH) diet and a low-glycemic index diet on stress, anxiety, depression and fatigue in multiple sclerosis patients: a randomized controlled clinical trial

Public title

The Effects of gain versus loss messages following adherence to the DASH diet and a low glycemic index diet in multiple sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having multiple sclerosis Age range of 18 to 55 years Stable in disease-modifying treatment for 6 months No relapse in the last 30 days Willing to participate in project (filling informed consent form) Access through Computer or smartphone to the Internet Extended Disability Status Scale (EDSS) less than 4.5 Literate people

Exclusion criteria:

Suffering from other types of multiple sclerosis, , if ,, , in the study Suffering from any other neurological disease Simultaneously participating in another study Taking insulin , menopause, history of kidney stones in the last 5 years Illiterate or unwilling to read Unwillingness to continue participation

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The entry of each patient into three different groups (receivers of gain-framed and Loss-Framed Messages, and control) is randomly divided based on permuted block randomization (with blocks of 3) using Random Allocation Software (RAS).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Open label, Parallel - controlled randomized trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Ahvaz Jundishapur university of medical sciences,Ahvaz,Iran.

Street address

Academic Town , Ahvaz , Ahvaz University of Medical Sciences and Health Care Services , Research and Technology Development Vice Chancellor Building

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-06-17, 1402/03/27

Ethics committee reference number

IR.AJUMS.REC.1402.165

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

Timepoint

At the beginning and end of study

Method of measurement

Using Modified Fatigue Impact Scale (MFIS) questionnaire

Secondary outcomes

1

Description

Stress

Timepoint

At the begin and end of study

Method of measurement

Using the Depression Anxiety Stress Scale-21 Items (DASS-21) questionnaire

2

Description
Anxiety
Timepoint
At the begin and end of study
Method of measurement
Using the Depression Anxiety Stress Scale-21 Items (DASS-21) questionnaire

3

Description
Depression
Timepoint
At the begin and end of study
Method of measurement
Using the Depression Anxiety Stress Scale-21 Items (DASS-21) questionnaire

4

Description
Physical Activity
Timepoint
At the begin and end of study
Method of measurement
Short form of the International Physical Activity Questionnaire (IPAQ-SF)

5

Description
Dietary intake (Energy, Carbohydrate, Fat, Protein)
Timepoint
At the begin and end of study
Method of measurement
Using Nutritionist IV software

6

Description
intensity of pain
Timepoint
At the begin and end of study
Method of measurement
using the visual analog scale (VAS) questionnaire

Intervention groups

1

Description
Intervention group 1: The gain-framed health messages refer to a DASH diet and low glycemic index with a positive capacity for 12 weeks.
Category
Prevention

2

Description
Intervention group2: The loss-framed health messages refer to a DASH diet and low glycemic index with a negative capacity for 12 weeks.
Category
Prevention

3

Description
Control group: Receive routine health care within 12 weeks
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
MS association of Ahvaz city
Full name of responsible person
Faezeh Moeini Badi
Street address
Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khouzestan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
Street address
Ahvaz Jundishapur University of Medical Sciences, Research and Technology Vice-Chancellor Address: Ahvaz Jundishapur Medical Sciences University, Research and Technology Vice Chancellor, Ahvaz, Iran
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Email
itc@ajums.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Faezeh Moeini Badi
Position
MSc student
Latest degree
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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
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The Effects of gain-framed versus loss-framed messages following adherence to the Dietary Approaches to Stop Hypertension (DASH) diet and a low-glycemic index diet on stress, anxiety, depression and fatigue in multiple sclerosis patients: a randomized controlled clinical trial
When the data will become available and for how

long

After the publication of the article

To whom data/document is available

All

Under which criteria data/document could be used

Study

From where data/document is obtainable

Fatemeh Borazjani

What processes are involved for a request to access data/document

E -mail

Comments