

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3321 9570

##### Email address

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**

Khuzestan

##### **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, Khuzestan, Iran

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

6135815751

##### **Phone**

+98 912 639 9027

##### **Email**

moeinibadifaezeh@gmail.com

## **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

##### **City**

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##### **Postal code**

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##### **Phone**

+98 61 3336 2414

##### **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**

Bachelor

**Other areas of specialty/work**

Nutrition

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Golestan Medical Sciences Dormitory , Golestan Boulevard , Ahvaz , Khuzestan , Iran

**City**

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Borazjani

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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Jundishapur university of medical sciences , university campus , golestan street

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**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Faezeh Moeini Badi

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Golestan Medical Sciences Dormitory, Golestan Boulevard , Ahvaz , Khuzestan , Iran

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6135815751

**Phone**

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**Email**

moeinibadifaezeh@gmail.com

**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**