

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of peer education and nurse education versus control group on the quality of life, resilience and anxiety of multiple sclerosis patients: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of peer education and nurse education versus control group on the quality of life, resilience and anxiety of multiple sclerosis patients

##### Design

This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

##### Settings and conduct

This study will be performed in the MS Association in Hamadan city on 120 eligible patients with multiple sclerosis. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 45 years Suffering from multiple sclerosis Having anxiety Being literate Exclusion criteria: Speech or hearing impairment Recurrence of the disease

##### Intervention groups

Intervention group 1: Routine recommendations in addition to educational sessions for 45 to 60 minutes every two days for 5 sessions by a person with multiple sclerosis with at least 5 years of disease history  
Intervention group 2: Routine recommendations in addition to educational sessions for 45 to 60 minutes every two days for 5 sessions by a nurse  
Control group: Routine recommendations

##### Main outcome variables

Primary outcome: Quality of life, resilience, anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N464**

Registration date: **2023-03-08, 1401/12/17**

Registration timing: **prospective**

Last update: **2023-03-08, 1401/12/17**

Update count: **0**

##### Registration date

2023-03-08, 1401/12/17

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2023-08-22, 1402/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of peer education and nurse education versus

control group on the quality of life, resilience and anxiety of multiple sclerosis patients: a randomized clinical trial

#### Public title

Effect of peer education and nurse education versus control group on the quality of life, resilience and anxiety of multiple sclerosis patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 20 to 45 years Suffering from multiple sclerosis  
Having anxiety Being literate

##### Exclusion criteria:

Speech or hearing impairment Recurrence of the disease

#### Age

From **20 years** old to **45 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare three sheets and write "intervention 1" and "intervention 2" and "control" on them. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

###### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

###### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2023-02-05, 1401/11/16

#### Ethics committee reference number

IR.UMSHA.REC.1401.979

### 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

Before the intervention and 2 months after

##### Method of measurement

Using the Multiple Sclerosis Quality of Life (MSQL)

#### 2

##### Description

Resilience

##### Timepoint

Before the intervention and 2 months later

##### Method of measurement

Using Connor & Davidson Resilience Scale

#### 3

##### Description

Anxiety

##### Timepoint

Before the intervention and 2 months after

##### Method of measurement

Using the Spielberger Anxiety Inventory

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group 1: Routine recommendations in addition to educational sessions for 45 to 60 minutes every two days for 5 sessions by a person with multiple sclerosis with at least 5 years of disease history

(including causes of multiple sclerosis, common treatments, importance of adherence to treatment, importance of nutrition, stress control, hygiene, adequate sleep, exercise and activity, imbalance and its management, self-management of constipation, control of urinary incontinence, self-management of memory disorders)

**Category**

Treatment - Other

**2****Description**

Intervention group 2: Routine recommendations in addition to educational sessions for 45 to 60 minutes every two days for 5 sessions by a nurse (including causes of multiple sclerosis, common treatments, importance of adherence to treatment, importance of nutrition, stress control, hygiene, adequate sleep, exercise and activity, imbalance and its management, self-management of constipation, control of urinary incontinence, self-management of memory disorders)

**Category**

Treatment - Other

**3****Description**

Control group: Routine recommendations

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

MS Association in Hamadan city

**Full name of responsible person**

Mohammad Mehdi Siahvashi

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

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info.research@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Mohammad Mehdi Siahvashi

**Position**

Nursing Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Azim Azizi

**Position**

PhD in Nursery

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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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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**

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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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