

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)

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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

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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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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

Latest degree

Ph.D.

Other areas of specialty/work

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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

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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