Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
poorolajal@umsha.ac.ir

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 (MSQOL)

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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

mohammadmehdi2177mui@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

6517838695 00988138380572

Email

mohammadmehdi2177mui@gmail.com

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
Nursery

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

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
a.azizi@umsha.ac.ir

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

Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0090

Email
poorolajal@umsha.ac.ir

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