Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The impact of teach-back education on the understanding of disease, severity of fatigue, and quality of life in patients with multiple sclerosis referred to the MS

Protocol summary

Study aim
Determining the effect of teach back education on disease perception, fatigue severity and quality of life in patients with multiple sclerosis

Design
A two-group, randomized, controlled clinical trial with 60 patients.

Settings and conduct
This study is a randomized controlled clinical trial involving 60 patients with multiple sclerosis, which will be conducted in 1404 (2025-2026) at Besat Hospital in Hamadan. Thirty patients in the intervention group will receive four days of teach back education on the disease process, follow-up, and treatment, while the control group will only receive routine care and standard education.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Not having any mental disorders under treatment, ability to speak Persian, having a score between 2 and 6 on the expanded disability status scale, having multiple sclerosis for at least one year as diagnosed by a neurologist. Exclusion criteria:The occurrence of any severe physical or mental disorder during the study,patient's reluctance to continue cooperating to participate in the study

Intervention groups
Intervention Group: Patients will receive individual, teach back-based training over 4 sessions (every other day, each session lasting at least 30 minutes) on the disease process, treatment follow-up, fatigue reduction, and improvement of physical function. After each session, patients will restate the content in their own words. One month later, fatigue and illness perception questionnaires will be completed, and two months later, after a phone call and coordination, the quality of life questionnaire will be completed during an in-person visit to the MS association. Control Group: Only routine care will be provided, and no specific intervention will be conducted.

Main outcome variables
Quality of life, fatigue severity, perception of illness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160110025929N44**
Registration date: **2025-03-27, 1404/01/07**
Registration timing: **prospective**

Last update: **2025-03-27, 1404/01/07**
Update count: **0**

Registration date
2025-03-27, 1404/01/07

Registrant information

Name
Mehdi Molavi Vardanjani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3422 5056

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-21, 1404/02/31

Expected recruitment end date
2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of teach-back education on the understanding of disease, severity of fatigue, and quality of life in patients with multiple sclerosis referred to the MS

Public title

Impact of teach-back education on the understanding of disease, severity of fatigue, and quality of life

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Having multiple sclerosis for at least one year as diagnosed by a neurologist Having a score between 2 and 6 on the expanded disability status scale. Ability to speak Persian Not having any mental disorders under treatment

Exclusion criteria:

Patient's reluctance to continue cooperating to participate in the study The occurrence of any severe physical or mental disorder during the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, four random blocks method is used. For this purpose, four sheets of paper are prepared. The letter A (intervention) is written on two sheets and the letter B (witness) is written on the other two sheets. The sheets are mixed together and removed by the researcher consecutively without placing them. This process is repeated for the number of qualified patients and whether each patient is group A or B is recorded.

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

Hamadan University of Medical Sciences, Shahid Fahmideh Street

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Province

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Postal code

38698-65178

Approval date

2024-10-26, 1403/08/05

Ethics committee reference number

IR.UMSHA.REC.1403.525

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

Two months after the intervention.

Method of measurement

Quality of life questionnaire for multiple sclerosis patients

2

Description

Fatigue severity

Timepoint

One month after the intervention.

Method of measurement

Fatigue severity questionnaire for multiple sclerosis patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group will be educated in 4 sessions of thirty minutes, every other day, regarding the process of developing multiple sclerosis, the importance of the disease, adherence to treatment, and methods of reducing fatigue and improving quality of life using teach back education. Education will be provided face-to-face and through an educational booklet. At the end of each session, patients will be asked to express the information in their own language and as they have understood it. Patients' problems and ambiguities will be resolved at the end of each session.

Category
N/A

2

Description
Control group: In the control group, no special measures will be taken except for routine hospital measures and training.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital in Hamadan

Full name of responsible person
Masoud Khodaveisi

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Hamadan University of Medical Sciences, Shahid Fahmideh Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Deputy of research and technology

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
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Position
Student

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Person responsible for updating data

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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
Not applicable
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