Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating family-centered empowerment on self-care of MS Jahrom patients in 2024-2025

Protocol summary

Study aim
Evaluating the Effect of family-centered empowerment on self-care of MS Jahrom patients in 2024-2025

Design
The clinical trial was designed as a randomized, triple-blind, parallel-group study with a control group. Participants were MS patients selected randomly using Random Number Generator software. The selected participants were then allocated to either the intervention or control group through random assignment facilitated by Random Allocation Software. Each group consisted of 31 participants, resulting in a total sample size of 62 individuals.

Settings and conduct
With ethics approval and IRCT code, MS patients from Jahrom MS Association were randomly chosen using Random Number Generator software and assigned to intervention or control groups via Random Allocation Software. All signed informed consent. A research assistant administered self-care questionnaires pre- and post-intervention. The control group received family-centered empowerment education post-study. The triple-blind trial kept group assignments hidden from the statistical consultant and data collector.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Confirmed diagnosis of multiple sclerosis by a neurologist. Age between 18 and 50 years. Not in an acute disease phase, with at least 6 weeks since the last relapse. Sufficient ability for self-care. At least 2 years since initial diagnosis. No history of psychiatric disorders or drug addiction. Exclusion Criteria: Acute worsening of condition requiring hospitalization. Death or migration.

Intervention groups
Intervention Group: MS patients from the Jahrom MS Association underwent a family-centered empowerment program with four steps: Perceived threat Enhancing self-efficacy Increasing self-esteem via educational participation Evaluation Control Group: Received standard interventions from the MS Association

Main outcome variables
self-care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250313065061N1**
Registration date: **2025-05-03, 1404/02/13**
Registration timing: **prospective**

Last update: **2025-05-03, 1404/02/13**
Update count: **0**

Registration date
2025-05-03, 1404/02/13

Registrant information

Name
MOHAMMAD GHAEDNIAY

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5426 1971

Email address
aminghaednia1995@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-05, 1404/02/15

Expected recruitment end date
2025-06-21, 1404/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating family-centered empowerment on self-care of MS Jahrom patients in 2024-2025

Public title

nvestigating family-centered empowerment on self-care of MS patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining informed consent for study participation. Definitive diagnosis of MS by a neurologist. Being aged between 18 and 50 years. Not being in the acute phase of the disease and at least 6 weeks having passed since the last disease relapse. Possessing sufficient ability for self-care. At least 2 years having passed since the initial diagnosis of the disease. Having no history of psychiatric disorders or drug addiction. Family members not being among healthcare providers. Having no underlying diseases in the family.

Exclusion criteria:

Acute worsening of the patient's condition and hospitalization. Death or migration of the patient and their family. Failure of the caregiver to attend more than two empowerment sessions. Lack of consent to continue the study for any reason.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a list of MS patients will be obtained from the MS Society of Jahrom. Using the Random Number Generator software, random sampling will be performed, and random allocation into intervention and control groups will be carried out using the Random Allocation Software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study was double-blinded, meaning that the statistical consultant and the data collector (research assistant) were unaware of the group assignments (intervention or control) at all stages.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jahrom University of Medical Sciences

Street address

Motahari Boulevard, Jahrom University of Medical Sciences

City

Jahrom

Province

Fars

Postal code

74157-13945

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.JUMS.REC.1403.116

Health conditions studied

1

Description of health condition studied

thalassemia

ICD-10 code

D56

ICD-10 code description

Thalassemia

Primary outcomes

1

Description

self-care

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Demographic characteristics questionnaire (patient and family caregiver) and self-care questionnaire of Momeni et al.

Secondary outcomes

1

Description

Timepoint

Method of measurement

2

Description
Timepoint
Method of measurement

Intervention groups

1

Description
Intervention group: MS patients from the Jahrom MS Association underwent a family-centered empowerment program with four steps:Perceived threatEnhancing self-efficacyIncreasing self-esteem via educational participation Evaluation
Category
Lifestyle

2

Description
Control group:Received standard interventions from the MS Association
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Society
Full name of responsible person
Dr Rasool Eslami Akbar
Street address
Motahari Boulevard, Jahrom University of Medical Sciences
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5434 0409
Email
eslamiakbarrasool@ gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Dr Rasool Eslami Akbar
Street address
Motahari Boulevard, Jahrom University of Medical Sciences
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5434 0409
Email
eslamiakbarrasool@ gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahrom 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
Jahrom University of Medical Sciences
Full name of responsible person
dr rasool Eslami Akbar
Position
Member of the university faculty, assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Motahari Boulevard, Jahrom University of Medical Sciences
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5434 0409
Email
eslamiakbarrasool@ gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
dr rasool Eslami Akbar
Position
Member of the university faculty, assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Motahari Boulevard, Jahrom University of Medical Sciences
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5434 0409
Email
eslamiakbarrasool@ gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
MOHAMMAD GHAEDNIAY
Position
Senior student
Latest degree
Bachelor
Other areas of specialty/work
Internal Medicine
Street address
ALLEY3,FAJR STREET,SHARAK ENGHELAB,JAHROM,FARS
City
JAHROM
Province
Fars
Postal code
7414846199
Phone
+98 71 5426 1971
Fax
Email
Aminghaednia1995@gmail.com

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