Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of the Family-Centered Empowerment Model on the Resilience of Patients with Multiple Sclerosis

Protocol summary

Study aim
Determining the Effect of a Family-Centered Empowerment Model on the Resilience of Patients with Multiple Sclerosis Registered with the Rafsanjan MS Society (1405)

Design
Stratified Random Allocation ، A randomized, single-blind, controlled clinical trial involving 64 patients (32 in the intervention group and 32 in the control group), with randomization performed using a stratified method.

Settings and conduct
The study was conducted at the Rafsanjan MS Association, spanning four 90-minute sessions based on the four stages of the family-centered empowerment model, utilizing a single-blind design.

Participants/Inclusion and exclusion criteria
• Definitive diagnosis of Multiple Sclerosis (MS) by a neurologist. • Age range of 18 to 65 years. • A Barthel Index score between 20 and 90, ensuring the required level of dependency. • Presence of at least one primary caregiver (family member) willing to actively participate in educational sessions. • Ability to comprehend instructions and complete questionnaires (self-report). • Provision of written informed consent for participation in all stages of the study. . No prior participation in similar educational programs.

Intervention groups
The educational intervention is conducted in four sessions, including familiarization with the nature of MS and its exacerbating factors, self-efficacy and problem-solving, self-confidence and self-esteem, and evaluation. The control group receives only routine care, and after the study period ends, an educational package is provided to them to comply with research ethics principles. The overall goal is to increase patients' and their families' awareness and empowerment in managing the disease.

Main outcome variables
Independent variable: Family-centered empowerment model – Dependent variable: Resilience of MS patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260911071006N1**
Registration date: **2026-10-07, 1405/07/15**
Registration timing: **prospective**

Last update: **2026-10-07, 1405/07/15**
Update count: **0**

Registration date
2026-10-07, 1405/07/15

Registrant information
Name
shayan orafa
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 34 3422 4297
Email address
shayanorafa81@gmail.com

Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-15, 1405/07/23
Expected recruitment end date
2026-12-14, 1405/09/23
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Investigating the Effect of the Family-Centered Empowerment Model on the Resilience of Patients with Multiple Sclerosis

Public title
Investigating the Effect of the Family-Centered Empowerment Model on the Resilience of Patients with Multiple Sclerosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
• Definitive diagnosis of Multiple Sclerosis (MS) by a neurologist • Age range: 18 to 65 years Having a performance score between 20 and 90 on the Barthel Index to ensure the desired level of dependency. • Having at least one primary caregiver (family member) willing to actively participate in training sessions. • Ability to understand instructions and respond to questionnaires (self-report) • Obtaining written informed consent for participation in all stages of the research. • No prior participation in similar training programs

Exclusion criteria:
A score of less than 20 or greater than 90, due to the patient's complete independence or severe dependency.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, following protocol approval and receipt of an ethics code from the Ethics Committee in Research of Rafsanjan University of Medical Sciences, the researchers will visit the MS Society center of Rafsanjan, and from among the total multiple sclerosis patients who are members of or have records at this center, 64 eligible patients will be selected using purposive sampling. To ensure homogeneity between the groups in terms of functional dependency level, a Stratified Random Allocation method will be used. First, in the initial stage, participants will be divided into two strata based on their Barthel Index scores: stratum one (high functional dependency, score 20–61) and stratum two (low functional dependency, score 62–90). In the second stage, for each stratum, participants will be randomly distributed (using a lottery method) between the intervention and control groups, such that ultimately each group will consist of 32 participants with a balanced distribution from both strata. After explaining the research objectives and obtaining informed, written consent from participants, the initial assessment stage (pre-test) will be conducted. At this stage, the demographic characteristics questionnaire, the Barthel functional index, and the Connor-Davidson Resilience Scale (CD-RISC) will be completed via self-report by participants in both the intervention and control groups. Subsequently, participants in the intervention group will take part in an educational program based on the "Family-Centered Empowerment Model" (FCEM). This intervention will be delivered in a group format, with the active participation of one family member (primary caregiver), at the MS Society center of Rafsanjan.

Blinding (investigator's opinion)
Single blinded

Blinding description
Given the educational and participatory nature of the intervention (active involvement of the patient and primary caregiver in group sessions), blinding of participants and the intervention provider was not feasible. To reduce bias in data collection and analysis, a single-blind method will be used: questionnaires completed at the three time points (Pre-test, Post-test, and Follow-up) will be given to the person responsible for data entry and analysis using only a numeric identification code, without any name or group label (intervention/control). The table matching participant codes to their assigned group will be kept by the principal researcher and will not be made available to the data analyst until data entry is complete and the initial analyses have been carried out.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Rafsanjan University of Medical Sciences

Street address
No. 42, Alley 39, Mostafa Khomeini Street, Partovi Square, Rafsanjan

City
Rafsanjan

Province
Kerman

Postal code
7714668433

Approval date
2026-10-05, 1405/07/13

Ethics committee reference number
IR.RUMS.REC.1405.118

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
Resilience of Patients with Multiple Sclerosis
Timepoint
Determination of patients' resilience scores before, immediately after, and one month after the intervention.
Method of measurement
Connor-Davidson Resilience Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will take part in an educational program based on the "Family-Centered Empowerment Model" (FCEM). This intervention will be delivered in a group format, with the active participation of one family member (primary caregiver), at the MS Society center of Rafsanjan. The educational protocol consists of 4 sessions of 90 minutes each (held at weekly intervals) and is designed around the following four operational steps:Session 1 (Orientation and Threat Perception): Through lectures and group discussion, patients' and their families' awareness and understanding of the nature of MS, its complications, aggravating factors, and factors effective in disease control are increased.Session 2 (Self-Efficacy/Problem-Solving): Patients and their families are confronted with the real-life problems of living with MS, and through group discussion and exchange of experience, they learn practical strategies for problem-solving and disease management.Session 3 (Self-Belief/Self-Confidence): The patient is asked to review the educational material from previous sessions with the help of the active family member and convey it to other family members, so as to strengthen their self-confidence and sense of mastery over the disease.Session 4 (Evaluation): Through questions and answers and group discussion, the patients' and families' level of learning and any remaining ambiguities are assessed.
Category
Behavior

2

Description
Control group: In addition to receiving routine care, the control group will not receive any educational intervention. To adhere to research ethics, the educational package (including PowerPoint files and educational content) will be provided to members of the control group upon completion of the study.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Rafsanjan MS Association
Full name of responsible person
Fatemeh Ayobi
Street address
School of Public Health, Enghelab Square, Rafsanjan, Kerman
City
Rafsanjan
Province
Kerman
Postal code
7719617996
Phone
+98 34 3426 4005
Email
info@rums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Mostafa Nasirzadeh
Street address
Fesenjan – Imam Ali Blvd. – Central Organization – Building No. 3, Deputy for Research and Technology
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0086
Email
vcrt@rums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Shayan Orafa
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Rafsanjan, Mostafa Khomeini Street, Alley
City
Rafsanjan
Province
Kerman
Postal code
7714668433
Phone
+98 34 3422 4297
Email
shayanorafa81@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Shayan Orafa
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 42, Alley 39, Mostafa Khomeini Street, Partovi Square, Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7714668433
Phone
+98 34 3422 4297
Email
shayanorafa81@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Shayan Orafa
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 42, Alley 39, Mostafa Khomeini Street, Partovi Square, Rafsanjan
City
Rafsanjan
Province
Kerman
Postal code
7714668433
Phone
+98 34 3422 4297
Email
shayanorafa81@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Some of the data—such as information regarding the primary outcome or the like—can be shared.
When the data will become available and for how long
Access period begins 6 months after the publication of results.
To whom data/document is available
All people interested in the research topic
Under which criteria data/document could be used
All researchers interested in the topic of my intervention
From where data/document is obtainable
Via my email at shayanorafa81@gmail.com

What processes are involved for a request to access data/document

Please submit your request via email or by sending a text message to 09381914125 (registered on Eitaa or WhatsApp).

Comments