Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of implementing the family-centered empowerment model on psychological well-being and health-promoting lifestyle in multiple sclerosis patients

Protocol summary

Study aim
Determining the effect of implementing a family-centered empowerment model on psychological well-being and health-promoting lifestyle in multiple sclerosis patients

Design
This study is a randomized clinical trial without blinding.

Settings and conduct
This study is a randomized clinical trial without blinding that will be conducted at the Multiple Sclerosis Clinic at Vali Asr Hospital, Fasa University of Medical Sciences.

Participants/Inclusion and exclusion criteria
In this study, 60 multiple sclerosis patients will participate. Inclusion criteria include willingness to participate in the study, being literate, and having at least 6 months of multiple sclerosis history. Exclusion criteria include missing more than two sessions of educational sessions, exacerbation and worsening of the disease, and unwillingness to continue participating in the study for any reason.

Intervention groups
30 multiple sclerosis patients will be included in the intervention group.

Main outcome variables
Psychological well-being, health-promoting lifestyle

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190917044802N12**
Registration date: **2025-01-10, 1403/10/21**
Registration timing: **prospective**

Last update: **2025-01-10, 1403/10/21**
Update count: **0**

Registration date
2025-01-10, 1403/10/21

Registrant information
Name
Mostafa Bijani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-19, 1403/10/30

Expected recruitment end date
2025-03-04, 1403/12/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of implementing the family-centered empowerment model on psychological well-being and health-promoting lifestyle in multiple sclerosis patients

Public title
The effect of implementing the family-centered empowerment model on psychological well-being and health-promoting lifestyle in multiple sclerosis patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Being literate in reading and writing Having at least a 6-month history of multiple sclerosis

Exclusion criteria:

Absence of more than two sessions in training sessions Aggravation and worsening of the disease Unwillingness to continue participating in the study for any reason

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **30**

30 patients in the intervention group and 30 patients in the control group

Randomization (investigator's opinion)

Randomized

Randomization description

60 cards are placed in a sealed envelope. 30 cards are put on stickers (A intervention group) and labels are placed on other 30 cards (B control group). Then the patients participating in the study are asked to take one of the cards. People who take card A will be in the intervention group and people who take card B will be in the 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 Fasa University of Medical Sciences

Street address

Ibn Sina Square

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2024-12-17, 1403/09/27

Ethics committee reference number

R.FUMS.REC.1403.115

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

Psychological well-being

Timepoint

Before the intervention, immediately and three months after the intervention

Method of measurement

Ryff’s Psychological Well-Being Questionnaire

2

Description

Health Promoting Lifestyle

Timepoint

Before the intervention, immediately and three months after the intervention

Method of measurement

Walker et al. Health Promoting Lifestyle Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, a training program based on the family-centered empowerment model will be implemented. The stages of the family-centered empowerment model will include four stages: 1- Understanding the threat, 2- Improving self-efficacy, 3- Self-belief and increasing self-confidence, 4. Evaluation. Step one, Understanding the threat: The first stage in the family-centered empowerment model is to increase perceived severity and sensitivity. The purpose of perceived severity (awareness and knowledge of the individual about the disease) is for the individual to understand the seriousness of the disease by recognizing the risks or complications of the disease and to feel threatened by it. Step two, Self-efficacy: Problem solving

or problem solving will be implemented in a group method. For this purpose, problem solving sessions (two 40- to 60-minute sessions) will be held for a group of patients and their families. Step three, Self-belief and increasing self-confidence: In this stage, the patient will be asked to teach the family the material discussed in the previous sessions during a session and to do this with the researcher's help and guidance if needed. The goal of this stage is to increase patients' self-confidence by observing their ability to provide information to family members and support them. Step Four, Evaluation: The evaluation of the process during the empowerment sessions will be carried out in such a way that the educational materials of the previous sessions are evaluated in the form of questions and answers in the next session.

Category
Lifestyle

2

Description
Control group: The control group will only receive the educational package and will not receive the educational intervention.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Multiple Sclerosis Clinic

Full name of responsible person
Mostafa Bijani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Mojtaba Farjam

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farjam@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Fasa 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
Fasa University of Medical Sciences

Full name of responsible person
Mostafa Bijani

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Full name of responsible person
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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
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All the questionnaires used in this study as well as the content of the training program will be provided to the applicants.
When the data will become available and for how long
The time period for accessing the data is after the publication of the article extracted from the study and there is no time limit.
To whom data/document is available
Researchers, nursing managers and hospital management can send their request to use the results of this research to the responsible author Mostafa Bijani in writing. Tell: 09173308451
Email:bizhani_mostafa@yahoo.com
Under which criteria data/document could be used
Nursing managers in the psychiatric department can use the results of this research to develop training programs for patients and patients' families.
From where data/document is obtainable
Researchers can send their request to use the results of this research to the responsible author Mostafa Bijani in writing. Tell: 09173308451
Email:bizhani_mostafa@yahoo.com
What processes are involved for a request to access data/document
Sending the request for the use of research documents and results to the responsible author and sending the results by the responsible author to the requesting person Tell: 09173308451
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Comments