Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of peer-based education based on Pender health promotion model on quality of life, stress management and Self-efficacy in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effect of peer-based education based on Pender health promotion model on quality of life, stress management and self-efficacy in patients with multiple sclerosis

Design

This study is a randomized clinical trial without blinding. The study population was patients with multiple sclerosis (MS). The sample size based on previous studies with 95% confidence level and 90% test power of 80 people (40 people in each group) will be considered. Random allocation sampling method It is simple to put 80 cards in an envelope written on 40 letters A and 40 cards B, then patients who meet the inclusion criteria are asked to take a card if If they take card A, they will be in the intervention group, and if they take card B, they will be in the control group, and this process will continue until the sample size is completed.

Settings and conduct

he study site of MS clinic is in Fasa city in the south of Fars province. This study is a double-blind randomized clinical trial. Blinding will be done in researcher and patient mode.

Participants/Inclusion and exclusion criteria

This study is a randomized clinical trial without blinding .The study population was patients with multiple sclerosis (MS). The sample size based on previous studies with 95% confidence level and 90% test power of 80 people (40 people in each group) will be considered.

Intervention groups

The educational intervention consists of five 1-minute training sessions once a week for the intervention group by a peer. Question and answer sessions will also be conducted by a peer and researcher during the week. The control group will receive routine training by the MS Clinic. They will also be provided with a training booklet.

Main outcome variables

Quality of life, stress management, self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N3**
Registration date: **2022-02-06, 1400/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-06, 1400/11/17**
Update count: **0**

Registration date

2022-02-06, 1400/11/17

Registrant information

Name

Mostafa Bijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 5012

Email address

bizhani_mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of peer-based education based on Pender health promotion model on quality of life, stress management and Self-efficacy in patients with multiple sclerosis

Public title
Investigating the effect of peer-based education based on Pender health promotion model on quality of life, stress management and Self-efficacy in patients with multiple sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Have a minimum literacy Age between 18 and 50 years
No speech or hearing impairment
Exclusion criteria:
Suffering from severe mental and emotional disorders
Acute disease

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method is simple random assignment in which we put 80 cards in an envelope written on 40 letters A and 40 cards B, then patients who meet the inclusion criteria are asked to If they take a card, if they take an A card, they will be in the intervention group, and if they take a B card, they will be in the control group, and this process will continue until the sample size is completed.

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 - Fasa University of Medical Sciences

City
Fasa

Province
Fars

Postal code
7461686688

Approval date
2021-03-16, 1399/12/26

Ethics committee reference number
IR.FUMS.REC.1399.197

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis (MS)

ICD-10 code
G35

ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Quality of Life

Timepoint
Before, immediately and three months later

Method of measurement
Quality of life questionnaire in MS patients

2

Description
Self-efficacy

Timepoint
Before, immediately and three months later

Method of measurement
General Self-Efficacy Questionnaire (GSES) Scherer et al

3

Description
stress management

Timepoint
Before, immediately and three months later

Method of measurement
Stress Management Questionnaire (Cobain et al.)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: The educational intervention consists of five 1-minute training sessions once a week for the intervention group by a peer. Question and answer sessions will also be conducted by a peer and researcher during the week
Category
Lifestyle

2

Description
Control group: will receive routine training by MS Clinic. They will also be provided with a training booklet. .
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital Fasa
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
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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
Vice Chancellor for Research, 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
Assistant Professor. Faculty member
Latest degree
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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
Yes - There is 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
To use the educational content and analyze the data, send an email to the executor of the project

When the data will become available and for how long
6 months after the publication of the article

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Request permission from the developer to receive information and use the data

From where data/document is obtainable
Send an email to the project executor at the following address bizhani _mostafa@yahoo.com

What processes are involved for a request to access data/document
Send an email to the project executor at the following address bizhani _mostafa@yahoo.com

Comments