

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 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

Quality of life, stress management, self-efficacy

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

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

Street address

Shariati Street . Shariati Hospital

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7461686688

Phone

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Email

bizhani_mostafa@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Farjam

Street address

Sinai Square. Fasa University of Medical Sciences

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Phone

Email

farjam@yahoo.com

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

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bijani

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Fasa University of Medical Sciences

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

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