

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the impacts of a peer-led and a nurse-led self-management program on the subject well-being of patients with multiple sclerosis

Protocol summary

Study aim

This clinical trial study was designed to compare the impacts of a peer-led and a nurse-led self-management program on the subject well-being of patients with multiple sclerosis

Design

Clinical trial including two education groups, with parallel groups

Settings and conduct

The research environment is the center for Comprehensive Treatment of Special Diseases Affiliated to Birjand University of Medical Sciences. Patients will be selected by available sampling method and the demographic information form and the scales for the main variables will be fully interviewed for all of them. Subjects were assigned to nurse-led education (42 people) and peer-led education (42 people) groups with permutation blocking method.

Participants/Inclusion and exclusion criteria

Inclusion criteria of the study include satisfaction to participate in the study, having a recurrence-remission type disease during the study and expanded Disability Status Scale between 0.5 and 5.5. Patients with other acute or chronic physical, mental or psychiatric disorders, such as severe depression, will not be included in the study.

Intervention groups

In this study, there are two nurse-led education and peer-led education groups that receive self-management program. In the nurse-led education group, patients will be divided into 2 groups of 10 and 2 groups of 11 people. Then, self-management training sessions will be held by a qualified nurse for each group for 6 sessions of 2 hours each week. The peer-led education group will be divided into 2 groups of 10 and two groups of 11 people. Then, two leaders will be selected from among patients with multiple sclerosis. In the next step, self-management

training sessions will be held by peer leaders for each group for 6 sessions of 2 hours each week.

Main outcome variables

Subjective well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190305042926N1**

Registration date: **2019-03-14, 1397/12/23**

Registration timing: **retrospective**

Last update: **2019-03-14, 1397/12/23**

Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Maryam Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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azizi.m@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-05, 1397/09/14

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the impacts of a peer-led and a nurse-led self-management program on the subject well-being of patients with multiple sclerosis

Public title
The impacts of a peer-led and a nurse-led self-management program on the subject well-being

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Satisfaction to participate in the study
Having reading and writing skills
Ages between 20 to 45 years
Spending at least one year of diagnosis of multiple sclerosis by specialist doctors
Not having a history of participation in educational programs related to self-management and psychology
Having a recurrence-remission type disease during the study, approved by a neurologist
Expanded Disability Status Scale be between 0.5 and 5.5
Exclusion criteria:
Participant dissatisfaction to attend the study
Having other acute or chronic physical, mental or psychiatric disorders such as severe depression.

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
patients who have inclusion criteria will be assigned to the nurse-led and peer-led education groups using a permutation blocking method (quadruple blocks) with the help of random allocation software.

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

کمیته اخلاق دانشگاه علوم پزشکی بیرجند

Street address

خیابان آیت الله غفاری، دانشگاه علوم پزشکی بیرجند

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.BUMS.REC.1397.190

Health conditions studied

1

Description of health condition studied

Subjective well-being in multiple sclerosis patients

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Subjective well-being

Timepoint

Before the intervention, immediately at the end of the intervention, as well as two months after the intervention

Method of measurement

In the study of comparison of the impacts of a peer-led and a nurse-led self-management program on the subject well-being of patients with multiple sclerosis for measuring the subjective two well-being, the scale of positive and negative experience balance and satisfaction with life scale (SWLS) will be used.

Secondary outcomes

1

Description

Life satisfaction

Timepoint

Before the intervention, immediately at the end of the intervention, as well as two months after the intervention

Method of measurement

Satisfaction with life scale (SWLS)

2

Description

Positive and negative affect

Timepoint

Before the intervention, immediately at the end of the intervention, as well as two months after the intervention

Method of measurement

Scale of positive and negative experience balance

Intervention groups

1

Description

Intervention group: In this study, there are two nurse-led education and peer-led education groups that receive self-management program. For this, in the nurse-led education group, patients will be divided into 2 groups of 10 and 2 groups of 11 people. Then, self-management training sessions will be held by a qualified nurse for each group for 6 sessions of 2 hours each week. At the end of the second week and thereafter also a telephone follow-up on the implementation of the self-management program will be done.

Category

N/A

2

Description

Intervention group: The peer-led education group will be divided into 2 groups of 10 and two groups of 11 people. Then, two leaders will be selected from among patients with multiple sclerosis. For group leaders, two training sessions on how to meet the goals of peer education and its nature, the principles of communicating with patients, guiding topics in peer education group and etc. will be held. Self-management booklet for multiple sclerosis patients prepared by reputable sources and endorsed by a neurologist will also be available to peer leaders. In the next step, self-management training sessions will be held by peer leaders for each group for 6 sessions of 2 hours each week. At the end of the second week and thereafter also a telephone follow-up on the implementation of the self-management program will be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Treatment of Special Diseases

Full name of responsible person

Jalal Ahmadi

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No. 3, Shahid Beheshti Ave., Birjand City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research, Birjand University of Medical Sciences

Street address

Vice chancellor for research, Birjand University of Medical Sciences, Ayatollah Ghafari Street

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research@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand University of Medical Sciences

Proportion provided by this source

70

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

Birjand University of Medical Sciences

Full name of responsible person

Maryam Azizi

Position

MSc student in nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Undecided - It is not yet known if there will be a plan to make this available

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