Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone
+98 56 3238 1319

Email address
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
Street address
No. 3, Shahid Beheshti Ave., Birjand City
City
Birjnad
Province
South Khorasan
Postal code
9719873839
Phone
+98 56 3238 1342
Email
azizi.m@bums.ac.ir

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
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1200
Email
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
Street address
Nursing and Midwifery College, Birjand University of Medical Sciences, Ayatollah Ghaffari Street
City
Brjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1410
Email
azizi.m@bums.ac.ir

Person responsible for scientific 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
Street address
Nursing and Midwifery College, Birjand University of Medical Sciences, Ayatollah Ghaffari Street,
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 985632381410
Email
azizi.m@bums.ac.ir

Person responsible for updating data

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
Street address
Nursing and Midwifery College, Birjand University of Medical Sciences, Ayatollah Ghaffari Street
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1410
Email
azizi.m@bums.ac.ir

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