

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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)

##### 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**

Birjand

#### **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**

9719873839

##### **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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

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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**

Birjand University of Medical Sciences

**Full name of responsible person**

Maryam Azizi

**Position**

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**Latest degree**

Bachelor

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South Khorasan

**Postal code**

9717853577

**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