

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effect of self care program based on Orem's theory on the quality of sleep and psychological indices in patients with multiple sclerosis

#### Protocol summary

##### Summary

Multiple sclerosis (MS) is a chronic disease and a major source of disability across the world. Orem's theory emphasizes an individual's ability to self-care. Thus, the aim of the study was to examine the effects of an educational program based on Orem's Self-care Theory on sleep quality and Some indicators of mental in patients with Multiple sclerosis. The current clinical trial included 78 MS patients during 2014-15. The population included all MS patients registered at the MS Association of Zahedan who were invited to participate in the study through a public call. The objectives of the study were explained, and the ones willing and qualified according to inclusion criteria were registered. They were randomly allocated to a control and case group (n=39 in each group). The tools included a demographics form, Pittsburgh Sleep Quality Index Snyder's Hope Scale, DASS21 and Patient Needs Assessment Form who were completed by the patients before and three months after the educational intervention. The intervention involved nine educational sessions based on Orem's theory. Application of the program materials during the three months of education by patients was followed through self-report forms. Both needs assessment and self-report forms were researcher-made.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015050522100N1**

Registration date: **2015-08-21, 1394/05/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-08-21, 1394/05/30

#### Registrant information

##### Name

Hanie Dahmardeh

##### Name of organization / entity

Birjand University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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#### Recruitment status

##### Recruitment complete

#### Funding source

Birjand University of Medical Sciences and Health Services

#### Expected recruitment start date

2015-02-19, 1393/11/30

#### Expected recruitment end date

2015-03-21, 1394/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of self care program based on Orem's theory on the quality of sleep and psychological indices in patients with multiple sclerosis

#### Public title

The effect of self-care program on quality of sleep and Some indicators of mental in patients with multiple sclerosis

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: age between 20-50; Literacy; lack of

continuous use of sleep medication; sleep quality score of five or higher devices; independent of the wheelchair; not in the acute phase of the disease; the lack of other acute disorders or chronic physical and mental or psychological such as depression; impaired speech or hearing. Exclusion criteria: lack of willingness to continue participation in the trial for any reason; patients who have complications during the intervention; physical-mental disorders and diseases are serious.

#### Age

From **20 years** old to **50 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **84**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### 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

Birjand University Of Medical Sciences and Health Services

##### Street address

Ghaffari Street, Birjand

##### City

Birjand

##### Postal code

#### Approval date

2015-04-06, 1394/01/17

#### Ethics committee reference number

IR.BUMS.1394.1

## Health conditions studied

### 1

#### Description of health condition studied

multiple sclerosis

#### ICD-10 code

G35

#### ICD-10 code description

multiple sclerosis

## Primary outcomes

### 1

#### Description

Quality of sleep

#### Timepoint

Early intervention and 3 months

#### Method of measurement

Pittsburgh Sleep Quality Index...

### 2

#### Description

Hope

#### Timepoint

3 months

#### Method of measurement

Schneider hopes questionnaire

## Secondary outcomes

### 1

#### Description

Some mental health indicators

#### Timepoint

Early intervention and 3 months

#### Method of measurement

Schneider hopes questionnaireDASS21.

## Intervention groups

### 1

#### Description

Intervention group: Patients in the intervention group completed the questionnaire and 45-minute sessions over a two-week training program in 9th place, with medical supervision neurologist offered to them. In the meetings, after additional details about the research and its objectives in the form of self reported by patients and care program on how to register will be explained to them in this form. Then the content of the curriculum as defined by the disease, its causes and symptoms, methods of diagnosis and treatment and self-care skills related to physical problems and muscle weakness, fatigue and how to relieve muscle spasms, gait disorders, urination and defecation disorders, disorder physical and cognitive performance and mental disorders will be presented. The program will be presentations and displays images of patients are taught and trained for the review of cases will be considered for the patient questions to be answered. Patients were followed for 3 months after intervention and support researcher training program to run daily on Czech daily list of self-reported home pay and complete the. Researcher on a specific day in the community and patients will be able to attend your questions and problems to ask her in

person or by phone. After three months, people will be invited to attend the forum. Then the questionnaires completed by the participants

**Category**

Rehabilitation

**2****Description**

Control group: Patients in the control group completed questionnaires at baseline and these patients will not be any interference. After three months, the control group will be invited to attend forums and questionnaires completed by patients.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

MS Society Of Zahedan

**Full name of responsible person**

Mr. Dorrani

**Street address****City**

Zahedan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences and Health Services

**Full name of responsible person**

Mr. Afkar

**Street address**

Ghaffari Street- Birjand

**City**

Birjand

**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 and Health Services

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

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

Birjand University Of Medical Sciences

**Full name of responsible person**

Hanie Dahmardeh

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Graduate Student

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Hanie Dahmardeh

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Fax**

**Email**  
**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*

**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*