Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Hanie Dahmardeh
Name of organization / entity
Birjand University Of Medical Sciences
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Iran (Islamic Republic of)
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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 scelerosis

ICD-10 code
G35

ICD-10 code description
multiple scelerosis

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

Position

Graduate Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University Of Medical Sciences.

Full name of responsible person

Seyyed Abolfazl Vagharseyyedin

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Hanie Dahmardeh

Position

Other areas of specialty/work

Street address

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Phone

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Fax

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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