Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of self-care education on self-concept and self-efficacy in patients with multiple sclerosis

Protocol summary

Study aim
The effect of self-care education on self-concept and self-efficacy in patients with multiple sclerosis

Design
Clinical trial with control and intervention groups,parallel,single blind.randomized

Settings and conduct
The research population is included of 90 patients with multiple sclerosis disease, who are members of MS Society of Iran. These individuals were divided into two 45-member groups of intervention group and control group by somebody (except the researcher) through the random number table. considering the researcher did not know about the presence of people in the two groups, so the intervention was single blind.In the intervention group Self-care empowerment program was conducted for patients. For the patients in the control group, the usual care of the MS Society has been continued.Self-concept questionnaire and self-efficacy questionnaire were completed before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 20 to 65 years, not being in the acute phase of multiple sclerosis, not having another disabling disease, not being a member of the medical and paramedical staff and having the ability of reading and writing. exclusion criteria: Suffering from progressive-relapsing multiple sclerosis

Intervention groups
Intervention group: Self-care education conducted in five sessions of two hours during eight weeks with content 1. Prevention of intestinal and bladder disorders 2. Prevention of disturbances in mobility, weakness and muscular cramps and imbalances 3. Prevention of fatigue 4.Psychological care education. Control group: Continue the routine care in the Multiple Sclerosis Society of Iran.

Main outcome variables
Self-concept, Self-efficacy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180914041036N1**
Registration date: **2019-01-18, 1397/10/28**
Registration timing: **retrospective**

Last update: **2019-01-18, 1397/10/28**
Update count: **0**

Registration date
2019-01-18, 1397/10/28

Registrant information
Name
Mohammad saber Sholehvar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 83 4322 3496
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ms-sholehvar@razi.tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-08-23, 1396/06/01
Expected recruitment end date
2018-02-20, 1396/12/01
Actual recruitment start date
2017-08-23, 1396/06/01
Actual recruitment end date
2018-02-20, 1396/12/01
Trial completion date
2018-02-20, 1396/12/01

Scientific title

The effect of self-care education on self-concept and self-efficacy in patients with multiple sclerosis

Public title
The effect of self-care education on self-concept and self-efficacy in patients with multiple sclerosis
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 20 to 65 years Not being in the acute phase of multiple sclerosis Not having another disabling disease Not being a member of the medical and paramedical staff Literacy reading and writing
Exclusion criteria:
Suffering from progressive-relapsing multiple sclerosis
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator

Sample size
Target sample size: **90**
Actual sample size reached: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, simple randomization method is used with random number table. In the way that the patient enters the groups of the study by selecting one number of the table (the odd numbers for the control group and the even numbers for the intervention group). The study was single blind clinical trial, that means the sampler is unaware of how people are assigned to the groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Placing people in the intervention and control group using the random numbers table was performed by someone else (not the investigator).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Department of Research and Technology,Central Organization of Tehran University of Medical Sciences,Ghods St.Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-08-02, 1396/05/11
Ethics committee reference number
IR.TUMS.FNM.REC.1396.2939

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
Self-concept in patients with multiple sclerosis
Timepoint
Before beginning the study and 8 weeks after training
Method of measurement
Rogers self-concept questionnaire

2

Description
Self-efficacy in patients with multiple sclerosis
Timepoint
Before beginning the study and 8 weeks after training
Method of measurement
Sherer General Self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At the beginning of the study, demographic information questionnaire, Rogers self-concept questionnaire, and Sherer's self-efficacy questionnaire (GSES) were completed. Self-care education was conducted in five sessions of two hours during eight weeks in group and face-to-face with content of : 1.Prevention of intestinal and bladder

disorders include bladder training, doing pelvic muscle exercises, urination and stool management training using Valsalva maneuver, having appropriate diet to prevent constipation, doing exercise and having adequate mobility and drinking adequate fluid, 2.Prevention of impaired mobility, weakness and muscle cramp and imbalance include relaxation and coordination exercises, how to use auxiliary equipment and hot water shower, 3.Fatigue prevention includes having a regular, tolerable and athletic sport planning, prioritizing tasks, energy conservation and designing the living environment appropriately, 4.Psychological care education included methods for increasing self-confidence, proper relationship with family and relatives, increasing the hope and encouraging participation in social activities.

Category

Lifestyle

2

Description

Control group: No program was implemented by the researcher for the control group and they followed the regular program of the Iranian Multiple Sclerosis Society.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Multiple Sclerosis Society

Full name of responsible person

Abdul Hussein Houshmand

Street address

No. 35, Shahid Mohammad Shams Alley, Taleghani Crossroad, Enghelab Street

City

Tehran

Province

Tehran

Postal code

1416864731

Phone

+98 21 6695 3907

Email

iranmsociety@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mohammad ali sahraian

Street address

Deputy of Research and Technology, Central Organization of the University, Corner of Quds Street, Keshavarz Blvd., Tehran

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msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad saber Sholehvar

Position

Master student of medical & surgical nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad saber Sholehvar

Position
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After defending the thesis and approval by the Tehran University of Medical Sciences, the data collected will be provided to Researchers and patients fully (after unidentification of the participants).

When the data will become available and for how long
6 months after printing results

To whom data/document is available
Information will be provided to researchers and patients

Under which criteria data/document could be used
The data will be available to researchers and patients with the aim of improving the quality of life of patients with multiple sclerosis.

From where data/document is obtainable
TEL: 00989181280911 E.mail: www.ms-sholehvar@razi.tums.ac.ir

What processes are involved for a request to access data/document
If collecting data is needed, the applicant can express his request by sending an email to the researcher .The researcher will respond to his request within one week.

Comments