

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

Email address

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

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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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Email

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

Street address

Nosrat st. Tohid sq. Tehran I.IRAN 141973317

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Postal code

1417743855

Phone

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Fax

Email

www.ms-sholehvar@razi.tums.ac.ir

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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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

Person responsible for updating data

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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