Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of education program Self-Care based on theory of planned behavior of Control physical complications from the disease in patients with Multiple sclerosis

Protocol summary

Summary

This quasi-experimental research, based on the before-after design is conducted in Qom MS Society aiming to investigate effectiveness of training the patients with Multiple Sclerosis in a self-care plan according to the theory of planned behavior on improving the symptoms. The research is done by permission of Qom University of Medical Science and approval from authorities of MS Society. A list of all members of Qom MS Society is checked prior to intervention and 80 patients were chosen as the sample based on inclusion criteria i.e. membership of MS Society, being between the ages of 18 and 50 and literacy as well as exclusion criteria i.e. taking the medicines to relieve the symptoms of the illness and less than 6 months of onset of the disease. The patients invited to participate in the research project are assigned to experimental and control groups at random. Following obtaining consent, the participants fill out personal information, self-care, self-report and constructs of the theory questionnaires. Training self-care plan classes then are designed according to Information obtained from questionnaires as well as specifying the participants' difficulties. Three 45-minute training sessions based on the theory of planned behavior are conducted with merely the experimental group. Once we make sure that self-care plans are appropriately performed by participants, to keep evaluating proper performance of the plan within next 3 months after intervention, the monthly self-report questionnaires of trained items and issues are developed for 3 months the plan is being conducted to be filled out by the patients in experimental group. The questionnaires are collected and assessed after 3 months. It is of importance to point out that the witness group receives no intervention. The questionnaires are filled out again by the patients in both groups, 3 months after giving the training intervention is stopped, and questionnaires are analyzed afterwards. Such symptoms of the Multiple Sclerosis as constipation, muscle spasms, Forgetfulness and Fatigue are predicted to subside following training self-care plan.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071628957N1**
Registration date: **2016-12-17, 1395/09/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-17, 1395/09/27

Registrant information

Name

Zahra Dashti

Name of organization / entity

Qom University of Medical Sciences and Health Services- School of Public Health

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

MS Society of Qom province

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education program Self-Care based on theory of planned behavior of Control physical complications from the disease in patients with Multiple sclerosis

Public title

The effect of education program Self-Care to control physical complications resulted from multiple sclerosis

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: being between the ages of 18 and 50; literacy; not being wheelchair-dependent; not being at Severe stage of the disease; giving consent to participate in the study; not having mental disorders; membership of MS Society. Exclusion criteria: taking the medicines to relieve the symptoms of the Multiple Sclerosis; taking part in training self-care programs during 6 months ago; developing other acute or chronic physical illnesses (like debilitating Cardiovascular, Respiratory tract, liver, skeletal muscle and renal diseases); less than 6 months of onset of the disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

After the sample selection based on inclusion criteria, patients randomly are placed in two intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences and Health Services

Street address

Plaque 83 - Alley 4 - Alley 1/1 - Street Safashahr

City

Qom

Postal code

Approval date

2016-06-22, 1395/04/02

Ethics committee reference number

IR.MUQ.REC.1395.34

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

The physical complications of multiple sclerosis in 4 areas constipation, muscle cramps, fatigue and Amnesia

Timepoint

Before the intervention, one month, two months, three months after the intervention.

Method of measurement

Self-report Questionnaire (according to score)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: only experimental group undergoes the intervention within 3 theoretical and practical 45-minute training sessions according to the theory of planned behavior. After being certain about correct performance of self-care plans by experimental group, the plan will be conducted for 3 months. Various training methods including lecture, group discussion, Socratic and role-playing methods are going to be utilized in these sessions. Besides, the patients benefit telephone consultations.

Category

Behavior

2

Description
Control group: no action
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
MS Society of Qom province
Full name of responsible person
Zahra Dashti
Street address
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
MS Society of Qom province
Full name of responsible person
Zahra Dashti
Street address
Clinic Baqiyatallah - St. Dvrshhr
City
Qom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
MS Society of Qom province
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
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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