Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Comparison of the Effect of Self-Care Education Based on Team Members Teaching Design and lecture on Quality of Life and Self-efficacy in Patients with Multiple Sclerosis

Protocol summary

Study aim

The purpose of this study was to determine and compare the effect of self-care education based on Team Members Teaching Design and lecture on quality of life and self-efficacy in patients with multiple sclerosis.

Design

This is an experimental intervention study, without blinding with two intervention groups and one control group. The sample size is 60 patients and the samples are randomly selected and then randomly assigned into three groups of 20 each.

Settings and conduct

This study is performed on patients with multiple sclerosis referred to MS Association of Jahrom city in the year 2019. The study population included all patients with multiple sclerosis referred to MS Association of Jahrom city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged between 18-60 years and literate, at least two years past first diagnosis, not in acute phase of illness and at least 6 weeks past last recurrence and ability Take care of yourself. Exclusion criteria: The patient withdrew from the study for any reason and missed more than two sessions during the intervention or was unable to carry out the self-care program due to complications.

Intervention groups

Interventions consisted of six sessions of lecture in the first group and six sessions of teaching in the second group according to the patients' educational needs and no intervention in the control group. Quality of life and self-efficacy before and immediately after the intervention and 30 days after the intervention by the questionnaire will be reviewed.

Main outcome variables

Improving quality of life and self-efficacy in MS patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042506N1**
Registration date: **2020-01-08, 1398/10/18**
Registration timing: **retrospective**

Last update: **2020-01-08, 1398/10/18**
Update count: **0**

Registration date

2020-01-08, 1398/10/18

Registrant information

Name

fariba fakhravari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5444 7373

Email address

f.fakhravari@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Comparison of the Effect of Self-Care Education Based on Team Members Teaching Design and lecture on Quality of Life and Self-efficacy in Patients with Multiple Sclerosis

Public title
The Comparison of the Effect of Self-Care Education Based on Team Members Teaching Design and lecture on Quality of Life and Self-efficacy in Patients with Multiple Sclerosis

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
1. The patient is informed to participate in the study of satisfaction. A definitive diagnosis of MS by a neurologist. Patients aged 18-60 years. Have literacy to read and write Not in the acute phase of the disease and at least 6 weeks after the last relapse of the disease Have the ability to take care of yourself At least 2 years after the first diagnosis of the disease.

Exclusion criteria:
Absence of more than 2 sessions during the intervention will exclude them from participating in the study. Patient for any reason not to continue to participate in the study. The patient will not be able to implement the self-care program due to the complications of the disease. During the intervention, there are acute and critical attacks of the disease. There are other acute illnesses, such as heart disease, kidney, respiratory, digestive and metabolic diseases other than MS.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Using computer and randomly assigned patients in one of the three groups of self-care education based on team members (intervention), self-care education is based on lecture (intervention) and control group. In random assignment, each patient is code-fed through a computer system, randomly, code one in the self-care training group based on team members (intervention), code 2 in the self-care education group based on lecture (intervention), and Code three is in the control group.

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
Ethics committee of jahrom university of medical sciences

Street address
Motahari Ave

City
Jahrom

Province
Fars

Postal code
7414846199

Approval date
2019-03-13, 1397/12/22

Ethics committee reference number
IR.JUMS.REC.1397.152

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 Life

Timepoint
Before intervention, immediately after intervention, 30 days after intervention

Method of measurement
Standard questionnaire Multiple sclerosis quality of life: MSQOL-54 -Barbara G. Vickrey (1995) University of California, Los Angeles

2

Description
Self-efficacy

Timepoint
Before intervention, immediately after intervention, 30 days after intervention

Method of measurement
Multiple sclerosis Self-efficacy Scale-Rigby et al. (2003) - England

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Self-Care Education Based on Team Members Teaching Design:The education plan will be held for 4-6 sessions per hour in accordance with the educational needs. The number of sessions may be more or less relevant to educational needs. 1. The patients will be divided into four teams of five people from a few days ago.2. The researcher will prepare a self-care education based on the outcome of the need assessment and share it in equal amounts and will be distributed among all patients one week before and they will be required to read the content in advance to expedite their implementation.3. On the day of the performance, according to the previous division of the members, the first persons of each of the four teams in one category, the second team of each team in a category and the third team of each team in another group, and so on, the fourth and fifth teams of each team Will be in another category. In fact, there will be four groups of five, each with a single item in their main teams.4. Then, patients are asked to discuss, discuss, and understand the contents of all five subjects with the same content in each of the categories for 10 minutes.5. After completing the first stage, all members of the team will return to their main teams and, for 10-15 minutes, they will provide their own materials in their teams, as well as ask questions and answer questions.6. At the end of the summary, the questions will be answered by the researcher.

Category

Lifestyle

2

Description

Intervention group: Effect of Self-Care Education Based on lecture:The education plan will be held for 4-6 sessions per hour in accordance with the educational needs. The number of sessions may be more or less relevant to educational needs.Teaching in the lecture group will include presenting the Content by lecture with questions and answers, summarizing the Contents and answering the questions by the researcher.

Category

Lifestyle

3

Description

Control group: They will not be given to the control group during the study, but in order to comply with the research ethics, after the patients completed the post-intervention questionnaire, for the control group the self-care education program was more efficiently based on the results of the research , Will be done by the researcher.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Multiple Sclerosis Society

Full name of responsible person
Mr Kambiz Sohrabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Dr Ali Dehghani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

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Position

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Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available