Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of a self-management program on treatment adherence and life satisfaction in patients with multiple sclerosis: a clinical trial.

Protocol summary

Summary

1. This research aims to determine the effect of self-management program on treatment adherence and life satisfaction in patients with multiple sclerosis referred to the Institute for Protection of MS in Zahedan, 2016. 2. Design: This research is a randomized interventional study done on 78 patients with MS. Inclusion criteria include: age over 18; having reading and writing skills; no communication problem (like blindness and deafness). Exclusion criteria: Being in the active phase of the disease 3. Method: The available sampling is done, and then patients are randomly divided to the control and intervention groups. 4) Population: participants including major eligibility criteria: The study populations included patients with multiple sclerosis referred to the Institute for Protection of MS patients and were eligible for the study. The available sampling is done among Multiple sclerosis patients, based on inclusion criteria. 5) Intervention: The control group received routine care. For the intervention group, self-management program is implemented based on five self-management skills, including: 1. Problem-solving skills. 2. Decision-making skills. 3. Use of resources. 4. Formation of therapeutic communication between caregiver and patient. 5. Operational program. Patients in both groups will complete the MS-TAQ treatment and SWLS life satisfaction questionnaires before intervention. In intervention group, self-management sessions will be performed in five sessions of one–and-half-hour , one session a week. 6) Main outcome measures (variables): treatment adherence and life satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082134873N1**
Registration date: **2017-08-21, 1396/05/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-08-21, 1396/05/30

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2016-08-10, 1395/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a self-management program on treatment adherence and life satisfaction in patients with multiple sclerosis: a clinical trial.

Public title

Impact of self-management program on MS patients

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria include: age over 18; Having reading and writing skills; No communication problem (like blindness and deafness). Exclusion criteria: being in the active phase of the disease
Age
From **18 years** old
Gender
Both

Phase
2-3
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

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences and Health Services
Street address
University of Medical Sciences, Docter Hesabi square, Zahedan
City
Zahedan
Postal code
9816743463
Approval date
2016-07-10, 1395/04/20
Ethics committee reference number
IR.ZAUMS.REC.1395. 123

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
Treatmenet adherence
Timepoint
Before the intervention and two months after the intervention
Method of measurement
MS-TAQ questionnaire

2

Description
Life satisfaction
Timepoint
Before the intervention and two months after the intervention
Method of measurement
SWLS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
For the intervention group, self-management program is implemented based on five self-management skills, including: 1. Problem-solving skills. 2. Decision-making skills. 3. Use of resources. 4. Formation of therapeutic communication between caregiver and patient. 5. Operational program. Patients in both groups will complete the MS-TAQ treatment and SWLS life satisfaction questionnaires before intervention. In intervention group, self-management sessions will be performed in five sessions of one–and-half-hour , one session a week.
Category
Other

2

Description
The control group received routine care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Institute for Protection of MS patients in Zahedan
Full name of responsible person
Dorrani Reza
Street address

Khayam Department, Khayam Aveniue, Khayam 8, Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Dr Noormohammad Bakhshani

Street address

University of Medical Sciences, Docter Hesabi sq, Zahedan.

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Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Sciences

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

School of Nursing and Midwifery

Full name of responsible person

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Position

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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