

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name

fariba Yaghoubinia

Name of organization / entity

Country

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Phone

+98 54 3343 0059

Email address

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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 Avenue, 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,
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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