

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Exploration the Risk Factors Related to Lifestyle and Psychological Problems in MS Patients and Development the Intervention Based on it, and the Effect of the Intervention in Self-Management, lifestyle and Psychological Capitals on these Patients

Protocol summary

Study aim

The effect of Cognitive behavioral intervention on health promoting lifestyle, self-management and psychological capital of MS patients.

Design

To examine the effectiveness of intervention, 50 MS patients who volunteered to participate in the study will be included in two groups of control (25 patients) and a test (25) randomly.

Settings and conduct

After the determination of the two groups, the control and test groups are taken from both groups and the test group is then subjected to educational intervention and finally, the post-test is taken from both groups.

Participants/Inclusion and exclusion criteria

Diagnosis of MS by neurologists using MRI Clinical syndrome of the disease for one year Being between the age of 25 and 45 years Not attending counseling or simultaneous treatment

Intervention groups

In order to evaluate the effectiveness of intervention, the semi-experimental method with the control group with pre-test and post-test design and follow-up (two months later) will be used.

Main outcome variables

Increasing the health promotion behaviors, self-management and psychological capital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180508039581N1**

Registration date: **2019-03-12, 1397/12/21**

Registration timing: **retrospective**

Last update: **2019-03-12, 1397/12/21**

Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

Sajjad Saadat

Name of organization / entity

University of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 9135

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-11, 1397/03/21

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploration the Risk Factors Related to Lifestyle and Psychological Problems in MS Patients and Development the Intervention Based on it, and the Effect of the Intervention in Self-Management, lifestyle and Psychological Capitals on these Patients

Public title

The effect of cognitive-behavioral intervention in MS patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of MS by neurologists using MRI Clinical syndrome of the disease for one year Being between the age of 25 and 45 years

Exclusion criteria:

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

N/A

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 Guilan University of Medical Sciences

Street address

Namjoo Street

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2018-06-02, 1397/03/12

Ethics committee reference number

IR.GUMS.REC.1397.087

Health conditions studied

1

Description of health condition studied

MS patients

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Participants score in the Walker Health Promoting Lifestyle Profile

Timepoint

Pre-test before intervention, post-test after intervention and follow-up test after two months

Method of measurement

Health-Promoting Lifestyle Profile, Multiple Sclerosis Self-Management Scale-Revised, and Psychological Capital Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Does not receive any intervention.

Category

N/A

2

Description

Intervention group: cognitive behavioral intervention is taught for 8 sessions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Clinical Research Development Unit

Full name of responsible person

Ali Ashraf

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Isfahan
Full name of responsible person
Mehrdad Kalantari
Street address
Azadi Sq
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Isfahan
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8174673441
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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
University of Isfahan
Proportion provided by this source
20
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
University of Isfahan
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Sajjad Saadat
Position
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Person responsible for updating data

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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

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available