

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Designing, implementation and evaluation of an intervention based on PRECEDE-PROCEED model to promote quality of life in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effectiveness of an intervention program designed to reduce stress and improve the quality of life of patients with multiple sclerosis

Design

This study is a quasi-experimental intervention. The study population will include all patients with multiple sclerosis who referred to the MS Society of Isfahan. The final sample size was estimated to be 83 people in each group and a total of 166 people.

Settings and conduct

Patients with multiple sclerosis referred to Isfahan MS Association

Participants/Inclusion and exclusion criteria

Patients with multiple sclerosis who their disease have been confirmed by a neurologist, to have no chronic disease other than multiple sclerosis, patients who their disease have been diagnosed for at least one year and have informed and voluntary consent. 139/5000 If the patient is unable to cooperate due to the severity of the disease or other reasons and the person's unwillingness to participate in the research are criteria for exclusion from the research.

Intervention groups

Educational intervention aimed at reducing stress among patients with multiple sclerosis

Main outcome variables

quality of life, stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200720048142N1**

Registration date: **2020-07-22, 1399/05/01**

Registration timing: **prospective**

Last update: **2020-07-22, 1399/05/01**

Update count: **0**

Registration date

2020-07-22, 1399/05/01

Registrant information

Name

Atefeh Homayooni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4269 7271

Email address

atefeh_0913@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, implementation and evaluation of an intervention based on PRECEDE-PROCEED model to promote quality of life in patients with multiple sclerosis

Public title

Designing, implementation and evaluation of an intervention based on PRECEDE-PROCEED model to promote quality of life in patients with multiple sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with multiple sclerosis who their disease is confirmed by a neurologist. Do not have a chronic illness other than multiple sclerosis. At least one year has passed since their disease diagnosis Conscious and voluntary satisfaction

Exclusion criteria:

unwillingness to participate in the research If the patient is unable to cooperate due to the severity of the disease or other reasons

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 166

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

15 KHORDAD NORTH

City

Najafabad

Province

Isfahan

Postal code

8513716181

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.HUMS.REC.1399.065

Health conditions studied

1

Description of health condition studied

MULTIPLE SCLEROSIS

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effectiveness of educational intervention on stress reduction among patients with multiple sclerosis

Timepoint

Measurement of stress at the beginning of the study (before the start of the intervention) and 3 months after the end of the educational intervention

Method of measurement

inventory

Secondary outcomes

1

Description

quality of life

Timepoint

Before the intervention and 3 months after the end of the educational intervention

Method of measurement

inventory

Intervention groups

1

Description

Intervention group:

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

isfahan ms institute

Full name of responsible person

sedighe abedini

Street address

.....

City

bandarabbass

Province

Hormozgan

Postal code

.....

Phone
+98 31 4269 7271
Fax
+98 31 4269 7271
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Street address
.....
City
bandarabbass
Province
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Postal code
.....
Phone
+98 76 3333 8788
Email
sabedini45@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
teamur aghamolaei
Street address
.....
City
bandarabbass
Province
Hormozgan
Postal code
.....
Phone
+98 76 3333 7192
Fax
+98 76 3333 7192
Email
teaghamolaei@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
sedighe abedini
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
sedighe abedini
Position
associate professor
Latest degree
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Other areas of specialty/work
Health Promotion
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Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
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Position
associate professor
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Phone

.....

Email

sabedini45@yahoo.com

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

Not applicable

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