Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 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
Isfehan
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
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
Street address
.....
City
bandarabbass
Province
Hormozgan
Postal code
.....
Phone
+98 76 3333 8788
Email
sabedini45@yahoo.com

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
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
.....
City
bandarabbass
Province
Hormozgan
Postal code
.....
Phone
+98 76 3333 8788
Email
sabedini45@yahoo.com

Person responsible for updating data

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
Street address
.....
City
bandarabbass
Province
Hormozgan
Postal code
.....
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