Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of family-centered empowerment model on the health literacy of care givers and behavior of patients with multiple sclerosis

Protocol summary

Study aim
The determining the effect of family-centered empowerment model on the health literacy of care givers and behavior of patients with multiple sclerosis in Bojnord

Design
70 caregivers of MS patients were randomly assigned to parallel intervention and control groups and participants are given a code. The intervention is conducted in 5 sessions of 90 minutes for the intervention group.

Settings and conduct
Place of intervention is the North Khorasan MS Society. The intervention group is trained based on a family-centered empowerment model and the control group does not receive any training and they are evaluated with a questionnaire after three months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: living with the patient; and day-care responsibilities of the patient Exclusion criteria: having a history of diseases (such as mental disorders; cognitive impairment; history of drug addiction and other neurological disorders), refusal to continue participating in the study.

Intervention groups
70 patients and carers were randomly divided into two groups (n = 35). The intervention group is empowered and the control group does not receive any training.

Main outcome variables
Health Literacy, Behavior

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160917029843N4**
Registration date: **2018-03-09, 1396/12/18**
Registration timing: **retrospective**
Last update: **2018-03-09, 1396/12/18**
Update count: **0**

Registration date
2018-03-09, 1396/12/18

Registrant information

Name
Mohammad Vahedian-Shahroodi

Name of organization / entity
Social Determinants of Health Research Center, Mashhad University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 51 3189 2202

Email address
vahedianm@mums.ac.ir

Recruitment status
Recruitment complete

Funding source
Mashhad University of Medical Sciences

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2017-11-22, 1396/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of family-centered empowerment model on the health literacy of care givers and behavior of patients with multiple sclerosis

Public title
Empowering people with MS family-based approach - central

Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Living with the patient Have desire and cooperation to participate in the research Responsibility for daily care of the patient
Exclusion criteria:
Unwillingness to continue cooperation
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a random number table
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 Mashhad University of Medical Sciences
Street address
University 18 Ave., School of Public Health
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2017-07-01, 1396/04/10
Ethics committee reference number
IR.MUMS.REC.1396.107

Health conditions studied

1

Description of health condition studied
MS patient behavior
ICD-10 code
G35
ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
Health Literacy of care givers
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Health Literacy Questionnaire TOFHLA

2

Description
MS patient behavior
Timepoint
self made questionnaire on the behavior of a patient with MS
Method of measurement
Before intervention, immediately after intervention, 2 months after intervention

Secondary outcomes

1

Description
Self Efficacy
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Questionnaire

2

Description
Self Esteem
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Questionnaire

3

Description
Knowledge about MS
Timepoint
Before intervention, immediately after intervention, 2 months after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
The intervention group, which includes 35 caregivers of MS patients, receives educational intervention. Training intervention consists of 5 sessions of 90 minutes and training is based on the dimensions of the family-centered empowerment model (knowledge, self-esteem and self-esteem).
Category
Behavior

2

Description
Control group: included 35 caregivers of MS patients and there is no intervention on the control group
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
North Khorasan MS Society
Full name of responsible person
یاسمن جعفری
Street address
Plaque 131,Before the City Park, East Taleghani Avenue
City
Bojnourd
Province
North Khorasan
Postal code
9415645745
Phone
+98 58 3241 8507
Email
vahedianm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Daneshgah St18– Mashhad – Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 3007
Email
vahedianm@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohammad Vahedian Shahroodi
Position
Assistant Professor of Health Education and Health Promotion
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
University 18 Ave., School of Public Health
City
Mashhad
Province
Razavi Khorasan
Postal code
9137673119
Phone
+98 51 3854 4833
Fax
+98 51 3852 2775
Email
vahedianm@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohammad Vahedian Shahroodi
Position

Assistant Professor of Health Education and Health Promotion

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

Street address
University 18 Ave., School of Public Health

City
Mashhad

Province
Razavi Khorasan

Postal code
9137673119

Phone
+98 51 3854 4833

Fax

Email
vahedianm@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohammad Vahedian Shahroodi

Position
Assistant Professor of Health Education and Health Promotion

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

Street address
University 18 Ave., School of Public Health

City
Mashhad

Province
Razavi Khorasan

Postal code
9137673119

Phone
+385 44633

Fax

Email
vahedianm@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Title and more details about the data/document
Potential data can be shared only after identification.

When the data will become available and for how long
Get started one month after the results are published.

To whom data/document is available
Researchers working in academia and academic

Under which criteria data/document could be used
The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

From where data/document is obtainable
Dr. Mohammad Vahedian-Shahroodi
vahedianm@mums.ac.ir

What processes are involved for a request to access data/document
The data are sent by official request through academic or organizational emails of the researchers after confirmation and identification of the sender.

Comments