

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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+98 58 3241 8507

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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

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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

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

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Person responsible for scientific inquiries

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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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Vahedian Shahroodi

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