

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of education and telephone follow up on Family Caregivers burden of Patients with multiple sclerosis referred to the Hamadans MS association in 2019

Protocol summary

Study aim

The purpose of this study is to empower caregivers to access health goals. And determination of the effect of education and follow up on the caring burden of the family of MS patients in Hamedan in 1398.

Design

Clinical trial with control and intermediate group, with parallel group, blind, randomized

Settings and conduct

Hamadans MS association. The participants were blind.

Participants/Inclusion and exclusion criteria

The criteria for entry for caregivers include: having satisfaction for participation in the study, at least elementary education, age from 18 to 55 years, direct responsibility for patient care and lack of mental illness diagnosed and treated, with a score of 21-88 in the patient's care.

Intervention groups

Before intervention, demographic and zarit questionnaires will be completed by the family carers of MS patients, and the EDSS scale will be determined in both groups. After completing the control group sampling, in the intervention group, caregivers of MS patients are trained at the center of the Hamadan MS Society during three sessions of one hour during the two weeks. Tutorials will be delivered as lectures, consultations, questions and answers, and group discussions. In the control group, they will receive the routine training of the MS Society and two months after the start of the study, again, the questionnaires will be completed from both groups.

Main outcome variables

Caregivers burden

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20170130032303N6**

Registration date: **2019-12-28, 1398/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-28, 1398/10/07**

Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

Morteza Shamsizadeh

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0535

Email address

shamsizadeh@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-22, 1398/04/31

Expected recruitment end date

2020-03-14, 1398/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education and telephone follow up on Family Caregivers burden of Patients with multiple sclerosis referred to the Hamadans MS association in 2019

Public title

The effect of education and telephone follow up on Family Caregivers burden of Patients with multiple sclerosis

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having satisfaction for participating in the study in caregivers Caregivers have at least elementary education Caregiver take direct care of the patient Has a caregiver burden rating of 21 to 88 Age between 18 and 55 years old Satisfaction of patients to participate in the study

Exclusion criteria:

Hospitalization Death of the patient Lack of family cooperation

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **94**

More than 1 sample in each individual

Number of samples in each individual: **47**

Minimum required sample size with 5% error and 90% power, 47 persons per group (intervention or control).

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical

Sciences

Street address

ShahidFahmid Ave., Paguhesh Square., Hamedan Town.

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Province

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65178

Approval date

2019-05-17, 1398/02/27

Ethics committee reference number

IR.UMSHA.REC.1398.149

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35-G37. D

ICD-10 code description

G35,G37. Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

care giver burden score21to88

Timepoint

Measure the care burden before and after training

Method of measurement

Zarit's Cargiven burden Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" They will be trained by a nurse who is aware of the patients medical condition. Patients will then be followed up by telephone two months after discharge.

Category

Lifestyle

2

Description

Control group: In the control group, routine care has been taken and there is no intervention. Before and after the study, patients with caregiver burden questionnaire will be examined.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Special Issues of Hazrat Ghaem - Association for the Protection of Patients MS Mehr.

Full name of responsible person

Mehrdokht Mazdeh

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Morteza Shamsizadeh

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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