

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Clinical trial of the effect of home care of people with multiple sclerosis on burden and quality of life of family caregivers at 2019.

Protocol summary

Study aim

The purpose of this study will be investigate the effect of home care of patients with multiple sclerosis on the burden of care and quality of life of their family caregivers.

Design

A randomized clinical trial with parallel group included control and intervention groups. The sample size for each group was calculated as 32 persons.

Settings and conduct

64 caregivers of patients with multiple sclerosis in Isfahan Welfare Organization at 2019 will be randomly divided into two groups: intervention (home care) and control (care received by family care givers).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 18 to 65 years, no drug addiction and psychoactive drug and the home care plan has not been implemented for the patient and his or her family. Exclusion criteria: Not willing to cooperate at any stage of research and The patient's or family caregiver's death during studying..

Intervention groups

Intervention group: In the intervention group, the researcher will provide home care to patients and their family caregivers by going to home of multiple sclerosis patients for 8 two-hour sessions. It also provides caregivers with an instruction booklet about home care of patients with multiple sclerosis. Control group: The control group will receive only care by family caregivers, after the intervention, they will receive an Instruction booklet and the researcher will provide them with 3 home care sessions

Main outcome variables

Primary outcome of this study included: quality of life; family care givers burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190712044181N1**
Registration date: **2019-08-07, 1398/05/16**
Registration timing: **prospective**

Last update: **2019-08-07, 1398/05/16**

Update count: **0**

Registration date

2019-08-07, 1398/05/16

Registrant information

Name

shahla Abolhassani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7548

Email address

abolhasani@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of home care of people with multiple sclerosis on burden and quality of life of family caregivers at 2019.

Public title

The effect of home care of people with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 18 to 65 years No drug addiction and psychoactive drug The home care plan has not been implemented for the patient and his or her family Not be health care personnel Ability to read and write

Exclusion criteria:

Unwillingness to cooperate at each stage of the research The patient's or family caregiver's death during studying

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

First, 64 subjects will be selected by systematic random sampling and then divided into two groups of intervention and control through Even and Odd Numbers.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jereb Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.067

Health conditions studied**1****Description of health condition studied**

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Quality of life score of health-related quality of life in multiple sclerosis

Timepoint

At baseline, immediately after the intervention and one month after the intervention

Method of measurement

Health-related quality of life in multiple sclerosis questionnaire

2**Description**

Burden score of Zarit burden scale

Timepoint

At baseline, immediately after the intervention and one month after the intervention

Method of measurement

Zarit burden scale

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: The control group will receive only care by family caregivers, after the intervention, they will receive an Instruction booklet and the researcher will provide them with 3 home care sessions

Category

Lifestyle

2**Description**

Intervention group: In the intervention group, the researcher will provide home care to patients and their family caregivers by going to home of multiple sclerosis patients for 8 two-hour sessions. It also provides caregivers with an instruction booklet about home care of patients with multiple sclerosis

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Welfare organization in Isfahan province

Full name of responsible person

Marziyeh Farshad

Street address

Isfahan Welfare Organization, Panzdah-e Khordad Street, Apadana intersection, Isfahan

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pasokhgoo@irimlsa.ir

Web page address

https://pm.mcls.gov.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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research@mui.ac.ir

Web page address

https://research.mui.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shahla Abolhassani

Position

Assistant Professor of Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data

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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

Other

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable