Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Isfehan
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
City
Isfahan
Province
Isfehan
Postal code
816637316
Phone
+98 31 6411 3919
Email
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
Street address
Isfahan University of Medical Sciences, Hezar Jereb Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
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
Street address
Isfahan University of Medical Sciences, Hezar Jereb Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 37927500
Email
abolhasani@nm.mui.ac.ir
Web page address
https://nm.mui.ac.ir/

Person responsible for scientific 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
Street address
Isfahan University of Medical Sciences, Hezar Jereb Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone

+98 37927500

Email

abolhasani@nm.mui.ac.ir

Web page address

https://nm.mui.ac.ir/

Person responsible for updating data

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

Street address

Isfahan University of Medical Sciences, Hezar Jereb Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 37927500

Email

abolhasani@nm.mui.ac.ir

Web page address

https://nm.mui.ac.ir/

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