

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the Effect of A Group Compassion-based Program on Social Isolation and Depression of Family Caregivers of Patients with Multiple Sclerosis

Protocol summary

Study aim

Determining the effect of a group compassion-based program on social isolation and depression of family caregivers of patients with multiple sclerosis referring to selected centers of Isfahan University of medical sciences in 2023

Design

Two parallel groups randomized clinical trial, with a control group, on 60 family caregivers of patients with Multiple Sclerosis. The sample units will be randomly assigned into two equal groups.

Settings and conduct

Participants of intervention group will be enrolled in weekly sessions in classrooms of Al-Zahra and Kashani hospitals.

Participants/Inclusion and exclusion criteria

Inclusion criteria for caregivers: Age between 18 and 70 years Minimum level of literacy needed for reading and writing Consent to participate in study If the patient has more than one caregiver, the caregiver who spends more time with the patient The physical ability to participate in class sessions for at least two hours The mental capacity to participate in the educational program without a self-reported learning or memory disorder No history of depression or any other disease affecting social interactions Caregiver of only a single person Exclusion criteria for caregivers: Unwillingness to continue to participate Absence in class sessions for more than two sessions Diagnosis of depression or any other disease affecting social interactions during the study Inclusion criteria for patients: Expanded disability status scale ranging from 2 to 9.5 No history of other chronic diseases Diagnosed with Multiple Sclerosis for at least six months Exclusion criteria for patients: Patients' death or relapse of symptoms Unwillingness to continue to cooperate

Intervention groups

Intervention group: six weekly in-person sessions of CFT-based educational program Control group: no intervention

Main outcome variables

Depression score in BDI-II Social isolation score in UCLA loneliness scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059233N1**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **prospective**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

Fatemeh Nabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2024-01-20, 1402/10/30 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty Scientific title Investigating the Effect of A Group Compassion-based Program on Social Isolation and Depression of Family Caregivers of Patients with Multiple Sclerosis Public title Study of Effects of Group CFT on Social Isolation and Depression in Patients with Multiple Sclerosis Purpose Education/Guidance Inclusion/Exclusion criteria Inclusion criteria: A minimum age of 18 and maximum age of 70 years old for the caregivers Minimum level of literacy needed for reading and writing for the caregivers Caregivers' consent to participate in study If the patient has more than one caregiver, the caregiver who spends more time with the patient than others The physical ability of caregivers to participate in the in-person educational program for at least two hours The mental capacity of caregivers to participate in the educational program without a self-reported learning or memory disorder Expanded disability status scale ranging from 2 to 9.5 for patients Diagnosed with Multiple Sclerosis for at least six months Exclusion criteria: Self-reported history of depression or any other disease affecting social interactions for caregivers Being the caregiver of more than a single person for caregivers History of other chronic diseases for patients Age From 18 years old to 70 years old Gender Both Phase N/A Groups that have been masked No information Sample size Target sample size: 60 Randomization (investigator's opinion) Randomized Randomization description Using the online method of randomization, participants will be randomly assigned into intervention or control groups by the online random number calculator of the GraphPad® website; the procedure consists of the assignment of a random number - from 1 to 60 - to each participant, and then the online calculator will assign the numbers into two equal groups. 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 Research Ethics Committees of Nursing, Rehabilitation and Management schools- Isfahan University of Street address Hezar Jarib Ave., Isfahan City City Isfahan Province Isfahan Postal code 8174673461 Approval date 2023-10-28, 1402/08/06 Ethics committee reference number IR.MUI.NUREMA.REC.1402.128 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 Depression Timepoint Before intervention, immediately after the intervention, and two months after the intervention Method of measurement Beck Depression Inventory II 2 Description Social isolation Timepoint Before intervention, immediately after the intervention, and two months after the intervention Method of measurement
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Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention is an in-person educational program of six 120-minutes sessions based on Gilbert's CFT protocol. The participants of intervention group will be divided into three equal groups of ten participants, with each group receiving six in-person 120-minutes group CFT sessions weekly held in the classrooms of selected centers. The first session consists of preliminary communication with and introduction to caregivers, a review of educational program, and introduction to general principles of compassion. Second session teaches mindfulness, breathworks, and body scan basics, ending with a scheduled exercise for next week for participants. The third session introduces the participants to the attributes of a compassionate person. The fourth session focuses on the compassion skills (including compassionate reasoning, attention, feeling, sensations, imagery, and behavior). The fifth session teaches participants the readiness and acceptance of future events. The sixth (and final) session teaches how to write compassionate letters and concludes with a review of previous sections. The certified researcher will be the holder of all sessions under the supervision of the advisor of the study. The content of each session will be presented through face-to-face education using PowerPoint slides and educational pamphlets designed by the researcher. At the end of each session, the participants will receive at-home exercises. The researcher will observe the practice of exercises by caregivers at the same session. The repeated practice will be encouraged, and the caregivers will be asked to verbally report about their practices in the next session. The caregivers will be given the phone number of the researcher in case of any question or issue.

Category

Treatment - Other

2

Description

Control group: The control group will receive no intervention. In accordance to ethical and professional principles if the effectiveness of the educational program is confirmed, the control group will have access to the recorded educational content.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mehrdad Noroozi

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Hojatollah Yousefi

Position

Professor

Latest degree

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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