Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Impact of Self-Compassion education on the Family Caregiver reaction of older adults with chronic disease

Protocol summary

Study aim

Primary Objective: To evaluate the effect of self-compassion training on the reactions of family caregivers of elderly individuals with chronic diseases.

Design

Randomized, parallel-group, single-blind clinical trial with 70 family caregivers of elderly individuals with chronic diseases. Participants will be randomly assigned to intervention (self-compassion training) or control (usual care) groups. Randomization will be performed using block randomization with concealed allocation. The study will be conducted at a single urban health center.

Settings and conduct

The trial will be conducted at a single urban health center. Family caregivers will be randomly assigned to intervention (self-compassion training) or control (usual care). The study is single-blind, with outcome assessors and data analysts blinded.

Participants/Inclusion and exclusion criteria

Family caregivers of elderly with electronic health records. Providing ≥20.5 hours/week of care for at least 3 months. Age ≥18 years. Ability to speak Persian and use a smartphone with internet. No prior self-compassion training or psychological disorders. Unwillingness to continue participation. Missing more than one session. Severe illness, family crises, or death of the elderly during the study.

Intervention groups

Intervention: Eight 45-min self-compassion sessions including mindfulness and emotional regulation. Control: Usual care, no intervention.

Main outcome variables

Caregiver reactions; positive reactions; negative reactions; changes in reaction scores before and after intervention; comparison between intervention and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251031067832N1**
Registration date: **2026-04-24, 1405/02/04**
Registration timing: **retrospective**

Last update: **2026-04-24, 1405/02/04**
Update count: **0**

Registration date

2026-04-24, 1405/02/04

Registrant information

Name

Ahmadreza Khosravifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4239 5820

Email address

ahmadkhosravi191@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-21, 1404/09/30

Expected recruitment end date

2026-02-19, 1404/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Impact of Self-Compassion education on the Family Caregiver reaction of older adults with chronic disease

Public title
Investigating the Impact of Self-Compassion education on the Family Caregiver reaction of older adults with chronic disease
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Seniors with electronic records Continuous care of the elderly with chronic illness for at least 20.5 hours per week for 3 months Age over 18 years Family caregivers include spouse, children, friends, and relatives Access to a smartphone and the ability to operate it and access the internet Ability to speak Persian
Exclusion criteria:
Having a history of participating in self-compassion training classes Having psychological disorders based on caregivers' self-reports Cognitive diseases in elderly people under care
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a randomized controlled trial aiming to evaluate the effect of self-compassion training on the reactions of family caregivers of elderly people with chronic diseases. Seventy eligible caregivers from one urban comprehensive health center will be selected. Participants will be randomly assigned to intervention and control groups using block randomization with a block size of four. The random sequence will be generated by Random Allocation Software, and allocation concealment will be ensured using opaque, sealed, and sequentially numbered envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be conducted as a single-blind randomized controlled trial. Due to the nature of the educational intervention, it is not possible to blind the participants or the intervention facilitator. However, to minimize assessment bias, the data collector and statistical analyst will be blinded to group allocation. Participants will be instructed not to disclose their group assignment to the assessor. The coding of data will be done by an independent researcher, and only after the completion of data analysis will the groups be revealed. This approach ensures partial blinding and reduces the risk of subjective bias in data evaluation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Nursing and Midwifery and Faculty of Rehabilitation - Tehran University of Medical Scienc
Street address
No. 1470 , Opposite 16th Street (Farshi Moghaddam) , North Kargar Street , Tehran
City
Tehran
Province
Tehran
Postal code
1439957181
Approval date
2025-11-01, 1404/08/10
Ethics committee reference number
IR.TUMS.FNM.REC.1404.157

Health conditions studied

1

Description of health condition studied
The studied condition is family caregiver stress and burden resulting from caring for older adults with chronic disease. It refers to the emotional, physical, and social strain experienced by family caregivers.
ICD-10 code
Z63.8
ICD-10 code description
Other specified problems related to primary support group

Primary outcomes

1

Description
Primary outcome variable: Caregivers’ reactions score measured by the Caregiver Reaction Assessment (CRA). This variable assesses the emotional, social, and physical responses of family caregivers of elderly individuals with chronic diseases before and after the self-compassion training intervention.
Timepoint
The primary outcome (caregivers’ reactions score) will be

measured before the intervention (baseline), immediately after the completion of the self-compassion training program (8 weeks after the start), and one month after the intervention to assess the sustainability of the effect.

Method of measurement

The primary outcome variable (caregivers' reactions) will be measured using the Caregiver Reaction Assessment (CRA) questionnaire, a validated self-report instrument that evaluates emotional, social, and physical responses of family caregivers of elderly individuals with chronic diseases. The CRA consists of multiple subscales scored on a Likert scale.

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: The intervention group will receive a self-compassion training program. This program consists of 8 45-minute sessions, twice a week, the content of which is designed based on the book The Mindful Self-Compassion Workbook by Germer and Neff. To develop the sessions, exercises such as compassionate statements, kindness meditation, writing practice, and relaxing physical contact practice, which are mentioned in detail at the end of each chapter, are used as the content framework of the sessions. The content of the sessions will include training in skills such as understanding and accepting difficult emotions, mindfulness, reducing self-criticism, cultivating kindness towards oneself and others, emotional empowerment, resilience, and creating self-compassionate motivation in the caregiving process. The training will be provided in person and will be supplemented with an educational booklet and educational videos. Additionally, to enhance learning, supplementary content including motivational and self-compassionate messages, short educational clips, and introductions to relevant resources will be provided to caregivers via social media.

Category

Behavior

2

Description

Control group: The control group receives no intervention and simply continues their usual care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health and Medical Services Centers Affiliated to Tehran University of Medical Sciences

Full name of responsible person

Ahmadreza Khosravifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Raziyeh Massoumi

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Dr. Mirkhani Street (East Nosrat Street) , Tohid Square

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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Ahmadreza Khosravifar
Position
Master's Student
Latest degree
Bachelor
Other areas of specialty/work
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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
Due to confidentiality concerns and ethical considerations, individual participant data will not be shared. The study involves sensitive information from family caregivers of elderly individuals with chronic diseases, and releasing such data may risk breaching participants' privacy despite deidentification.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study protocol, statistical analysis plan, informed consent form (template), analytic codes, and data dictionary will be shared upon reasonable request after study completion. These documents include detailed descriptions of the study design, analysis procedures, ethical considerations, and variable definitions.
When the data will become available and for how long
The documents will be available after publication of the main study results and will remain accessible for at least five years following study completion.
To whom data/document is available
The data and documents will be available to academic researchers and graduate students who submit a formal request and provide justification for their intended use.
Under which criteria data/document could be used
Data and documents can be used only for academic and non-commercial research purposes, with prior approval from the study's principal investigator and ethics committee.
From where data/document is obtainable

The materials can be obtained by contacting the School of Nursing and Midwifery, Tehran University of Medical Sciences, or directly through the principal investigator's official email after approval.

What processes are involved for a request to access data/document

Interested researchers should submit a written request via email to the principal investigator, including the purpose of data use and institutional affiliation. Requests will be reviewed by the research team and approved by the university's ethics committee before data sharing.

Comments