Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of web-based self-compassion training on the caregiving burden and quality of life of family caregivers of cancer patients at the end of life.

Protocol summary

Study aim

To determine the effect of web-based self-compassion training on caregiver burden and quality of life among family caregivers of cancer patients at the end of life.

Design

This is a single-blind clinical trial with a control group and parallel groups. A total of 96 participants (48 per group) will be continuously recruited and then randomly assigned to the intervention or control group using four-person block randomization. Block sequences will be generated using R software.

Settings and conduct

This study will be conducted at three educational-therapeutic centers in Tehran: Firoozgar, Hazrat Rasoul Akram Educational-Research Complex, and Hazrat Fatemeh Hospital. Participants will be continuously recruited from family caregivers of patients with end-stage cancer. After baseline assessments, they will be randomly assigned to intervention or control groups using four-person block randomization generated with R. The intervention group will receive web-based self-compassion training, while the control group will only complete assessments. The study is single-blind, with the data analyst blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 years or older, primary caregiver with at least 6 months of caregiving experience, able to read and write, able to use a smartphone and internet, with no history of psychiatric disorders or psychotropic medication use. Exclusion criteria: Patient death, receiving psychological interventions, completing fewer than 4 of 7 recommended assignments, withdrawal from the study.

Intervention groups

Intervention group completes assessments, then receives 8-session video and podcast training; assessments repeated immediately and 4 weeks post intervention. Control group only completes assessments at the same time points without training.

Main outcome variables

Caregiver burden; Caregivers' quality of life

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20260203068753N1**
Registration date: **2026-02-09, 1404/11/20**
Registration timing: **prospective**

Last update: **2026-02-09, 1404/11/20**
Update count: **0**

Registration date

2026-02-09, 1404/11/20

Registrant information

Name

Anita Pouzesh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-24, 1404/12/05

Expected recruitment end date

2026-04-25, 1405/02/05

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of web-based self-compassion training on the caregiving burden and quality of life of family caregivers of cancer patients at the end of life.

Public title
Web-Based Self-Compassion for Cancer Caregivers
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
- Participants in the study should be of both sexes and aged 18 years or older. - Caregivers (family caregivers) should have at least 6 months or more of direct caregiving experience for a patient with stage III or IV cancer. - They should be the primary caregiver of the cancer patient. - Ability to read and write. - Ability to communicate verbally and to answer the questionnaire questions. - Owning a smartphone in order to use the electronic package. - Having the skills to use a mobile phone. - Having access to stable internet and virtual/online platforms. - Ability to complete assignments after watching the sessions. - No history of psychiatric disorders based on caregivers' self-reported verbal statements. - No use of psychiatric medications based on caregivers' self-reported verbal statements.

Exclusion criteria:
- Death of the cancer patient. - Receiving other psychological interventions. - Failure to complete more than 3 out of the 7 recommended assignments. - Decision to withdraw from the study.

Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the block randomization method with blocks of four, participants will be randomly allocated into the intervention and control groups. The arrangement of the blocks will follow sequences such as ABBA, AABB, BAAB, BABA, BBAA, ABAB, and so on, and participants will be assigned to either the control or intervention group based on allocation A or B. The random block sequences will be generated using R software
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding will be performed in a single-blind manner. Specifically, the statistical consultant responsible for data analysis will be kept blind to the allocation of participants to the study groups (intervention and control). After data collection, the data will be provided to the statistical consultant with coded group labels (using anonymous codes), so that he/she will not be aware of the type of intervention received by each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the School of Nursing and Midwifery, Iran University
Street address
Darvazeh Shemiran, Mojahedin-e Eslam, Shahid Sayad Khodaii St., No. 64, Unit 3
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Postal code
16936823
Approval date
2026-02-02, 1404/11/13
Ethics committee reference number
IR.IUMS.NURSE.REC.1404.021

Health conditions studied

1

Description of health condition studied
Self-Compassion, Caregivers' Quality of Life, Caregiver Burden
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life score in the Caregiver Quality of Life Index–Cancer Scale
Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention

Method of measurement
The Caregiver Quality of Life Index–Cancer Scale : was developed by Weitzner and colleagues in 1997. This scale measures the impact of cancer-related illness on family caregivers in terms of physical, emotional, social, and family functioning. It consists of 35 items across four subscales.

2

Description
Caregiver burden score in the Caregiver Burden Inventory
Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention
Method of measurement
The Caregiver Burden Inventory was developed by Novak and Guest in 1989 to assess caregiver burden. This instrument consists of 24 items organized into five subscales.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In the intervention group, after obtaining informed consent and completing the demographic information questionnaire, the Caregiver Burden Inventory and the Caregiver Quality of Life Index–Cancer Scale were administered. The educational content, prepared in eight sessions in the form of video clips and podcasts, was provided to participants via a link. After fully viewing the content, the instruments were completed again by the intervention group immediately and four weeks after the end of the intervention.
Category
Other

2

Description
Control group: In the control group, after obtaining informed consent and completing the demographic information questionnaire, the Caregiver Burden Inventory and the Caregiver Quality of Life Index–Cancer Scale were administered. This group did not receive the educational content. The instruments were completed again by the control group immediately and four weeks after the end of the intervention. It should be noted that, after completion of the intervention and in order to observe ethical considerations, the educational content was also provided to the control group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
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2

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3

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Sponsors / Funding sources

1

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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
Iran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is 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

Individual Participant Data (IPD): All collected participant data will be shared after de-identification, including demographic, clinical results. Study Protocol: Full protocol including objectives, design, and analysis plan. Statistical Analysis Plan: statistical code and instructions used for analysis. Informed Consent Form: Copies of consent forms used in the study. Clinical Study Report: Complete clinical report of the study outcomes. Data Dictionary: Coding definitions and variable descriptions.

When the data will become available and for how long

Data and study documents will be available starting 6 months after publication of the study results

To whom data/document is available

Access will be granted to qualified researchers affiliated with academic, clinical, or industry institutions.

Under which criteria data/document could be used

Data and documents may be used solely for academic research purposes, including re-analysis and secondary analyses, in accordance with ethical guidelines and data use agreements. Researchers must not attempt to re-identify participants. All analyses should respect participant privacy and follow approved protocols.

From where data/document is obtainable

Requests for data and documents should be submitted to Dr. Zahra Alizadeh. Address: Valiasr (AJ) Street,above Vanak Square,Rashid Yassami Street,Faculty of Nursing and Midwifery, Iran University of Medical Sciences,Tehran, Iran Email: [alizadeh_z10@yahoo.com] | Phone: [+98 9122859047]

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

Submit a formal request including a research proposal and intended analyses. Review by the principal investigator for eligibility. Sign a data use agreement. Receive access to de-identified data and related documents within 4–6 weeks of approval.

Comments

All shared data will be de-identified to protect participant privacy. Users must agree to not attempt re-identification of participants.