Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of careSTEPS intervention on general health, care burden and quality of life of caregivers of cancer patients

Protocol summary

Study aim
The present study was designed to determine the effect of the careSTEPS intervention on general health, caregiving burden, and quality of life of caregivers of cancer patients.

Design
The intervention will be a triple-blind, randomized, controlled trial on 94 caregivers of cancer patients and analyzed using parametric statistical tests.

Settings and conduct
The study will be conducted in the form of 6 training sessions on the topics of (self-care, symptom mediation, communication improvement, problem-solving skills, social support, and stress management) by the researcher at the Darab Health and Treatment Network meeting place for the intervention group.

Participants/Inclusion and exclusion criteria
All primary, informal caregivers of cancer patients referred to the insurance unit of Imam Hassan Mojtaba (AS) Hospital, Darab in 2025-2026

Intervention groups
Questionnaires will be distributed to caregivers in the intervention and control groups, and then the careSTEPS intervention will be implemented through six face-to-face training sessions, the presentation of pamphlets, the formation of a virtual group on the Soroush messenger, and the sending of educational materials for home study to the intervention group. One month after the intervention, the questionnaires will be completed by caregivers of both the control and intervention groups. No specific intervention will be carried out by the researchers for the control group, but after the intervention, if it is effective, due to compliance with the ethical principles of the research, two in-person training sessions will be conducted for caregivers of the control group. Pamphlets and educational content for the virtual group will also be made available to them.

Main outcome variables
Quality of life - burden of care - public health

General information

Reason for update

Acronym
careSTEPS

IRCT registration information
IRCT registration number: **IRCT20250726066640N1**
Registration date: **2025-10-20, 1404/07/28**
Registration timing: **prospective**

Last update: **2025-10-20, 1404/07/28**
Update count: **0**

Registration date
2025-10-20, 1404/07/28

Registrant information
Name
Elahe Khani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 5357 5925
Email address
khanielahe56@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2026-05-05, 1405/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of careSTEPS intervention on general health, care burden and quality of life of caregivers of cancer patients

Public title
Investigating the impact of the careSTEPS intervention on caregivers of cancer patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient caregiver's willingness and consent to participate in this study Being literate Absence of psychological disorders (depression, psychosis, and mania) and mental disorders based on self-report Not participating in a similar study in the past 6 months The person identified by the patient or their companion as the patient's primary caregiver Access to mobile or landline phone Over 18 years old

Exclusion criteria:
Lack of cooperation in completing questionnaires Failure to attend meetings more than 2 times Patient death Discontinuation of treatment for any reason Moving, relocating, and emigrating to another village, city, or country Change or death of primary caregiver Occurrence of mental disorders in the caregiver and referral to a psychiatrist

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
After approving the plan and receiving the code of ethics from the Honorable Vice President of Research, a letter will be received to start sampling at Imam Hassan Mojtaba (AS) Hospital in Darab. The researcher, as an active observer and interventionist, will call a few weeks before the intervention to announce the call, and after the caregivers complete a written consent form, will take the sample and review the inclusion criteria. Simple random sampling will be performed using the Random Number Generator V2 software from the list of caregivers of cancer patients referred to the insurance unit of Imam Hassan Mojtaba (AS) Hospital in Darab who meet the inclusion criteria for the study, and then the caregivers will be divided into two intervention and control groups by simple random allocation using the Random Allocation Software V2 software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participant blinding: Lack of knowledge of how the intervention was implemented Researcher blinding: Distribution of questionnaires by another person who is unaware of how the intervention was implemented Data analyst blinding: Data are recorded with a numerical number and there is no indication of which group they belong to

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee of jahrom university of medical sciences

Street address
Office of the president and deputy of development jahrom universityof medical sciences end of shahid beheshti blvd

City
Jahrom

Province
Fars

Postal code
74148-46199

Approval date
2025-08-19, 1404/05/28

Ethics committee reference number
IR.JUMS.REC.1404.068

Health conditions studied

1

Description of health condition studied
caregivers of patients with various types of cancers

ICD-10 code
C80.1

ICD-10 code description
Malignant (primary) neoplasm, unspecified

Primary outcomes

1

Description
burden of care- general health- quality of life

Timepoint
Before and one month after the intervention

Method of measurement
CHQ-28-Zarit questionnaires - Quality of Life

Questionnaire for Caregivers of Cancer Patients

Secondary outcomes

1

Description
Quality of life
Timepoint
Before and one month after the intervention
Method of measurement
Cancer Caregiver Quality of Life Questionnaire CQOLC7

2

Description
General health
Timepoint
Before and one month after the intervention
Method of measurement
GHQ-28) General Health Self-Report Scale

3

Description
Burden of care
Timepoint
Before and one month after the intervention
Method of measurement
Zarit Caregiver Burden Questionnaire

Intervention groups

1

Description
Intervention group: Conducting 6 in-person training sessions on the topics of self-care, improving communication, managing symptoms, problem-solving skills, and social support.
Category
N/A

2

Description
Control group: For the control group, no specific intervention will be carried out by the researchers, but after the intervention is implemented, if it is effective, due to compliance with research ethics, two in-person training sessions will be held for the caregivers of the control group. Pamphlets and educational content for the virtual group will also be made available to them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hassan Mojtaba (AS) Hospital, Darab
Full name of responsible person
Mohsen Hojat
Street address
Imam hasan mojtaba hospital, ayatollah khamenei blvd, darab, fars province iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Mohsen Hojat
Street address
Office of the president and deputy of development jahrom university of medical sciences, end of shahid beheshti blvd, jahrom, fars province,iran
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Web page address
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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
Jahrom 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
Jahrom University of Medical Sciences

Full name of responsible person
Mohsen Hojat

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
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Position
Associate Professor

Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Statistical data will be published without naming individuals.

When the data will become available and for how long
It depends on the opinion of the advisors and supervisors.

To whom data/document is available
The data from this study will be available to clinicians and researchers alike.

Under which criteria data/document could be used
They will be allowed to use the data according to the laws.

From where data/document is obtainable

After the article is published in journals, it is printed through the journal.

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

First, the request should be sent to the responsible author. After review, the information will be provided by him/her.

Comments