Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of resilience skills training on caregiver burden, resilience and coping strategies in family caregivers of advanced cancer

Protocol summary

Study aim
Investigating the effectiveness of resilience skills training on caregiver burden, resilience and coping strategies in family caregivers of advanced cancer patients

Design
A randomized trial with a control group, with parallel group, double-blind, on 114 cancer patients' caregivers, randomized by random allocation software

Settings and conduct
The participants will be selected from the clinic and chemotherapy centers of teaching hospitals affiliated to university and divided by convenience sampling with random allocation. The intervention group will participate in workshops. The control group do not receive any intervention. Double blinding is used in data collection, groups segmentation, and data analysis.

Participants/Inclusion and exclusion criteria
Inclusion: 1- Having the age of 18 to 65 years 2- Be literate in reading and writing 3- Absence of severe diseases or psychological problems 4- Having at least three months of care of patient with advanced cancer (stage 3 and 4) Exclusion: 1. Absence in training sessions 2. Psychological and physical crises during the study 3- Being a member of health care team 4. Sudden changes in patient's condition

Intervention groups
4 to 5 subgroups of 10-12 patients will be participate in resiliency skills training during 6 consecutive weeks in 6 sessions. The 3-hour sessions will include skills such as self-awareness, problem-solving, anger and stress management, and negative mood coping.

Main outcome variables
Burden of care, resilience and coping strategies

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120916010844N2**
Registration date: **2024-05-23, 1403/03/03**
Registration timing: **prospective**

Last update: **2024-05-23, 1403/03/03**
Update count: **0**

Registration date
2024-05-23, 1403/03/03

Registrant information

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Somayeh Ramezanli
Name of organization / entity
Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-04, 1403/03/15

Expected recruitment end date
2024-09-05, 1403/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of resilience skills training on caregiver burden, resilience and coping strategies in family caregivers of advanced cancer

Public title
Effect of resilience skills on caregiver burden, resilience and coping strategies in family caregivers of cancer patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria: 1- Willingness to participate in the study, 2- Having the age of 18 to 65 years 3- Be literate in reading and writing 4- To be responsible for patient care 5- Absence of severe diseases or psychological problems based on self-report 6- Have at least three months of history of caring of patient with advanced cancer (stage 3 and 4)

Exclusion criteria:
Exclusion criteria 1. Absence in training sessions 2. Psychological crises during the study, such as the death of a close relative or bankruptcy, or a family member with severe or acute physical or mental illnesses 3-Not a member of health care team 4. Sudden changes in the patient's condition, including hospitalization or death.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
The list of names of the research community (family caregivers) is prepared according to the list of patients with active cases in the chemotherapy departments where the study carried out. People are first selected based on a table of random numbers. Then, the family caregivers are allocated in two experimental and control groups using random permutation blocks of 4. The first two participants (caregivers) will be assigned to the experimental group and the next two participants (caregivers) will be assigned to the control group. The list of random blocks is set by the statistical consultant using the software. The list of random blocks prepared by the statistical consultant is placed in sealed envelopes and numbered. After selecting the patient's family caregivers, these envelopes are opened in order to assign people to the groups, and based on the content of the envelope, people are entered into one of the two experimental and control groups. This is done by opening all the envelopes until the end of the study. The sequence of random allocation is done by a statistical consultant and based on statistical software. After the sequence is prepared by the statistical consultant, it is put in the envelope by the research assistant. The sealed envelopes are given to another research assistant, and based on the contents of the envelopes, he puts people in one of the two experimental and control groups. In order to make the study blind, the help of a researcher who is not aware of the division of groups is used in collecting data and completing the questionnaires. Also, the statistician performing the data analysis will be blinded to the groups

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to make the study blind, the help of a researcher who is not aware of the division of groups is used in collecting data and completing the questionnaires. Also, the statistician performing the data analysis will be blinded to the groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Seventh floor, Shiraz University of Medical Sciences and Health Services, Next to Red Crescent Organization, Zand blvd

City
Shiraz

Province
Fars

Postal code
71345-1978

Approval date
2024-01-10, 1402/10/20

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.118

Health conditions studied

1

Description of health condition studied
Cancer disease

ICD-10 code
C00-C97

ICD-10 code description

II Neoplasms

Primary outcomes

1

Description
Caregiver burden
Timepoint
Before, immediately and a month later
Method of measurement
Zarit Burden Interview Scale

Secondary outcomes

1

Description
Resilience
Timepoint
Before, immediately and a month later.
Method of measurement
Connor and Davidson Resilience Scale

2

Description
Coping strategies
Timepoint
Before, immediately and a month later.
Method of measurement
Jalowiec Coping Scale

Intervention groups

1

Description
Intervention group: The resilience training program will be conducted in 4 to 5 groups of 10 to 12 people once a week for six consecutive weeks in the form of lectures, questions and answers, telephone calls to recall and answer questions for caregivers of cancer patients. Then, immediately and one month after the sessions, in order to determine the effectiveness of this intervention, the burden of care, resilience, and coping strategies questionnaires will be completed by the participants.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic and chemotherapy centers affiliated to Jahrom University of Medical Sciences
Full name of responsible person
Camellia Torabizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Seventh floor, Shiraz University of Medical Sciences and Health Services, Zand blvd
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Grant name
Shiraz University of Medical Sciences
Grant code / Reference number
29105
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Camellia Torabizadeh

Position
Professor
Latest degree
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Other areas of specialty/work
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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