Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effectiveness of Stress Management Cognitive-Behavioral Therapy on Caregiver Burden, Psychological Well-being, and Anxiety in Caregivers of Cancer Patients

Protocol summary

Study aim

Determining the effectiveness of cognitive behavioral therapy for stress management on caregiver burden, psychological well-being, and anxiety of caregivers of cancer patients

Design

A randomized controlled clinical trial on 30 caregivers of cancer patients

Settings and conduct

The location of the research sample selection is the Oncology Department of Imam Jafar Sadeq Hospital in Meybod County. Eligible participants will be randomly assigned to two experimental and control groups. The experimental group will undergo cognitive-behavioral stress management therapy intervention, while the control group will not receive any active intervention. Data collection will be carried out through questionnaires in three time phases After the end of the treatment sessions, the questionnaires will be completed again in both groups

Participants/Inclusion and exclusion criteria

Caregivers of cancer patients who have at least one family member with cancer. Be literate. Not receiving individual counseling or medication Having a severe mental illness

Intervention groups

In this study, an intervention including cognitive-behavioral stress management therapy will be used for caregivers of cancer patients. This therapy will be based on the book "Cognitive Behavioral Stress Management Guide" by Anthony (2007) and will consist of 8 sessions, with two 90-minute sessions held each week.

Main outcome variables

Caregiving Burden: A relatively complex and general concept, defined as a negative and unpleasant psychological state experienced by the caregiver as a result of providing care Psychological Well-Being: Psychological well-being can be defined as having a positive attitude towards oneself, constructive interaction with the world around one, and having hope and purpose in life Anxiety: A multifaceted reaction consisting of cognitive, physical, emotional, and behavioral elements.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260106068570N1**
Registration date: **2026-01-31, 1404/11/11**
Registration timing: **prospective**

Last update: **2026-01-31, 1404/11/11**
Update count: **0**

Registration date

2026-01-31, 1404/11/11

Registrant information

Name

Hamidreza Aryanpour

Name of organization / entity

Ardakan University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date
2026-05-20, 1405/02/30
Actual recruitment start date
2026-03-06, 1404/12/15
Actual recruitment end date
2026-05-20, 1405/02/30
Trial completion date
2026-07-21, 1405/04/30

Scientific title
The Effectiveness of Stress Management Cognitive-Behavioral Therapy on Caregiver Burden, Psychological Well-being, and Anxiety in Caregivers of Cancer Patients

Public title
The Effectiveness of Stress Management Cognitive-Behavioral Therapy on Caregiver Burden, Psychological Well-being, and Anxiety in Caregivers of Cancer Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Caregivers of cancer patients who have at least one family member with cancer Be literate in reading and writing Failure to receive individual counseling or medication
Exclusion criteria:
Having a severe mental illness
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Ardakan University Research Ethics Committee/Working Group
Street address
Ardakan - Ayatollah Khatami Boulevard, Ardakan University
City
Ardakan
Province
Yazd
Postal code
8951895491
Approval date
2025-12-07, 1404/09/16
Ethics committee reference number
IR.ARDAKAN.REC.1404.059

Health conditions studied

1

Description of health condition studied
anxiety
ICD-10 code
F 41.1
ICD-10 code description
At least six months with significant tension, worry, and feelings of apprehension, about everyday events and problems.At least one symptom out of the following list of items must be present: palpitations or pounding heart, accelerated heart rate, sweating

Primary outcomes

1

Description
Psychological well-being
Timepoint
Pre-test-post-test-follow-up
Method of measurement
It is the score that subjects obtain in the 18-question questionnaire of Riff. (1989). This questionnaire has six components: self-acceptance, positive relationships with others, autonomy, purposeful living, personal growth, and mastery of the environment.

2

Description
Care burden:
Timepoint
Pre-test-post-test-follow-up
Method of measurement
It is the score that respondents give to the 22-item questions of the Zarit Psychological Burden Questionnaire.

3

Description
anxiety
Timepoint
Pre-test-post-test-follow-up

Method of measurement
It is the score that subjects obtain on the Hospital Anxiety and Depression Scale, which consists of 14 items.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cognitive-behavioral stress management therapy group
Category
Behavior

2

Description
Control group: The control group will be placed on a waiting list and will receive the intervention.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology Department of Imam Jafar Sadeq Hospital of Meybod
Full name of responsible person
Mohammad Reza Shafiei (Oncology Department)
Street address
Salamat Street, Basij Boulevard, Janbaz Square, Meybod, Yazd, Iran
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Emamsadegh-hosp@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardakan University
Full name of responsible person
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info@ardakan.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardakan University
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
Ardakan University
Full name of responsible person
Hamidreza Aryanpour
Position
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Person responsible for updating data

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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Statistical Data-Protocol Complete statistical data of the study and the protocol used will be made available.
When the data will become available and for how long
1 month after results are published
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Researchers can use data and documentation by sending a request via email.
From where data/document is obtainable
To Hamidreza Arianpour's email address: hamidaryanpour@ardakan.ac.ir
What processes are involved for a request to access data/document
Only requests should be sent to Hamidreza Arianpour at the following email address: hamidaryanpour@ardakan.ac.ir
Comments