

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 35 3390 8250

Email address

hamidaryanpour@ardakan.ac.ir

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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8961977138

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Emamsadegh-hosp@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardakan University

Full name of responsible person

Ahmad Fattahi Ardakani

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Ayatollah Khatami Boulevard

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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

عضو هیات علمی

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Hamidreza Aryanpour

Position

Assistance Professor

Latest degree

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Other areas of specialty/work

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