

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the Effectiveness of Emotion Regulation Therapy for Cancer Caregivers (ERT-C) and Cognitive Behavioral Therapy (CBT) on Depression and anxiety symptoms, Emotion Regulation Deficits, Perseverative Negative Thinking

Protocol summary

Study aim

Comparison of effectiveness of Emotion Regulation Therapy for Cancer Caregivers and Cognitive Behavioral Therapy on Depression and Anxiety Symptoms, Emotion Regulation Difficulties, and Perseverative Negative Thinking in these persons

Design

A concealed, randomized, double-blinded controlled clinical trial with a parallel group design of 44 patients.

Settings and conduct

The trial will be conducted on family caregivers of cancer patients. Samples will be collected from the chemotherapy department of Seyed al-Shohda Hospital, Isfahan. The therapist will be unaware of the outcome variables. The person who evaluates the outcome variables will be unaware of the objectives and hypotheses of the study.

Participants/Inclusion and exclusion criteria

Being at least 18 years of age
A self-report of caregiving of a cancer patient with any stage of any type of cancer
No history of hospitalization due to mental disorder
Non-participation in other psychosocial trials
Scoring lower than cutoff criteria on Distress Thermometer measure ($DT < 4$)
Scoring lower than cutoff criteria on the Brief Penn State Worry Questionnaire (< 15)

Intervention groups

The first intervention group receives emotion regulation therapy for cancer caregivers. This treatment includes 8 online group therapy sessions. The second intervention group receives cognitive behavioral therapy. This treatment also includes 8 group therapy sessions and will be provided online.

Main outcome variables

anxiety and depression symptoms; emotion regulation difficulties; perseverative negative thinking

General information

Reason for update

In the outcome variables section, for the "emotion regulation deficits" variable, the "Five-facet mindfulness questionnaire" was removed; And for the "perseverative negative thinking" variable, the "Ruminative Response Scale" was added.

Acronym

ERT-C, CBT

IRCT registration information

IRCT registration number: **IRCT20230102057023N1**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **prospective**

Last update: **2023-02-22, 1401/12/03**

Update count: **1**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Kimia Kasaei nasab

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-03-11, 1401/12/20 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	Not used Assignment Parallel Other design features
Scientific title Comparison of the Effectiveness of Emotion Regulation Therapy for Cancer Caregivers (ERT-C) and Cognitive Behavioral Therapy (CBT) on Depression and anxiety symptoms, Emotion Regulation Deficits, Perseverative Negative Thinking	Secondary Ids empty
Public title Comparison of the Effectiveness of Emotion Regulation Therapy for Cancer Caregivers and Cognitive Behavioral Therapy Purpose Education/Guidance Inclusion/Exclusion criteria Inclusion criteria: Being at least 18 years of age A self-report of caregiving of a cancer patient with any stage of any type of cancer Exclusion criteria: History of hospitalization due to mental disorder Participation in other psychosocial trials Scoring lower than cutoff criteria on the Distress Thermometer measure (DT<4) Scoring lower than cutoff criteria on the Brief Penn State Worry Questionnaire (<15) Age From 18 years old Gender Both Phase N/A Groups that have been masked - Investigator - Outcome assessor - Data analyser	Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Isfahan University of Medical Sciences Street address Hezar Jarib City Isfahan Province Isfahan Postal code 8174673461 Approval date 2022-11-15, 1401/08/24 Ethics committee reference number IR.MUI.MED.REC.1401.296 Health conditions studied <u>1</u> Description of health condition studied Anxiety ICD-10 code Z63.7 ICD-10 code description Other stressful life events affecting family and household
Sample size Target sample size: 44 Randomization (investigator's opinion) Randomized Randomization description The randomization of this study was done by limited randomization method and block randomization type with random block sizes with individual randomization unit and through random allocation software. Opaque sealed envelopes with a random sequence were used to conceal the random allocation. Blinding (investigator's opinion) Double blinded Blinding description In this study, the person providing the treatment is unaware of the outcome variables. The person who evaluates the outcome variables is unaware of the objectives and hypotheses of the study, and the data analyst is unaware of the intervention groups. Placebo	<u>2</u> Description of health condition studied Depression ICD-10 code F32 ICD-10 code description Major depressive disorder, single episode <u>3</u> Description of health condition studied Cancer ICD-10 code Z85.9 ICD-10 code description Personal history of malignant neoplasm, unspecified <u>4</u> Description of health condition studied Caregiving

ICD-10 code

Y93.F

ICD-10 code description

Activities involving caregiving

Primary outcomes**1****Description**

Depression and anxiety Symptoms Score in Hospital Anxiety and Depression Scale

Timepoint

Before intervention, After intervention, 3 months after intervention

Method of measurement

Distress thermometer, and Hospital Anxiety and Depression Scale

2**Description**

Emotion Regulation Deficits score in Difficulties in Emotion Regulation Scale

Timepoint

Before intervention, After intervention, and 3 months after intervention

Method of measurement

Difficulties in Emotion Regulation Scale

3**Description**

Perseverative Negative Thinking score in Penn State Worry Questionnaire and Ruminative Response Scale

Timepoint

Before intervention, After intervention, and 3 months after intervention

Method of measurement

Penn State Worry Questionnaire and Ruminative Response Scale

Secondary outcomes

empty

Intervention groups**1****Description**

First Intervention group: This group receives emotion regulation therapy for cancer caregivers in 8 sessions in a group setting. This treatment includes psychoeducation for a better understanding of emotions and their underlying motivations, training in cue detection and self-monitoring skills, training in identifying reactive responses to emotions, training in self-regulation skills including "orienting and allowing", training in metacognitive skills in emotion regulation. "Courageous and Compassionate reframing", Courage and Compassion meditation training, imaginative

confrontation technique for facing perceived fears and frustrations and practicing conflicting voices.

Category

Behavior

2**Description**

Second Intervention group: This group receives cognitive behavioral therapy in 8 sessions in a group setting. This treatment includes psychoeducation, goal direction and explaining the principles of cognitive behavioral therapy, effective coping training, identifying maladaptive cognitions and ineffective beliefs, challenging and reconstructing maladaptive cognitions, behavioral activation, problem solving, training communication and assertiveness skills.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Seyedoshada Hospital in Isfahan

Full name of responsible person

Dr. Mehran Sharifi Esfahani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Web page address

https://research.mui.ac.ir/fa/dr.askari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Kimia Kasaei nasab

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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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

All participant data can be shared after de-identification.

When the data will become available and for how long

Start of the access period: 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Providing the data is only for a better understanding of the method of this research. Therefore, analysis on the data is not allowed.

From where data/document is obtainable

Kimia Kasaei nasab: kimia.kn@resident.mui.ac.ir , shirin_kasa@yahoo.com Phone: +989113548069 Dr. Reza Bagherian : bagherian@med.mui.ac.ir , Isfahan, Hezar Jarib Street, Isfahan University of Medical

Sciences, Medical School, Department of Health Psychology, Postal Code: 8174673461

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

First, send an email to Mrs. Kesai Nesab, if you do not receive a response from the university email, send a message to the personal email. And otherwise, send a message to Dr. Reza Bagharian's email. We try to respond within a week

Comments