Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of online mindfulness-integrated CBT and acceptance and commitment on psychological symptoms of cancer caregivers with control group

Protocol summary

Study aim

Comparing the effectiveness of online mindfulness-integrated CBT and acceptance and commitment on psychological symptoms of cancer caregivers with control group

Design

A clinical trial with a control group, with parallel groups including two intervention groups and one group without treatment, without blinding, randomized, on 45 patients, random number generator software was used for randomization

Settings and conduct

The current clinical trial was conducted at a university medical center with the available sampling method. The study's objectives were explained to the participants. Invitees will undergo screening for inclusion criteria, and those who meet the criteria will be randomly assigned to one of three groups, each consisting of 15 people. The first group will receive 4 sessions of cognitive behavioral psychotherapy based on mindfulness, the second group will receive 6 sessions of psychotherapy based on acceptance and commitment, and the third group will not receive any treatment. Survey scales will be completed before and after the treatment.

Participants/Inclusion and exclusion criteria

Being caregiver of a cancer patient; Age between 18 and 50 years; At least a diploma education; Ability to use smartphones; Have no neurological disorders

Intervention groups

Cognitive behavioral therapy is based on mindfulness in 4 sessions of 75 minutes once a week, and psychotherapy is based on acceptance and commitment in 6 sessions of 60 minutes.

Main outcome variables

Severity of depressive symptoms; Severity of anxiety symptoms; Severity of stress; The amount of quality of life; Severity of caregiver burdon

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220316054306N5**
Registration date: **2024-09-26, 1403/07/05**
Registration timing: **prospective**

Last update: **2024-09-26, 1403/07/05**
Update count: **0**

Registration date

2024-09-26, 1403/07/05

Registrant information

Name

Shahab Lotfinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

lotfiniashahab@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effectiveness of online mindfulness-integrated CBT and acceptance and commitment on psychological symptoms of cancer caregivers with control group

Public title
Cognitive behavioral therapy and psychotherapy based on acceptance and commitment for caregivers of cancer patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being caregiver of a cancer patient Age between 18 and 50 years At least a diploma education Ability to use smartphones Have no neurological disorders

Exclusion criteria:

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
All the people who entered the study were given a code, then these codes were entered into the Randomly assign online software (https://www.graphpad.com/quickcalcs/randomize1.cfm) and the software randomly assigned each code to a group.

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
Ethics committe of Shahid Beheshti University of Medical Science

Street address
Bldg No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2024-07-21, 1403/04/31

Ethics committee reference number
IR.SBMU.MSP.REC.1403.219

Health conditions studied

1

Description of health condition studied
Caregivers of cancer patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of depressive symptoms

Timepoint
Before and after intervention

Method of measurement
Based on the score obtained in Depression Anxiety Stress Scale

2

Description
Severity of anxiety symptoms

Timepoint
Before and after intervention

Method of measurement
Depression Anxiety Stress Scales

3

Description
Severity of stress

Timepoint
Before and after intervention

Method of measurement
Depression Anxiety Stress Scales

4

Description
The amount of quality of life

Timepoint
Before and after intervention

Method of measurement
Based on the score obtained in the World Health Organization Quality of Life Scale

5

Description
Severity of caregiver burdon
Timepoint
Before and after intervention
Method of measurement
Based on Caregiver Burden Inventory (CBI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cognitive behavioral therapy based on mindfulness will be conducted in 4 sessions of 75 minutes once a week, structured as follows:Session 1: Introduction to MiCBT treatment, explanation of its structure, introduction of three learning methods to clients, identification and adjustment of treatment goals with clients, emphasis on the need for regular practice of exercises and homework, introduction of PMR progressive muscle relaxation, introduction of physical mindfulness, explanation of homework and distribution of worksheets. Session 2: Introduction to breathing mindfulness and its rationale for clients, discussion of obstacles to mindfulness practice, cognitive mindfulness exercises, review of homework and progress, deepening of the experience, explanation of homework, and distribution of worksheets. Session 3: Review homework and progress, explain the physical examination rationale, introduce the four characteristics of bodily sensations, explain the homework, and distribute the worksheets. Session 4: Review of homework and progress, the introduction of silent practice, the introduction of stillness and immobility, measurement of composure and projection, explanation of homework, and distribution of worksheets.
Category
Treatment - Other

2

Description
Intervention group: Psychotherapy based on acceptance and commitment: First session: Establishing communication and introducing the intervention topic. Second session: Exploring and reviewing therapeutic and educational methods, evaluating their effectiveness, and discussing temporary and ineffective methods using parables. Third session: Identifying ineffective strategies and accepting painful personal events without conflict using metaphors. Fourth session: Explaining how to avoid painful experiences and understand the consequences, followed by step-by-step teaching of acceptance. Fifth session: Introducing the three-dimensional behavioral model to illustrate the relationship between behavior/emotions, psychological functions, and observable behavior. Discussing efforts to change behavior based on this model. Sixth session: Explaining the concepts of role and context, introducing the idea of values, creating motivation for change, and fostering commitment to action.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Shahab lotfinia
Street address
Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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1983963113
Phone
+98 21 2243 9770
Email
Intl_office@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahab Lotfinia

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Amir Sam Kianimoghadam

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

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Shahab

Position

دانشجو دکتری

Latest degree

Master

Other areas of specialty/work

Psychology

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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