Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Study of Effectiveness of Mindfulness integrated Cognitive Behavior Therapy on Psychopathology indicators in females with breast cancer: Randomized controlled trial

Protocol summary

Study aim
Determining of Effectiveness of Mindfulness integrated Cognitive Behavior Therapy on Psychopathology indicators in females with breast cancer

Design
A clinical trial with a control group, with parallel, randomized groups, on 30 people , will use the quadratic randomized blocking method for randomization.

Settings and conduct
The sample of this study will be selected from women with breast cancer who refer to Imam Reza Hospital in Kermanshah. To conduct this research, after the approval of the ethics committee of Kermanshah University of Medical Sciences and its registration in the clinical trial system (IRCT), the intervention will be performed in Imam Reza Hospital.

Participants/Inclusion and exclusion criteria
Main inclusion criteria: Breast Cancer disease with diagnosis of a Oncologist. Main exclusion criteria:Severe mental illnesses include schizophrenia, bipolar I, and severe personality disorders.

Intervention groups
15 participants will receive Mindfulness-integrated cognitive-behavioral therapy (experimental group) and 15 participants will receive psycho-education with the book (control group).

Main outcome variables
Depression, anxiety, Stress, sleep quality, Body image, Sexual function, demoralization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160103025817N6**
Registration date: **2022-04-06, 1401/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-06, 1401/01/17**
Update count: **0**

Registration date
2022-04-06, 1401/01/17

Registrant information

Name
Ali Akbar Parvizi Far

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Study of Effectiveness of Mindfulness integrated Cognitive Behavior Therapy on Psychopathology indicators in females with breast cancer: Randomized controlled trial

Public title

The Study of Effectiveness of Mindfulness integrated Cognitive Behavior Therapy on Psychopathology indicators in females with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being in the age group of 30 to 60 years Ability to read and write and participate in treatment sessions More than 6 months have passed since the diagnosis of cancer Having informed consent to participate in research and completing the informed consent form Non-development of chronic physical diseases such as diabetes and thyroid disorders Do not attend psychotherapy sessions for six months before starting treatment Have no other cancers No problems with hearing and vision Non-abuse of drugs Non-development of severe mental illnesses including schizophrenia, bipolar type 1 disorders and severe personality disorders

Exclusion criteria:

Participate in psychotherapy sessions and other support groups at the same time as the research period

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

random quadratic blocking method-The four blocks of intervention (A) and control (B) groups will be defined (AABB, ABAB, ABBA, BBAA, BABA, BAAB) and numbers 1 to 6 will be written on the cards. The cards are then placed in an envelope. Finally, the cards are randomly selected and a random string is created from the sequence of selected cards.

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 committee of Kermanshah University of Medical Sciences

Street address

Kermanshah, Shahid Beheshti Blvd., Building No. 2, University of Medical Sciences

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Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-12-12, 1400/09/21

Ethics committee reference number

IR.KUMS.MED.REC.1400.088

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F33.1

ICD-10 code description

Major depressive disorder, recurrent, moderate

2

Description of health condition studied

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Depression

Timepoint

Before the intervention, after the end of the intervention and two months after the end of the intervention

Method of measurement

DASS Depression Inventory

2

Description

anxiety

Timepoint

Before the intervention, after the end of the intervention and two months after the end of the intervention

Method of measurement

DASS Anxiety Inventory

3

Description

stress

Timepoint

Before the intervention, after the end of the intervention and two months after the end of the intervention

Method of measurement

DASS Stress Inventory

4

Description

sleep quality

Timepoint

Before the intervention, after the end of the intervention and two months after the end of the intervention

Method of measurement

Pittsburgh Sleep Quality Index

5

Description

Sexual function

Timepoint

Before the intervention, after the end of the intervention and two months after the end of the intervention

Method of measurement

Rosen Sexual Function Questionnaire

6

Description

Body image

Timepoint

Before the intervention, after the end of the intervention and two months after the end of the intervention

Method of measurement

Hopwood body image Questionnaire

7

Description

Demoralization

Timepoint

Before the intervention, after the end of the intervention and two months after the end of the intervention

Method of measurement

kissane demoralization Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive-behavioral therapy integrated with mindfulness is a regular therapeutic approach that integrates mindfulness meditation with the basic components of cognitive and behavioral techniques and will be performed individually on the intervention group for 8 sessions of 60 minutes per week (for two months). The Curriculum for MiCBT Sessions include: Session 1-Introductory presentation about the sessions and rules, an overview of MiCBT, the concept and principles of mindfulness,mindful breathing. Session 2 -Mindful breathing (continued), an overview of a few MiCBT concepts (such as situation, sensory perception, evaluation, body sensations and reaction), the internal causes of intrusive thoughts and their extinction, part-by-part body scanning. Session 3 -Part-by-part body scanning (continued), explaining about body sensations , informal practice. Session 4 -Body scanning exercises (continued), introducing some CBT components in MiCBT (like exposure methods), encountering unpleasant sensations using Subjective Units of Distress Scale(SUDS) (a kind of form that is used for exposure to target events)through bipolar exposure (imaginary exposure to unpleasant situations). Session 5- review of SUDS, Body scanning exercises (continued).Session 6 - Body scanning exercises (continued), interpersonal skills,assertiveness and role-playing. Session 7- Introducing the concepts of compassion and empathy,loving-kindness meditation.Session 8- Review and evaluation.

Category

Behavior

2

Description

Control group: The control group will be given psychological training along with a book on breast cancer and will be taught about the course and process of cancer and medication. Training will be individual and in one session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Kermanshah

Full name of responsible person

Dr.Negin Farshchian

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Parastar Blvd, next to the medical school

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. AA. parvizifard

Position
Assistant Professor of Clinical Psychology

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Participants are not yet known.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available