

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

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

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

##### Study aim

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

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

Update count: **0**

##### Registration date

2022-04-06, 1401/01/17

##### Design

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

##### Registrant information

###### Name

Ali Akbar Parvizi Far

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 918 330 8692

###### Email address

aa.parvizif@kums.ac.ir

##### 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.

##### Recruitment status

**Recruitment complete**

##### Funding source

##### 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.

##### 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

##### 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).

##### Scientific title

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

##### 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**

**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

**City**

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

##### **Street address**

Parastar Blvd, next to the medical school

##### **City**

Kermanshah

##### **Province**

Kermanshah

##### **Postal code**

75333 - 67427

##### **Phone**

+98 83 3427 6300

##### **Email**

soleymani.psy@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Reza Khodarahmi

**Street address**

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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

456238887

**Phone**

+98 83 3838 4185

**Email**

rkhodarahmi@kums.ac.ir

**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

**Street address**

Department of Clinical Psychology, School of Medicine, Razi Blvd.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 4617

**Email**

Parvizia@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. A.A parvizifard

**Position**

Assistant Professor of Clinical Psychology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Department of Clinical Psychology, School of Medicine, Zakaria Azi Blvd.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 4617

**Email**

Parvizia@yahoo.com

**Person responsible for updating data****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.

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**Postal code**

6715847141

**Phone**

+98 83 3427 4617

**Email**

Parvizia@yahoo.com

**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