# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 2026

## Comparison of effectiveness of group behavioral activation intervention and Mindfulness-Based Cancer Recovery intervention based on online method on sleep quality, pain perception, anxiety and depression of breast cancer patients

## Protocol summary

**Study aim**
Comparison of the effectiveness of active behavioral group intervention with mindfulness on improving cancer by online method on sleep quality, pain perception, disease, complications of breast cancer

**Design**
A controlled, parallel-group, unblinded, randomized, phase 2 clinical trial on 102 patients. The site https://www.sealedenvelope.com is used for randomization by permutation block method with the explanation that; Each block has 6 members.

**Settings and conduct**
Omid Hospital, online in virtual space Before the start of any intervention program, an explanatory meeting will be held for people with entry conditions and explanations will be given about the intervention, and written consent will be completed by the participants. Then we ask all patients to complete the Beck Depression and Anxiety Questionnaire, the Brief Pain Intensity Questionnaire (BPI) and the Petersburg Sleep Quality Questionnaire (PSQI). Patients who completed all questionnaires will be randomly assigned to 3 groups: control group, online MBCR group (N=30) and online group behavioral activation group (N=30)

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Their age group should be between 20 and 65 years old. Definite diagnosis of breast cancer. Exclusion criteria: Non-cooperation in the treatment process. Diagnosis of psychiatric disorders.

**Intervention groups**
Control group: no online intervention based on mindfulness and online intervention of behavioral activation will be implemented on the control members. Online MBCR Group: Mindfulness-Based Cancer Recovery (MBCR) is an 8-week group training program based on scientifically tested and internationally recognized evidence for cancer patients. Online Group Behavioral Activation Group: Activation Behavioral Therapy

**Main outcome variables**
Sleep quality, pain intensity, anxiety, depression

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230529058323N1**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

**Registration date**
2023-08-30, 1402/06/08

**Registrant information**

**Name**
Hasan Shabani

**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**
2023-08-23, 1402/06/01

**Expected recruitment end date**

2023-10-07, 1402/07/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of effectiveness of group behavioral activation intervention and Mindfulness-Based Cancer Recovery intervention based on online method on sleep quality, pain perception, anxiety and depression of breast cancer patients

**Public title**

Comparison of effectiveness of group behavioral activation intervention and Mindfulness-Based Cancer Recovery intervention

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Their age group is between 20 and 65 years. Definitive diagnosis of breast cancer by an oncologist. Have minimum education to answer the questionnaires. person in the early stages of receiving treatment (early breast cancer without metastasis) smartphone access to the internet

**Exclusion criteria:**

Absence of more than two sessions. Unwillingness of the person to complete the interventions Having previous experience of yoga or meditation exercises in the past few months Under treatment by a psychologist or other psychiatrist Failure to respond to questionnaires Failure to carry out relevant instructions and exercises in meetings

**Age**

From **20 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **102**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block Randomization: Block randomization is performed by first creating blocks of desired size from the target data. These blocks are then randomly shuffled and finally arranged in order, resulting in a randomly block-permuted sequence. Tool Used: The website https://www.sealedenvelope.com was used with the explanation that each block consists of 6 members and the shape of the blocks can be, for example: [ABCABC], [BBAACC], [BCACBA], etc. The codes A, B, and C are randomly assigned to intervention and control groups. The website selects 18 random blocks out of all possible six-member blocks to ensure that all patients are included in the study.

**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 Mashhad University of Medical Sciences

**Street address**

Omid Hospital, alaNadasht Crossroads, Koh Sengi St.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176613775

**Approval date**

2023-01-31, 1401/11/11

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1402.055

## Health conditions studied

### 1

**Description of health condition studied**

breast cancer

**ICD-10 code**

C50

**ICD-10 code description**

Malignant neoplasm of breast

## Primary outcomes

### 1

**Description**

Depression

**Timepoint**

1-before the intervention (week zero) 2-after the intervention (60 days after the evaluation) (initial, 8th week) 3- 30 days after the end of the intervention (12th week)

**Method of measurement**

Beck's depression questionnaire

**2**

**Description**
Pain
**Timepoint**
1-before the intervention (week zero) 2-after the intervention (60 days after the evaluation) (initial, 8th week) 3- 30 days after the end of the intervention (12th week)
**Method of measurement**
Pain Intensity Scale Questionnaire (BPI)

**3**

**Description**
Anxiety
**Timepoint**
1-before the intervention (week zero) 2-after the intervention (60 days after the evaluation) (initial, 8th week) 3- 30 days after the end of the intervention (12th week)
**Method of measurement**
Beck's anxiety questionnaire

## Secondary outcomes

**1**

**Description**
Sleep quality
**Timepoint**
1-before the intervention (week zero) 2-after the intervention (60 days after the evaluation) (initial, 8th week) 3- 30 days after the end of the intervention (12th week)
**Method of measurement**
Pittsburgh Sleep Quality Index

## Intervention groups

**1**

**Description**
The first intervention group: MBCR intervention group: Mindfulness-based cancer recovery (MBCR) is an 8-week training program and a group based on tested and internationally recognized scientific evidence for cancer patients. The program was developed by Dr. Linda Carlson and Dr. Michael Speck at the University of Calgary and has been running as a clinical program for over 20 years.
**Category**
Treatment - Other

**2**

**Description**
The second intervention group: group behavioral activation: the members of the online behavioral activation intervention group will also receive behavioral activation training for 8 sessions of 50 minutes According to from Leahy, Holland & McGinn protocol of Behavioral activation therapy.
**Category**
Treatment - Other

**3**

**Description**
Members of the control group: No online intervention based on mindfulness and online intervention of behavioral activation will be implemented on the control members and they will only receive routine care. The meaning of routine care is the medical treatment required based on the opinion of the attending physician.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Omid Hospital
**Full name of responsible person**
Farshad Sheybani
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
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Khalil Abnous
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abnouskh@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad 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**
Mashhad University of Medical Sciences
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**Position**
Assisstant professor
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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**
Not applicable
**Informed Consent Form**
Yes - There is 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**
The SPSS file contains the information of the questionnaires. The scores of people in the questionnaires can be shared after removing the names of the participants.
**When the data will become available and for how long**

The access period starts 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**

Send an email to the responsible author to receive the SPSS results file

**From where data/document is obtainable**

Responsible Author: Dr Farshad Sheybani Email: sheibanifr@mums.ac.ir

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

The applicant can email the responsible author and receive the result file within 10 days.

**Comments**