Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3842 6082

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shabanih5@mums.ac.ir

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
Street address
Omid Hospital, Alandasht Crossroad, Kohsang, Khorasan Razavi, st, Mashhad, ad,i St,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Khalil Abnous
Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri ۹۴) – Mashhad - Iran
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Email
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
Full name of responsible person
Farshad Sheybani
Position
Assisstant professor
Latest degree
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Other areas of specialty/work
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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