

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effectiveness of mindfulness-based therapy in reducing depression, anxiety and improving sleep in breast cancer patients

Protocol summary

Study aim

Determining the effectiveness of mindfulness-based therapy in reducing depression and anxiety in breast cancer patients

Design

Clinical trial, with parallel groups, without blinding, phase three, randomized, which will be performed on 48 patients randomly.

Settings and conduct

The study population will be women with breast cancer referring to Ayatollah Rouhani Babol educational and therapeutic center. The patients will be randomly divided into intervention and control groups by computer using the random number table method, and the intervention will be performed on them.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients in the 2 and 3 stages of breast cancer, Ability to answer the questionnaire and reading and writing literacy, obtaining the minimum anxiety and depression score based on the Hospital Anxiety and Depression Scale (HADS) Exclusion criteria: Failure to attend more than two sessions out of a total of 8 intervention sessions, using psychoactive drugs to reduce the symptoms of anxiety and depression Disease recurrence or metastasis in other parts of the body during research Cognitive disorders and delirium and dementia Taking other psychiatric drugs or substance dependence.

Intervention groups

Intervention group: Escitalopram (Escitalopram) of Abidi Pharmaceutical Company at the rate of 10 mg daily along with therapeutic intervention based on mindfulness for 8 weeks (1 session per week) Control group: Escitalopram (Escitalopram) of Abidi Pharmaceutical Company, 10 mg daily.

Main outcome variables

Reducing depression, anxiety and improving sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190317043079N3**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

farzan kheirkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3229 1951

Email address

f.kheirkhah@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of mindfulness-based therapy in reducing depression, anxiety and improving sleep in breast cancer patients

Public title

The effect of mindfulness-based therapy in reducing depression, anxiety and improving sleep in breast cancer patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients in the 2 and 3 stages of breast cancer Ability to answer the questionnaire and reading and writing literacy Obtaining the minimum anxiety and depression score based on the Hospital Anxiety and Depression Scale (HADS)

Exclusion criteria:

Failure to attend more than two sessions out of a total of 8 intervention sessions Using psychoactive drugs to reduce the symptoms of anxiety and depression Disease recurrence or metastasis in other parts of the body during research Cognitive disorders and delirium and dementia Taking other psychiatric drugs or substance dependence

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using permutation blocks of size 4 (AABB). In this way, blocks of 4 will consist of random combinations of 2. Patients will be randomly assigned to two groups of 24 using 12 blocks of size 4 and 1:1 ratio. Creating a random sequence in the blocks will be done by a statistician.

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 Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

IR.MUBABOL.REC.1401.084

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**

Psychological problems (depression, anxiety)

Timepoint

Before starting the intervention, after 4 weeks and finally 8 weeks

Method of measurement

Hospital Anxiety and Depression Standard Questionnaire (HADS)

2**Description**

Sleep Quality

Timepoint

Hospital Anxiety and Depression Standard Questionnaire (HADS)

Method of measurement

Petersburg Sleep Questionnaire (PSQI)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Escitalopram (Escitalopram) of Abidi Pharmaceutical Company at the rate of 10 mg daily along with therapeutic intervention based on

mindfulness for 8 weeks (1 session per week)

Category

Treatment - Drugs

2

Description

Control group: Escitalopram (Escitalopram) of Abidi Pharmaceutical Company, 10 mg daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Farzan Kheirkhah

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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f.kheirkhah@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Farzan Kheirkhah

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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

There is still no plan for its publish

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