

# 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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Babol

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Mazandaran

**Postal code**

47176-41367

**Phone**

+98 11 3233 8301

**Email**

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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m.rajabnia@mubabol.ac.ir

**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

**Street address**

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**Contact**

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

Babol University of Medical Sciences

**Full name of responsible person**

Farzan Kheirkhah

**Position**

Professor

**Latest degree**

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**Other areas of specialty/work**

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Ganjafrooz Avenue**City**

Babol

**Province**

Mazandaran

**Postal code**

47176-41367

**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