

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The Effectiveness of Mindfulness Based Cognitive Therapy (MBCT) on the quality of life, depression and plasma level of cortisol in patients with breast cancer and depressed people

#### Protocol summary

Quality of life, Cortisol, Depression

##### Study aim

-The effectiveness of mindfulness-based cognitive therapy on depression, quality of life and serum cortisol levels of people with breast cancer and depressed people

##### Design

Sixty women with breast cancer and depression were selected by sampling method and they were randomly divided into two groups of 15 people of the experimental and control group

##### Settings and conduct

Two experimental and control groups of breast cancer patients and depressed people were referred to Omid Hospital and Andisheh Raftar Clinic Clinic in Mashhad until a certain number was screened.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in research the age range between 18 to 75 Major depressive disorder based on DSM - V Score between 20 to 28 in the second edition of the Beck Depression Scale At least fifth elementary degree Clinical diagnosis of stage 0 to 3 breast cancer based on clinical findings of cytology and physician diagnosis (in the group of people with cancer) Exit criteria : Men with breast cancer(in the group of people with cancer) Metastasis to other organs of the body including liver, kidney and brain (in the group of people with cancer) Spectrum of schizophrenia and other psychotic disorders, bipolar and related disorders Substance Abuse Disorders Taking drugs that affect the psyche and antidepressants History of participating in a mindfulness program at the time of project implementation Common meditation or yoga exercises during the last three months before entering the study

##### Intervention groups

The experimental group held therapy sessions for eight 90-minute sessions per week and the control group did not receive any therapy.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211031052929N1**

Registration date: **2022-01-10, 1400/10/20**

Registration timing: **retrospective**

Last update: **2022-01-10, 1400/10/20**

Update count: **0**

##### Registration date

2022-01-10, 1400/10/20

##### Registrant information

##### Name

Zahra Olyaei

##### Name of organization / entity

Islamic Azad university of Shiraz

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3768 7900

##### Email address

olyaiez@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-11, 1399/10/22

##### Expected recruitment end date

2021-03-15, 1399/12/25

##### Actual recruitment start date

2021-01-11, 1399/10/22

##### Actual recruitment end date

2021-03-15, 1399/12/25

**Trial completion date**  
empty

**Scientific title**  
The Effectiveness of Mindfulness Based Cognitive Therapy (MBCT) on the quality of life, depression and plasma level of cortisol in patients with breast cancer and depressed people

**Public title**  
The Effectiveness of Mindfulness Based Cognitive Therapy on the quality of life, depression and plasma level of cortisol in patients with breast cancer and depressed people

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Satisfaction to participate in research the age range between 18 to 75 Major depressive disorder based on DSM - V Score between 20 to 28 in the second edition of the Beck Depression Scale At least fifth elementary degree Clinical diagnosis of stage 0 to 3 breast cancer based on clinical findings of cytology and physician diagnosis (in the group of people with cancer)  
**Exclusion criteria:**  
Men with breast cancer(in the group of people with cancer) Metastasis to other organs of the body including liver, kidney and brain (in the group of people with cancer) Spectrum of schizophrenia and other psychotic disorders, bipolar and related disorders Substance Abuse Disorders Taking drugs that affect the psyche and antidepressants Common meditation or yoga exercises during the last three months before entering the study History of participating in a mindfulness program at the time of project implementation

**Age**  
From **18 years** old to **75 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**  
Actual sample size reached: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The subjects were divided into experimental and control groups based on simple randomization through a table of random numbers in two separate groups of breast cancer patients and depressed individuals. To use the table of random numbers, first the framework of the statistical community of 30 people in both groups was identified and they were given a two-digit code, respectively. Then the same numbers of digits were selected in the row or column direction. This work continued until 30 items in each group were selected as a sample.

**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**  
Committee on Ethics in Mashhad University of Medical Sciences  
**Street address**  
University of research and technology assistance, second floor , Qoreishi building, Daneshgah ST  
**City**  
mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9138813944

**Approval date**  
2020-09-26, 1399/07/05

**Ethics committee reference number**  
IR.MUMS.REC.1399.447

## Health conditions studied

**1**

**Description of health condition studied**  
Breast Cancer  
**ICD-10 code**  
C50  
**ICD-10 code description**  
Malignant neoplasm of breast

**2**

**Description of health condition studied**  
Depressed People  
**ICD-10 code**  
F32.1  
**ICD-10 code description**  
Major depressive disorder, single episode, moderate

## Primary outcomes

**1**

**Description**  
Depression score in Beck questionnaire (BDI-II)

**Timepoint**  
Before and after intervention

## Method of measurement

Beck depression questionnaire (BDI-II)

## 2

### Description

Quality of life score in the questionnaire SF36

### Timepoint

Before and after intervention

### Method of measurement

SF36 quality of life questionnaire

## 3

### Description

Serum cortisol levels

### Timepoint

Before and after intervention

### Method of measurement

Blood test

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

intervention group: mindfulness-based cognitive therapy : 1- Introduction of the program, structure and goals of the group including familiarity with cancer, depression, familiarity with mindfulness and expression of its logic and presentation of homework for the consolidation of educational materials 2- Education and practice of mindfulness or breathing awareness techniques to increase attention and concentration capacity include 45 minute meditation of body care, ten minutes of breathing along with mindfulness and expressing the logic of each of these techniques, thinking about exercises and accurate sensation of each of them and a three-minute breathing space and expressing its logic 3- Implementation of muscular relaxation technique, practicing conscious movement, keeping thoughts and minds widespread through pursuit of meditative exercises and focusing on conscious breathing and body organs, familiarity with mindfulness (the concept of automatic guide and mind states), familiarity with logic and the goals of this therapy and the practice of mindfulness technique, three-minute breathing 4- 45-minute training and practice, sitting meditation technique and expressing its logic, three-minute breathing exercise and providing simulated exercises for use in times of emotion, understanding negative spontaneous thoughts on depression and cancer, training how the table creates emotional thoughts and training ten-minute breathing along with mindfulness 5- 45-minute body check practicing, training and exercising of discovering reactions to common patterns and applying the potential talents of mindfulness skills to ease the reaction to the present time experiences (control of the wanderer mind), teaching and practicing meditation to

accept and evaluate spontaneous thoughts and identification of common cognitive errors in depression 6-45-minute sitting meditation practicing, reviewing patients' problems during home exercise, emotions and anxieties during exercises, teaching techniques to respond to negative spontaneous thoughts, practicing three-minute body check technique and conscious breathing and making awareness the reactions against depression 7- Performing meditation exercises, practicing three-minute breathing, designing a problem during the exercise and discovering their effects on the body and mind, discussing how best continue to move and order created in the last few weeks, a list of pleasurable symptoms and skillfulness and exercising body check 8- Summation and reviewing the program, receiving feedback from group members, applying lessons for dealing with future creation, closing ceremonies, and post-test implementation

### Category

Behavior

## 2

### Description

Control group: patients in this group received no treatment.

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Omid Hospital of Mashhad

#### Full name of responsible person

Dr. Kazem Anvari

#### Street address

Koohsangi Street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9176613775

#### Phone

+98 51 3842 6082

#### Email

anvarik@mums.ac.ir

## 2

### Recruitment center

#### Name of recruitment center

Andisheh Raftar Clinic

#### Full name of responsible person

Javad Bahador Khan

#### Street address

Sanabad Street

#### City

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9127674749

**Phone**

+98 51 3848 2220

**Email**

bahadorkhan.javad@yahoo.com

**Street address**

5 Km of Sadra City

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۴۷۳۱ - ۷۱۹۸۷

**Phone**

07136410041-44

**Email**

olyaiez@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University of Shiraz Branch

**Full name of responsible person**

Dr. Shahram Hesami

**Street address**

5 km of Sadra City

**City**

Shiraz

**Province**

Fars

**Postal code**

71987-74731

**Phone**

+98 71 3619 1547

**Email**

iaushiraz.research@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

دانشگاه آزاد اسلامی واحد شیراز

**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**

Islamic Azad University of Shiraz

**Full name of responsible person**

Zahra Olyaei

**Position**

Ph.D Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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

Islamic Azad University of Shiraz

**Full name of responsible person**

Zahra Olyaei

**Position**

Ph.D Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

5 km from Sadra City

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۴۷۳۱ - ۷۱۹۸۷

**Phone**

07136410041-44

**Email**

olyaiez@yahoo.com

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

Islamic Azad University of Shiraz

**Full name of responsible person**

Zahra Olyaei

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

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**City**

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**Province**

Fars

**Postal code**

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**Phone**

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**Email**

olyaiez@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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