

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Email address

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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	Not blinded Blinding description Placebo Not used
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	Assignment Parallel Other design features
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	Secondary Ids empty Ethics committees
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	<u>1</u> 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
Age From 18 years old to 75 years old Gender Female Phase N/A Groups that have been masked No information	<u>1</u> Description of health condition studied Breast Cancer ICD-10 code C50 ICD-10 code description Malignant neoplasm of breast
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)	<u>2</u> Description of health condition studied Depressed People ICD-10 code F32.1 ICD-10 code description Major depressive disorder, single episode, moderate Primary outcomes <u>1</u> 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

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Province

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2

Recruitment center

Name of recruitment center

Andisheh Raftar Clinic

Full name of responsible person

Javad Bahador Khan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University of Shiraz Branch
Full name of responsible person
Dr. Shahram Hesami
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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

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Person responsible for updating data

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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