Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effectiveness of Mindfulness-based Cognitive Therapy on Quality of Life and Mood (anxiety and depression) in Women with Breast Cancer undergoing Mastectomy

Protocol summary

Summary

Abstract Introduction: The present research has been carried out to investigate the effectiveness of group mindfulness-based cognitive therapy on quality of life and mood (anxiety and depression) in women with breast cancer undergoing mastectomy. Materials and Methods: This research is a quasi-experimental study (pretest-posttest with control). In this clinical trial, 50 voluntary patients who had undergone mastectomy in 2013 and 2014 were screened among the patients admitted to Omid Hospital and Reza Treatment Center in Mashhad, the Patients initially selected voluntarily and were randomly divided into experimental group (n=25) and control group (n=25). First, both groups were pretested. Then, the experimental group received group MBCT treatments during eight sessions of 120 minutes (one session per week), but the control group received no treatment. At the end of treatment, both groups received the post-test. Data collection tools included standard questionnaires temperament (POMS) and the quality of life questionnaire (SF-36). The main outcomes of present study were quality of life and mood.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017040933315N1**
Registration date: **2017-06-03, 1396/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-03, 1396/03/13

Registrant information

Name

Zahra Olyaie

Name of organization / entity

Science and Research Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

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+98 51 3768 7900

Email address

olyaiez@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-06-19, 1392/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of Mindfulness-based Cognitive Therapy on Quality of Life and Mood (anxiety and depression) in Women with Breast Cancer undergoing Mastectomy

Public title

Mindfulness-based Cognitive Therapy in Women with Breast Cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in research; Iranian nationality; age less than 70; passing at least primary school education. Exclusion criteria: history of chronic diseases; mental disorders; presence of other cancers; using drugs or psychotropic substances during one week before the study; experiencing stressful events during the last 6 months; addiction to drugs

Age
To **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
At first, the patients received a form to fill out if they might want to fill it. Volunteers and purposive samples registered and were selected based on sampling and categorized randomly in two groups of testing and control

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of Mashhad University of Medical Sciences

Street address
Qureshi Building, University Street, Mashhad

City
Mashhad

Postal code
91375 - 345

Approval date
2013-05-22, 1392/03/01

Ethics committee reference number
23420701912010

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
Quality of Life

Timepoint
Befor and After Intervention

Method of measurement
Quality of Life Questionnaire (SF-36)

2

Description
Mood

Timepoint
Befor and After Intervention

Method of measurement
Standard Questionnaires Temperament (POMS)

Secondary outcomes

1

Description
Anxiety

Timepoint
Befor and After Intervention

Method of measurement
Standard Questionnaires Temperament (POMS)

2

Description
Depression

Timepoint
Befor and After Intervention

Method of measurement
Standard Questionnaires Temperament (POMS)

Intervention groups

1

Description
Intervention group: patients in this group received group MBCT (group mindfulness-based cognitive therapy)

during eight 120-minute sessions (one session per week).

Category
Other

2

Description
Control group: patients in this group received no treatment.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid Hospital

Full name of responsible person
Dr Sodabeh Shahid Sales

Street address
Omid Hospital, Koohsangi Avenue, Alandash Square.

City
Mashhad

2

Recruitment center

Name of recruitment center
Reza Treatment Center

Full name of responsible person
Dr Varshoee

Street address
Misaq 19, Misaq Blvd, Vakil abad Blvd.

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for reseach of Neyshabor Islamic Azad University

Full name of responsible person
Dr Ahmad Zendehdel

Street address
Islamic Azad University, Pazhuhesh Street, Neyshbor, Khorasan Razavi

City
Neyshbor

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for reseach of Neyshabor Islamic Azad University

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Reza Treatment Center

Full name of responsible person
Mrs Sabeti

Position
Management Research

Other areas of specialty/work

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Misaq 19, Misaq Blvd, Vakil abad Blvd.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran Science and Research Branch, Islamic Azad University, Tehran, Khorasan Razavi

Full name of responsible person
Zahra Olyaie

Position
MA in Clinical Psychology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Omid Hospital

Full name of responsible person
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Position
Oncology subspecialist, Assistant Professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty