

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of the Effectiveness of Cognitive Therapy Based on Knowledge on Quality of Life in Women with Breast Cancer.

Protocol summary

Summary

Objectives : The aim of this study is to determine the effect of cognitive therapy based on mind-awareness on the quality of life of women with breast cancer. Design and method: In this study, 30 breast cancer patients were randomly divided into control and intervention groups based on entry and exit criteria and after explaining the study and obtaining written consent. Inclusion Criteria: Women with breast cancer in the age-group 18 and older; reading and writing literacy; not being affected by another cancer; not being treated with psychiatric medications. Inclusion criteria: Not attending sessions for more than one session; Using neurological drugs; not being at the relapse of the disease. After obtaining written and verbal consent, they are randomly divided into two intervention and control groups by lot. Both patients are matched in double blocks (one patient in the intervention group and another one in the control group). The questionnaires are available to both groups at the beginning of the study. The intervention-based cognitive therapy based on the mindfulness of consciousness, according to the protocol, is held 8 sessions of 40 minutes and twice a week (only for the intervention group) in the Cancer division The hospital (classroom). After accomplishing the intervention, immediately the post-test of the groups is performed. After one month, the questionnaires will be returned to both groups and the quality of life will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072235227N1**

Registration date: **2017-09-19, 1396/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

Name

Kolsoum Abdollahi Far

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Phone

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2017-06-25, 1396/04/04

Expected recruitment end date

2017-07-26, 1396/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Cognitive Therapy Based on Knowledge on Quality of Life in Women with Breast Cancer.

Public title

The Effect of Mindfulness on the Quality of Life of Women with Breast Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women with breast cancer in the age-group 18 and older who have been diagnosed the disease in their medical records; patients should be able to write, read and answer the questions; they should not have another cancer; they should have completed stages of surgical and chemotherapy treatment; They should not have drug abuse; they should be able to attend group therapy sessions; they should not be treated with psychiatric medications while conducting research.

Exclusion criteria: Being absent from the intervention sessions for more than one time; Using nerve drugs to reduce symptoms of anxiety and depression; Not being at the onset of relapse of the disease.

Age

From **18 years** old to **54 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Postal code

19839-63113

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.SBMU.PHNM.1395.695

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

D24

ICD-10 code description

Benign neoplasm of breast

Primary outcomes

1

Description

Quality of Public Life

Timepoint

Before and Immediately After the Intervention and One Month After The Intervention

Method of measurement

Questionnaire

2

Description

Quality of Private Life

Timepoint

Before and Immediately After the Intervention and One Month After The Intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive awareness-based cognitive therapy for one month (8 sessions)

Category

Behavior

2

Description

Control group: The control group does not receive intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital
Full name of responsible person
kolsoum Abdollahi Far
Street address
End of Keshavarz Blv, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Private
Full name of responsible person
Kolsoum Abdollahi Far
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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
Private
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

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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