

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of mindfulness -integrated cognitive behavior therapy on executive function, cognitive emotion regulation strategies, body image and self-compassion in patients' breast cancer

Protocol summary

Summary

Objective: The aim of this study was to investigate the effect of cognitive behavioral therapy combined with mindfulness in executive function, cognitive emotion regulation, body image and self-compassion in patients breast cancer. Study design: Single-blind randomized clinical trial. Random assignment will be done by the use of computer-generated random numbers. Inclusion criteria: Patients with a diagnosis of breast cancer and aged 20 to 50 years will be included in this study. Exclusion criteria: Unwillingness to cooperate will be excluded in the study. Population and sample size: 40 patients with breast cancer of eligible and referred to hospital doctor Beheshti and Hospital Matini to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected. Intervention: Patients will be divided into two groups guided imagery and control, and both groups received routine medical treatment, but the effectiveness of cognitive behavioral therapy combined with mindfulness on groups imagery will be implemented. At the beginning and end of the intervention: Tower of London, cognitive emotion regulation questionnaire, a scale image and self-compassion in both intervention and control groups will be implemented. Intervention time: 8 weeks. Outcomes: executive functions, cognitive emotion regulation, body image and self-compassion will be quantified at study baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042233571N1**
Registration date: **2017-05-09, 1396/02/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-09, 1396/02/19

Registrant information

Name

Yeghane Karimi

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mindfulness -integrated cognitive behavior therapy on executive function, cognitive emotion regulation strategies, body image and self-compassion in patients' breast cancer

Public title

Effect of mindfulness -integrated cognitive behavior therapy in patients' breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients' breast cancer; aged 20 to 50 years. Exclusion criteria: Unwillingness to cooperate.

Age

From **21 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Postal code**Approval date**

2017-03-07, 1395/12/17

Ethics committee reference number

IR.KAUMS.REC.1395.152

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**

Executive function

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Tower Of London Test

2**Description**

Cognitive emotion regulation

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Cognition Emotion Régulation Questionnaire

Secondary outcomes**1****Description**

Body Image

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Body image questionnaire

2**Description**

Self-compassion

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Self-compassion questionnaire

Intervention groups**1****Description**

Patients participate in mindfulness-integrated cognitive behavior therapy at 2 month for 8 sessions.

Category

Other

2**Description**

Control group do not participate in group therapy.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Beheshti and Matini hospitals

Full name of responsible person

Yeghane Karimi

Street address

Ghotbe Ravandi Boulevard, Kashan

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Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

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Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kashan University of Medical Sciences

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

Kashan University of Medical Sciences

Full name of responsible person

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Position

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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