Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Country

Iran (Islamic Republic of)

Phone

+98 912 630 7904

Email address

karimi-y@kaums.ac.ir

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
City
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
City
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
Yeghane Karimi
Position
MSc of clinical psychologic
Other areas of specialty/work
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Postal code
Phone
+98 21 5554 0021
Fax
Email
kyeganeh68@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Yeghane Karimi
Position
MSc of clinical psychology
Other areas of specialty/work
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Postal code
Phone
+98 21 5546 3378
Fax
Email
kyeganeh@ymail.com; kyeganeh68@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Yeghane Karimi
Position
MSc of clinical psychology
Other areas of specialty/work
Street address
Ghotbe Ravandi Boulevard, Kashan
City
kashan
Postal code
Phone
+98 21 5554 0021
Fax
Email
kyeganeh68@gmail.com
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