Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of mindfulness-based cognitive therapy on post-traumatic growth, self-management and functional disability among patients with breast cancer.

Protocol summary

Summary

The aim of the study is the effectiveness of mindfulness-based cognitive therapy on post-traumatic growth, autonomy and functional disability in patients with breast cancer. Study design: Randomized, two experimental and control groups, single-center. The study population included 30 patients with breast cancer were selected, 15 were randomly assigned to an experimental group that received mindfulness-based cognitive therapy and 15 others are randomly placed in the control group. Inclusion criteria: age between 20 and 45 years, with the diagnosis of breast cancer by cancer specialists, lack of psychiatric disorders such as psychotic disorders and personality disorders, higher education cycle. Exclusion criteria: age younger than 20 and older than 45 years, multiple detection of breast cancer by cancer specialists, medical diagnosis at the same time, having psychotic disorders. Intervention and main outcome measures: Patients were randomly assigned to two experimental and control groups are substituted. During each session, mindfulness-based cognitive therapy is performed for 60 minutes. At its first meeting the required measures are taken to determine the base lines. Mindfulness-based cognitive therapy will be one session per week. The treatment protocol operations are provided. In the third session, fifth and once at the end of treatment and within one month and after a period of two months after the end of treatment, re-measurements are made. In order to comply with ethical principles, first obtaining the patient's informed consent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080825732N7**
Registration date: **2016-09-15, 1395/06/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-15, 1395/06/25

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University, Faculty of Psychology and Educational Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of mindfulness-based cognitive therapy on post-traumatic growth, self-management and

functional disability among patients with breast cancer.

Public title
The effectiveness of mindfulness-based cognitive therapy on post-traumatic growth, self-management and functional disability among patients with breast cancer.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: having age between 20 and 45 years; with the diagnosis of breast cancer by cancer specialist; not having psychiatric disorders such as psychotic disorders and personality disorders; having a higher education cycle. Exclusion criteria: Having a lower age than 20 or older than 45 years; multiple detection of breast cancer by cancer specialists; medical Sickness diagnosis at the same time; having psychotic disorders.
Age
From **20 years** old to **45 years** old
Gender
Both

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)
Not 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, Semnan University
Street address
Semnan University, Damghan 5 km Road, Semnan
City
Semnan
Postal code
3514799442
Approval date
2016-02-07, 1394/11/18
Ethics committee reference number
98/94/1285

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50.9
ICD-10 code description
Breast, unspecified

Primary outcomes

1

Description
Mindfulness-based cognitive therapy
Timepoint
Each week a session
Method of measurement
The proposed protocols - a standard questionnaire

2

Description
Illness severity
Timepoint
During treatment
Method of measurement
Control of confounding variables

Secondary outcomes

1

Description
Self-management evaluation
Timepoint
Before running the norms of the target population
Method of measurement
Activation patient questionnaire

2

Description
Evaluation of functional disability in patients with chronic pain
Timepoint
The questionnaire implemented before the target population of the norm.
Method of measurement
The World Health Organization Disability Assessment Questionnaire

Intervention groups

1

Description
In the control group, no intervention, was performed to compare the two study groups are just.
Category

Behavior

2

Description
The experimental group during each session mindfulness-based cognitive therapy is performed for 60 minutes. At its first meeting the required measures are taken to determine the base lines. Mindfulness-based cognitive therapy will be one session per week. The treatment protocol operations are provided. In the third session, fifth and once at the end of treatment and within one month and after a period of two months after the end of treatment, re-measurements are made.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Haft-e-Tir Hospital

Full name of responsible person
Dr Ehsagh Rahimian

Street address
Shahid Rajaei Street, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University

Full name of responsible person
Eshagh Rahimian

Street address
Semnan University, Damghan 5 km Road, Semnan

City
Semnan

Grant name

Grant code / Reference number

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

Title of funding source
Semnan 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
Semnan University

Full name of responsible person
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Position
Health Psychology

Other areas of specialty/work

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Person responsible for updating data

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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