

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 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

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Name of organization / entity

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Iran (Islamic Republic of)

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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

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

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Semnan University, Damghan 5 km Road, Semnan

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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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Health Psychology

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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