

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Group Acceptance and Commitment Therapy (ACT) on pain related anxiety and Cognitive Emotion Regulation in Breast cancer patients and comparing with control group

Protocol summary

Summary

Objectives: This study is the effects of group acceptance and Commitment therapy on pain related anxiety and cognitive emotion regulation in breast cancer patients and comparing the results to those of control group.

Design: This study is a semi-experimental research based on pre-test and post-test with a control group. Research population consists of all breast cancer patients. From the above-mentioned population, 30 subjects have been selected through available non-random sampling. Setting and conduct: Subjects are divided into two experimental and control groups in a random manner. Then, subjects in the experimental group are being trained for logo therapy in 8 sessions. Subjects in control group will not receive any training.

Major Inclusion and Exclusion criteria: Diagnosis of breast cancer in the subjects, Self awareness from cancer, high education are of criteria for entering into the study. Accompanied diseases (such as other cancer), lack of knowledge regarding the disease and lack of inclination of patients for attending at intervention sessions are of criteria for exiting from the study.

Interventions: Subjects in both experimental and control groups will be initially tested using measuring tools for pain related anxiety and cognitive emotion regulation .Then, subjects in the experimental group are being trained for "acceptance and Commitment therapy" and will be post-tested for the extent of change pain related anxiety and cognitive emotion regulation and compared to those in control group. Main outcome measures: coping strategies, hope and adjustment are elementary consequent variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100615590N5**

Registration date: **2017-10-16, 1396/07/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-16, 1396/07/24

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-03-01, 1396/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Group Acceptance and Commitment Therapy (ACT) on

pain related anxiety and Cognitive Emotion Regulation in Breast cancer patients and comparing with control group

Public title

Acceptance and commitment therapy on cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of breast cancer; Self awareness from cancer; high education in patients

Exclusion criteria: Have other disease (for example: other kind of cancer); Lack of knowledge regarding the disease; lack of inclination of patients for attending at intervention sessions

Age

From **20 years** old to **40 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

Committee for Ethics in biomedical research of Tabriz University of Medical Science

Street address

4th office, First Floor, Ghazi Hospital, Tabriz University of Medical Science, Golghasht Street, Tabriz

City

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Postal code

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

TBZMED.REC.1396.625

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Cognitive emotion regulation

Timepoint

Before treatment and 1 week after

Method of measurement

Cognitive emotion regulation Questionnaire

2

Description

Pain related anxiety

Timepoint

Before treatment and 1 week after

Method of measurement

Pain related anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Experiment group will intervened with acceptance and commitment therapy in 8 sessions. The component of intervention is: Knowing about the breast cancer, coping with stress, Relaxation, having relationship with body, accept pain and suffer.

Category

Behavior

2

Description

Control group do not receipt any treatment program.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology and Oncology Research Center, Tabriz

University of Medical Sciences, Tabriz, Iran

Full name of responsible person

Pari Ghaem

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Person responsible for scientific inquiries

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of
Medical Sciences

Full name of responsible person

Zohreh Sanat

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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

Vice chancellor for research, Tabriz 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

Islamic Azad University Of Ahahr

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Shirin Zeinali

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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