

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Efficacy of group-based Acceptance and Commitment Therapy on Self-differentiation, Emotion dysregulation, Fear of disease progression and mental health in patients with breast cancer

Protocol summary

Study aim

Determine the Effectiveness of ACT Treatment for the Distinction of Patients with Breast Cancer - Determine the Effectiveness of ACT Group Therapy on the Emotion of Patients with Breast Cancer-Determine the Effectiveness of Group Therapy ACT Fear of Progression in Patients with Breast Cancer-Determine the Effectiveness of ACT Therapy on Mental Health of Patients with Breast Cancer.

Design

The trial has intervention and control group. Women with breast cancer who referred to the Toba Clinic who had a history of breast cancer (N = 160), after contact with them, 62 were interviewed and accepted in the classroom, and after a semi-structured interview with a psychiatrist, 45 They did not have a specific problem. They completed the questionnaires. 30 subjects who obtained the necessary scores in the questionnaires and entered the research were selected and randomly divided into two groups of 15 (through codes on each sheet)

Settings and conduct

Women with breast cancer who referred to the Toba in the year 92 and were diagnosed with breast cancer who responded to the call after contact with them. Of these, 62 were interviewed the company, and then From the interview, 45 persons completed the questionnaires. 30 were selected and randomly divided into two groups: intervention and control, with code on the sheet.

Participants/Inclusion and exclusion criteria

Log-in: between 25 and 60 people are under chemotherapy-not attending other courses for at least 6 months. Exit: -Cancer to other cancers -Ability to be present due to cancer -A history of acute mental illness with a psychiatrist's opinion

Intervention groups

ACT is performed in an intervention group of eight 90-

minute sessions

Main outcome variables

Self-differentiation, fear of disease progression, emotional regulation and mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181209041894N1**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **retrospective**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

Registrant information

Name

Maryam Hasanegzad reskati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 0605

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-30, 1396/09/09

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

2017-12-30, 1396/10/09
Actual recruitment end date
2018-06-06, 1397/03/16
Trial completion date
2018-06-06, 1397/03/16

Scientific title
Efficacy of group-based Acceptance and Commitment Therapy on Self-differentiation, Emotion dysregulation, Fear of disease progression and mental health in patients with breast cancer

Public title
Efficacy of group-based Acceptance and Commitment Therapy in patients with breast cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:

- Age between 25 and 60 - People under chemotherapy - Apart from cancer, there is no physical or psychological illness - Absence in other courses at least 6 months

Exclusion criteria:
Having other cancers Inability to attend meetings due to physical illness A history of acute mental illness with a psychiatrist's opinion

Age
From **25 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
After entering the study, patients are randomly assigned to the first and second groups by computer software. Group 1 treatment groups are treated based on acceptance and commitment, and the second group is the control group under which There is no cure

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not used
Assignment

Other
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of sari Islamic Azad University
Street address
Khazar Blvd. sari Islamic Azad University
City
Sari
Province
Mazandaran
Postal code
48164-194
Approval date
2018-11-19, 1397/08/28
Ethics committee reference number
IR.IAU.SARI.REC.1397.020

Health conditions studied

1
Description of health condition studied
Effect of ACT Group Therapy on Patients with Breast Cancer
ICD-10 code
F40-F48
ICD-10 code description
F40-F48

Primary outcomes

1
Description
Percentage of people who have a self-differentiating questionnaire score of under 70
Timepoint
At the beginning of the study (before the intervention), the end of the study, two months later
Method of measurement
Dreik-Mordak self-differentiation questionnaire

2
Description
The percentage of people who score in the difficulty questionnaire in adjusting their excitement of Gertz and Roemer are over 108.
Timepoint
At the beginning of the study (before the intervention), the end of the
Method of measurement
Gritz & Roemer's Thrill Setting Questionnaire

3
Description
Percentage of people whose FOP-Q questionnaire score is above 74
Timepoint
At the beginning of the study (before the intervention), the end of the

Method of measurement

, FOP-Q Questionnaire

4

Description

The percentage of people with a general health questionnaire score of 28 (GHQ-28) is above 42

Timepoint

At the beginning of the study (before the intervention), the end of the

Method of measurement

General Health Questionnaire (GHQ-28)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment based on the acceptance and commitment of the third-generation psychotherapy method, which lasts for eight 90-minute sessions. Duration of the intervention in the intervention group is two months. The content of the sessions is with the training of mind, metaphor and homework. over eight 90-minute sessions

Category

Behavior

2

Description

Control group: A group that has received breast cancer diagnosis and has met criteria for entry. No interventions in psychotherapy and medicine.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Toba Sari Specialist and Specialist Center

Full name of responsible person

Bahram Mirzaian

Street address

Khazar Blvd , Sari Islamic Azad University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Web page address

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Hasannezhad

Position

PhD Student in Educational Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available