

# 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**

maryam.hasanegzad@gmail.com

##### **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

##### City

Sari

##### Province

Mazandaran

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48164-194

##### Phone

+98 11 3444 5761

##### Email

Bahrammirzaian@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Mohamad Farsi

##### Street address

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##### Province

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##### Phone

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##### Fax

##### Email

maryam.hasannegzad@gmail.com

##### 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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Khazar Bluv, Islamic Azad University

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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