# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison of the effectiveness of acceptance and commitment based therapy and Cognitive - behavioral on anxiety , resilience and life expectancy in Breast Cancer patients

## Protocol summary

**Study aim**

1- Determining the effectiveness of acceptance and commitment therapy (ACT) on death anxiety and resilience and life expectancy in breast cancer patients.
2- Determining the effectiveness of cognitive-behavioral therapy (CBT) on death anxiety, resilience and life expectancy in breast cancer patients.

**Design**

A clinical trial with a control group, with parallel groups, randomized on 45 patients, was used for randomization from the table of selected numbers.

**Settings and conduct**

All women aged 25 to 65 with breast cancer who referred to the oncology department of the province hospital in Qazvin and were selected by a simple random method by observing the entry and exit criteria and obtaining informed consent.Treatment (ACT) and (CBT) are held in 8 sessions of 90 minutes once a week for two experimental groups and the control group does not receive treatment intervention.Life expectancy is completed by intervention and control groups.Along with the 3-month follow-up period, it is clear that the therapeutic interventions have maintained their effectiveness.

**Participants/Inclusion and exclusion criteria**

Entry conditions : Patients with breast cancer, one month has passed since being admitted to the hospital and undergoing chemotherapy and radiation therapy or surgery and related side measures ; Patients must be in the age range of 25 to 65 years old and have the physical ability to attend therapeutic intervention sessions ; Not receiving psychological treatments before group therapy sessions and during group therapy sessions. Conditions of non-entry : presence of psychological disorders or history of mental illness and hospitalization ; Abuse of drugs and psychiatric drugs

**Intervention groups**

group of therapy based on acceptance and commitment; group of cognitive-behavioral therapy;The control group does not receive any treatment

**Main outcome variables**

Death anxiety؛ resilience؛ life expectancy

## General information

**Reason for update**

**Acronym**

درمان مبتنی بر پذیرش و تعهد ( ACT ) _ درمان شناختی - رفتاری ( CBT )

**IRCT registration information**

IRCT registration number: **IRCT20221113056486N1**
Registration date: **2023-01-26, 1401/11/06**
Registration timing: **prospective**

Last update: **2023-01-26, 1401/11/06**
Update count: **0**

**Registration date**

2023-01-26, 1401/11/06

**Registrant information**

**Name**
Mahdieh Sadeghpoor
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-01-30, 1401/11/10

**Expected recruitment end date**
2023-03-30, 1402/01/10
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the effectiveness of acceptance and commitment based therapy and Cognitive - behavioral on anxiety , resilience and life expectancy in Breast Cancer patients

**Public title**
Improving resilience and life expectancy and reducing death anxiety in cancer patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
People with breast cancer who have been admitted to the hospital for at least one month after undergoing chemotherapy and radiation therapy or surgery and related side measures. Patients should be in the age range of 25 to 65 years and have physical ability to attend therapy intervention sessions. Not receiving cognitive therapy before group therapy sessions or during group therapy sessions.
**Exclusion criteria:**
Existence of psychological disorders or history of the mental illness and hospitalization. Abuse of narcotics and psychiatric drugs.
**Age**
From **25 years** old to **65 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **45**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The sampling method in this research will be voluntary sampling method. At first, 45 people are randomly selected from the volunteers and given a characteristic code using a random number table and placed inside the envelopes and given to me and given to them. 15 people will be divided into three (acceptance and acceptance treatment group, behavioral treatment group, and control group).
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
The clinical trial is completed with two intervention and control groups, simple randomized, each group of 15 participants.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Committees of Islamic Azad University-Roudehen Branch
**Street address**
Roudehen - University complex of Islamic Azad University
**City**
Roudehen
**Province**
Tehran
**Postal code**
3973188981
**Approval date**
2022-04-14, 1401/01/25
**Ethics committee reference number**
IR.IAU.R.REC.1401.003

## Health conditions studied

### 1

**Description of health condition studied**
Breast Cancer
**ICD-10 code**
C50.4
**ICD-10 code description**
Malignant neoplasm of upper-outer quadrant of breast

## Primary outcomes

### 1

**Description**
Death anxiety
**Timepoint**
Before and after the implementation of therapeutic interventions and after a period of three months after the therapeutic interventions
**Method of measurement**
Using Templer's Death Anxiety Questionnaire

### 2

**Description**
Resilience
**Timepoint**
قبل و بعد از اجرای مداخلات درمانی و بعد از گذشت یک دوره سه ماهه بعد از مداخلات درمانی

**Method of measurement**
پرسشنامه مقیاس تاب آوری کونور و دیودسون

**3**

**Description**
life expectancy
**Timepoint**
Before and after the implementation of therapeutic interventions and after a period of three months after the therapeutic interventions
**Method of measurement**
Schneider life expectancy questionnaire

## Secondary outcomes

**1**

**Description**
Quality of Life
**Timepoint**
Before the intervention and 8 sessions after the intervention
**Method of measurement**
Quality of life questionnaire

**2**

**Description**
depression
**Timepoint**
Before the intervention and 8 sessions after the intervention
**Method of measurement**
Beck depression questionnaire

**3**

**Description**
anxiety
**Timepoint**
Before the intervention and 8 sessions after the intervention
**Method of measurement**
Beck's anxiety questionnaire

## Intervention groups

**1**

**Description**
Intervention group 1: Treatment based on acceptance and commitment is held in the form of eight ninety-minute group sessions by the researcher once a week.First, death anxiety scores, resilience and life expectancy are determined with the pre-test, and after the implementation of eight therapeutic intervention sessions, a post-test will be taken from the participants to check the effectiveness.The content of treatment intervention sessions based on acceptance and commitment includes the following: First session: introduction, stating the basic concepts of treatment, obtaining informed consent, taking a pre-test and examining people's attitudes about unpleasant thoughts and feelings, acceptance and committed action using metaphors and homework.The second session: reviewing past sessions and practicing contact with the present, paying attention to awareness, wanting instead of avoiding, practicing conscious breathing, practicing wanting instead of avoiding using metaphors. Third session: reviewing past sessions, paying attention to awareness and the mental functions of breaking through using metaphors, homework.The fourth session: review of the previous session, examination of values and committed action, examination of obstacles to conduct behavior consistent with values using metaphors and homework.The fifth session: reviewing the previous session, paying attention to awareness and self as a context, identifying the internal obstacles of a valuable life using metaphor, homework.Sixth session: Examining past sessions, paying attention to awareness, making mistakes, breaking grammatical rules using metaphors, homework.The seventh session: stability of the results and review of exercises of the previous session.Eighth session: summing up the sessions and encouraging the participants to continue the exercises after finishing the sessions and treatment, announcing the end of the sessions and taking the post-test.
**Category**
Behavior

**2**

**Description**
Intervention group 2: cognitive-behavioral therapy in the form of eight ninety-minute group sessions held by the researcher once a week.First, death anxiety scores, resilience and life expectancy are determined with the pre-test, and after the implementation of eight therapeutic intervention sessions, a post-test will be conducted to check the effectiveness of the participants.The content of cognitive-behavioral intervention sessions is as follows : First session: Introducing and explaining the basic concepts of treatment and recipes and taking the pre-test and explaining the physiological, cognitive, behavioral processes, homework.The second session: review of the previous session, getting to know your own thoughts, cognitive distortions, identifying them in your thinking, recognizing resistance to treatment and designing strategies to deal with it and homework.The third session: reviewing the previous session, getting to know the foundations of behavioral consequences, teaching the nature of schemas, the relationship between schemas and spontaneous thoughts, and identifying schemas through the vertical arrow and homework.The fourth session: review of the previous session, work on the vertical arrow and solve the problems that the research participants have in using the vertical arrow in order to identify their negative schema and homework.The fifth session: review of the previous session, getting the participants a clearer picture of how the negative beliefs are connected and compatible with each other, organizing the list of negative beliefs and homework.Sixth session: review of the previous session,

acceptance of the fact that beliefs can be changed and it is possible that people can revise their beliefs and homework.Seventh session: review of the previous session, understanding that beliefs are different in terms of usefulness and they can be evaluated based on criteria and homework.Eighth session: reviewing the previous session, learning the application of logical analysis about their beliefs, participants' achievement of the concept of opposing belief and announcing the end of the sessions and taking the post-test.

**Category**

Behavior

**3**

**Description**

Control group 3: general explanation of research objectives and obtaining informed consent and then conducting a pre-test, while the control group does not receive any intervention, and after two months, a post-test is also taken from this group.

**Category**

Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Velayat Hospital

**Full name of responsible person**

Mahdieh Sadeghpoor

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University, Roudehen branch

**Full name of responsible person**

Pegah Farrokhzad, Mohammad Ebrahim Sarichalo, Hossein Ebrahimi Moghadam, Mahdieh Sadeghpour

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info@riau.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University, Roudehen branch

**Proportion provided by this source**

100

**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**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Islamic Azad University, Roudehen branch

**Full name of responsible person**

Pegah Farrokhzad, Mohammad Ebrahim Sarichlou, Hossein Ebrahimi Moghadam, Mahdieh Sadeghpour

**Position**

Assistant professor, assistant professor, associate professor, PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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