

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 شناختی - رفتاری _ (ACT) درمان مبتنی بر پذیرش و تعهد (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 Sadeghpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 28 3334 2709

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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 Sadeghpour

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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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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**Contact****Name of organization / entity**

Islamic university - Roudehen Branch

Full name of responsible person

Pegah Farrokhzad, Mohammad Ebrahim Sarichlou,
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Position

Assistant professor, assistant professor, associate
professor, PhD student

Latest degree

Ph.D.

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Islamic University - Roudehen Branch

Full name of responsible person

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

Position

Assistant professor, assistant professor, associate
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Latest degree

Ph.D.

Other areas of specialty/work