Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of Acceptance and Commitment Therapy on fear of progression and quality of life of breast cancer patients in 1 and 2 and 3 stages

Protocol summary

Study aim

The effect of acceptance and commitment-based therapy on fear of disease progression, anxiety sensitivity and quality of life in breast cancer patients in stages 1, 2 and 3

Design

Clinical trial with control group, one-way blind, sample selection available but assigned to groups by block randomization which is used for randomization using EXCEL statistical software, this study is performed on 80 people.

Settings and conduct

This study is performed in Mehraneh specialized clinic and the patients referred to Mehraneh or referred by the oncology consultant are selected as available and after filling in the questionnaire of fear of disease progression. They are invited for an interview and if they have inclusion and exclusion criteria, the names of patients are given to the statistical consultant for random assignment to the groups. The treatment is performed in 5 sessions of 90 minutes on the intervention group. Patients are informed that they may or may not be in the control group.

Participants/Inclusion and exclusion criteria

Patients with breast cancer in stages 1, 2, and 3 without metastasis and in the age range of 18-55 years without a diagnosis of psychosis and personality disorder can participate in this study, but patients who are unable to continue treatment due to physical problems or any other problem or more Have been absent from one session of treatment. They are excluded from further study.

Intervention groups

It is an intervention group that will receive acceptance and commitment-based treatment with a treatment book and three follow-ups, but the control group will only receive a treatment book and three follow-ups. Of course, at the end of the study, the control group will receive treatment from the intervention group according to ethical principles.

Main outcome variables

fear of progression, anxiety sensivity, quality of life of cancer patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210727052000N1**
Registration date: **2021-08-09, 1400/05/18**
Registration timing: **prospective**

Last update: **2021-08-09, 1400/05/18**
Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Fatemeh Hassani alimolk

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Acceptance and Commitment Therapy on fear of progression and quality of life of breast cancer patients in 1 and 2 and 3 stages

Public title

The effect of acceptance and commitment therapy on fear of disease progression, anxiety sensitivity and quality of life in patients with breast cancer in stages 1, 2 and 3

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 50 years No tumor metastasis Patients who have only had 1 to 3 sessions of chemotherapy or radiotherapy Patients must either be from Zanjan or have been staying in a guest house for at least 2 months To have Physically ability to attend sessions No psychosis disorders and personality disorders Haven't been in psychotherapy during the last month Not using psychiatric drugs No diagnosis of misue of alcohol or addictive substances Patients' satisfaction and interest in participating in the study

Exclusion criteria:

Patients' dissatisfaction with continuing treatment Worsening of patients' mental or physical condition during treatment Absence of more than one session of treatment

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, in order to achieve an equal number of patients in the control group and the intervention group, the block randomization method will be used, each block will be 5 people, the reason for using this random allocation is to ensure the equal number of people in intervention and Control In this study, we will have two blocks of intervention and control, the size of each block will be 5 people. For proper blinding, random assignment of patients to groups, after patient selection, ie after interviewing patients by the researcher, for random assignment to groups, patient statistics will be given to the statistical consultant to randomly assign patients in groups. To take. EXCEL statistical software will be used for random allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

The names of all patients will be given to the statistical consultant for randomization after initial selection and review of inclusion and exclusion criteria for assignment to intervention and control groups. Also, patients in both control and intervention groups will be given a treatment book after random assignment to the groups, and the control group will have all three follow-up periods as the intervention group, but only the intervention group will receive treatment based on acceptance and commitment. They will. Therefore, patients will be unaware of whether they will be in the intervention group or the control group.

Placebo

Not used

Assignment

Parallel

Other design features

In the present study, we have an intervention group and a control group that only the intervention group received acceptance and commitment-based treatment, and both of these groups receive comments before and after the intervention and 3 months after the intervention. Needless to say, treatment books will be given to both groups. The researcher suggests that at the end of the 3-month test, if the control group wishes, the intervention group treatment will be performed for them.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Shahid Beheshti hospital, Ark gate, Zanjan city, Zanjan province

City

Zanjan

Province

Zanjan

Postal code

7531974143

Approval date

2021-07-24, 1400/05/02

Ethics committee reference number

IR.ZUMS.REC.1400.139

Health conditions studied

1

Description of health condition studied
Fear of disease progression in patients with breast cancer in stages 1, 2 and 3
ICD-10 code
C50.011
ICD-10 code description
Malignant neoplasm of nipple and areola, right female breast

Primary outcomes

1

Description
Score of fear of disease progression questionnaire
Timepoint
Filling in the fear questionnaire of disease progression before the intervention, after the intervention and 3 months after the intervention
Method of measurement
Dr. Hersbach's Fear of Progress Questionnaire

2

Description
Quality of life questionnaire score for cancer patients
Timepoint
Filling out the quality of life questionnaire for cancer patients before the intervention, after the intervention, 3 months after the intervention
Method of measurement
Quality of life questionnaire for cancer patients

3

Description
Anxiety sensitivity questionnaire score
Timepoint
Filling out the anxiety sensitivity questionnaire before the intervention, after the intervention, 3 months after the intervention
Method of measurement
Anxiety Sensitivity Questionnaire

Secondary outcomes

1

Description
Scale of experimental avoidance subscale of Acceptance and Practice Questionnaire
Timepoint
Admission and practice questionnaire is completed before the intervention, after the intervention, 3 months after the intervention.
Method of measurement
Bond's Admission and practice questionnaire

2

Description
Psychological flexibility (acceptance and practice questionnaire score)
Timepoint
Admission and practice questionnaire is filled out before the intervention, after the intervention and 3 months after the intervention.
Method of measurement
Bond's Acceptance and practice questionnaire

3

Description
Cognitive integration (Gilders Cognitive integration questionnaire score)
Timepoint
The cognitive integration questionnaire is filled out before the intervention, after the intervention and 3 months after the intervention.
Method of measurement
Gilders Cognitive Integration Questionnaire

Intervention groups

1

Description
Intervention group: 5 sessions of 90-minute group therapy based on acceptance and commitment, which was first proposed by Dr. Hayes. (Dr. Zenozian and Dr. Patterson, with the help of the Second Supervisor Research Team and Dr. Hayes' approval of the treatment process) developed the protocol. Protocol processes include: values, cognitive fault, acceptance. There will be only 5 patients in each treatment group. Patients will attend the treatment session only once a week. Between sessions, assignments appropriate to the content of the sessions are given to patients, and at the beginning of each session, homework is reviewed. Not to mention, in each session, after 30 minutes of work, patients will have a 15-minute rest, and in each session, patients will be given masks, alcohol, biscuits and fruit juice packed with flowers.
Category
Rehabilitation

2

Description
Control group: will only have treatment and follow-up books without receiving acceptance and commitment-based psychotherapy. However, after 3 months of follow-up, according to the ethical principles, the patients in the control group will benefit from the treatment of the intervention group if they wish. The treatment book contains a summary of the intervention, but without any practice or presence of the therapist and without any metaphor used in the treatment sessions. The contents of the book include processes: values, cognitive fault, acceptance.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Mehraneh Specialized Clinic

Full name of responsible person
Mohammadreza Moieni

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Mehraneh specialized clinic, Mehraneh Blvd, Prof,Soubouti Bldv, Gavazang road, Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
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Web page address
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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
Zanjan University of Medical Sciences

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
Zanjan University of Medical Sciences

Full name of responsible person
Fatemeh Hassani alimolk

Position
Master student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Except for unnecessary information that the patient does not agree to publish, the rest of the information is shared after the person is not identified.

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Once published in articles, it can be made available to academics or therapists.

Under which criteria data/document could be used

The use of information in order to fill the research gap is allowed.

From where data/document is obtainable

Fatemeh Hassani Alimolk E-mail: fatima.hassani@yahoo.com

What processes are involved for a request to access data/document

After the articles are published, the data will be made available by the journal. Of course, the data will be available 6 months after the results are published.

Comments