

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

the effectiveness of acceptance and commitment therapy (ACT) on anxiety, depression, marital satisfaction, pain acceptance, psychological flexibility and body composition among married people with breast cancer .

Protocol summary

Anxiety, Depression, Marital Satisfaction, Acceptance of Pain and Psychological Flexibility and Body Composition

Study aim

the effectiveness of acceptance and commitment therapy (ACT) on anxiety, depression, marital satisfaction, pain acceptance, psychological flexibility and body composition among married people with breast cancer

Design

This research is a randomized study with two groups of acceptance and commitment therapy and control group. Subsequently, 40 breast cancer patients will be selected based on target selection criteria. The participants in the intervention and control groups Randomly ordered.

Settings and conduct

The research site is Ayatollah Yasrebi Hospital in Kashan. For sampling, patient's contact number was first delivered from the hospital and 40 patients were randomly assigned to two groups (one treatment group, one control group). This research is a blind clinical trial. The members of each group will come to the treatment in different days and hours, and the two members will not meet each other.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of breast cancer and at least 6 months of illness, lack of other serious diseases, having at least 18 years of age, having at least guidance school of literacy, being married, tendency to participate in the program, depression score higher or equal to 10 according to DASS-21 test, anxiety score higher or equal to 8 according to DASS-21 test Exclusion criteria: drug use, suicidal thoughts, Participation in psychiatric intervention while conducting research

Intervention groups

Acceptance and commitment therapy group: 8 sessions, once a week Control group: In this group, members will continue to take their usual treatment.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190518043620N1**

Registration date: **2020-02-14, 1398/11/25**

Registration timing: **retrospective**

Last update: **2020-02-14, 1398/11/25**

Update count: **0**

Registration date

2020-02-14, 1398/11/25

Registrant information

Name

Vajihah Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
the effectiveness of acceptance and commitment therapy (ACT) on anxiety, depression, marital satisfaction, pain acceptance, psychological flexibility and body composition among married people with breast cancer .

Public title
the effectiveness of acceptance and commitment therapy (ACT) on anxiety, depression, marital satisfaction, pain acceptance, psychological flexibility and body composition among married people with breast cancer .

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of breast cancer and at least 6 months of illness lack of other serious diseases (chronic heart, kidney, pulmonary diseases in the advanced stages, etc.) Having at least 18 years of age Having at least guidance school of literacy Being married Tendency to participate in the program Depression score higher or equal to 10 according to DASS-21 test Anxiety score higher or equal to 8 according to DASS-21 test
Exclusion criteria:
Drug use Suicidal thoughts Participation in psychiatric intervention while conducting research

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
40 patients with breast cancer are intentionally selected. They are then randomly assigned to two groups (ACT, control, 20).

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, after the participants are selected, we begin the treatment randomly and without knowing the two groups in this study in the intervention or control group, but the treatment that will be applied to them will be explained. The blindness of the participants in the treatment is that they are unaware that there is another group. But after the end, they will know about the existence of the other group and they will be treated if

they wish. The researcher is aware of the existence of an intervention group and control.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Kashan University of Medical Sciences

Street address

Ghotb Ravandi Boulevard

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Kashan

Province

Isfahan

Postal code

3713979671

Approval date

2019-01-07, 1397/10/17

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.092

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

Primary outcomes

1

Description

anxiety

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Anxiety-Depression-Stress Questionnaire 21

2

Description

depression

Timepoint

Before intervention, after intervention, two months after

intervention

Method of measurement

Anxiety-Depression-Stress Questionnaire 21

3

Description

Marital Satisfaction

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Enrich marital satisfaction questionnaire

4

Description

pain acceptance

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Chronic Pain Acceptance Questionnaire(CPAQ)

5

Description

psychological flexibility

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Acceptance and Action Questionnaire (AAQ-II)

6

Description

body composition

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Inbody device

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The control group is the same group that does not receive any treatment except its medication.

Category

Other

2

Description

Intervention group: Acceptance and commitment therapy,an integrated therapeutic approach developed

by Hayes, Straussal and Wilson, consisting of eight 90-minute therapeutic sessions, held for 8 consecutive weeks.Instead of changing cognitions, this treatment seeks to enhance a person's psychological connection to his or her thoughts and feelings, and includes six central processes that lead to psychological flexibility.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital of Kashan

Full name of responsible person

Vajiheh GHorbani

Street address

Shahid Beheshti Hospital, Kashan University of Medical Sciences, Boulevard Ravandi,Kashan,Isfahan

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2

Recruitment center

Name of recruitment center

Ayatollah Yasrebi Hospital of Kashan

Full name of responsible person

Dr. Mostafa Sarvizadeh

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Ayatollah Yasrebi Hospital,Parastar Blvd, Qotb Ravandi Boulevard,Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Hamid Reza Banafsheh

Street address

Kashan University of Medical Sciences,Ghotb Ravandi Blvd

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88715973474

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medicine@kaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Vajiheh Ghorbani

Position

Master of clinical psychology student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Full name of responsible person

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Position

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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