Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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

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

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

Vajiheh Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3442 3755

Email address

ghorbani-v@kaums.ac.ir

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

City

Kashan

Province

Isfehan

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

Street address

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
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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
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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