Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study the effect of acceptance and commitment therapy on sexual self-esteem, sexual function, and concern for physical imaging in women with breast cancer

Protocol summary

Study aim
Investigation the effect of acceptance and commitment therapy on sexual self-esteem, sexual function, and concern for physical imaging in women with breast cancer

Design
This study is a non-blinded clinical trial. The research population will be included of all patients referring to the Taleghani hospital in Kermanshah city. 40 eligible patients will be selected conveniently and randomly assigned to intervention and control groups.

Settings and conduct
The study, which will be conducted at Taleghani hospital in Kermanshah city, is non- blinded one. Before the beginning of the study and at the end of the study, the questionnaires will be provided for both groups and the two groups will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of breast cancer by oncology specialist; Being married Exclusion criteria: Simultaneously receive other psychological treatments; Patients who failed to attend at least two treatment session

Intervention groups
The intervention group will receive group commitment training, 8 sessions for 90 minutes (weekly one session). The control group will receive group stress management training 8 sessions for 90 minutes (weekly one session).

Main outcome variables
Sexual self-esteem; Sexual function; Body image

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N96**
Registration date: **2018-08-01, 1397/05/10**
Registration timing: **prospective**

Last update: **2018-08-01, 1397/05/10**
Update count: **0**

Registration date
2018-08-01, 1397/05/10

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-11, 1397/05/20

Expected recruitment end date
2018-10-02, 1397/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study the effect of acceptance and commitment therapy on sexual self-esteem, sexual function, and concern for physical imaging in women with breast cancer

Public title
Investigating the Effect of Acceptance and Commitment Therapy on Women with Breast Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of breast cancer by oncology specialist Lumpectomy literacy more than middle school Being married
Exclusion criteria:
Simultaneously receive other psychological treatments; Patients who failed to attend at least two session Patients who failed to attend at least two treatment session
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomly Individually by random number table via code receipt
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2018-05-22, 1397/03/01
Ethics committee reference number
ir.kums.rec.1397.089

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50.8
ICD-10 code description
Malignant neoplasm of overlapping sites of breast

Primary outcomes

1

Description
Sexual self-esteem
Timepoint
Before beginning the study and at the end of the study
Method of measurement
Based on Women's Sexual Self-Esteem Questionnaire (SSEL-W-SF)

2

Description
Sexual function
Timepoint
Before beginning the study and at the end of the study
Method of measurement
Base on Female Sexual Function Index(FSFI)

3

Description
Body image concern
Timepoint
Before beginning the study and at the end of the study
Method of measurement
Based on the body image concern questionnaire(BICI)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive group commitment training, 8 sessions for 90 minutes (weekly one session).
Category
Lifestyle

2

Description

The control group will receive group stress management training 8 sessions for 90 minutes (weekly one session).

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Marziyeh Parvin

Street address

Shahid Beheshti Blvd., Taleghani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Marziyeh Parvin

Position

MSc student of clinical psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Dr.Mozafar Aznab

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for updating data

Contact

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MSc student of clinical psychology

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The main outcomes of the study will be shared.

When the data will become available and for how long
6 months

To whom data/document is available
If requested, results will be made available to other academic researchers

Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable
To receive the documentation, email send for update manager

What processes are involved for a request to access data/document
In a 15-day period, the documents will be sent e-mail

Comments