

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

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

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Phone

+98 83 3836 7984

Email

m.parvin@yahoo.com

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

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

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

Street address

Islamic Azad University, Kasra Street

City

Kermanshah

Province

Kermanshah

Postal code

6718997551

Phone

+98 83 3724 3181

Email

m.parvin@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Mozafar Aznab

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6309

Email

draznab@yahoo.com

Person responsible for updating data

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

Street address

Islamic Azad University, Kasra Street

City

Kermanshah

Province

Kermanshah

Postal code

6718997551

Phone

+98 83 3724 3181

Email

m.parvin@yahoo.com

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