

# 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

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**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

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**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

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6718997551

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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

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Emam Reza Hospital, Parastar Boulevard

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## 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**

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**Postal code**

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**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**