

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effectiveness of acceptance and commitment group therapy on body image, sexual self-schema and marital intimacy in women with uterine cancer and breast lumpectomy surgery

#### Protocol summary

##### Study aim

To investigate the effectiveness of acceptance and commitment group therapy on body image, sexual self-schema and marital intimacy in women with uterine cancer and breast lumpectomy surgery

##### Design

This clinical trial with control group, with parallel groups, randomized and without blinding will be performed on 30 women with uterine cancer and breast lumpectomy surgery. Random allocation software is used for randomization

##### Settings and conduct

In this study, which will be performed at reza radiotherapy and oncology center, a psychological method will be performed in woman patients with uterine cancer and breast lumpectomy surgery. Before and after the intervention, individuals will answer the relevant questionnaires. There will be no blinding in this study

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 21 to 51 years, Having at least a high school diploma, Willingness to participate in the study, Not receiving psychological treatment since diagnosis, Having uterine cancer, Having breast lumpectomy surgery Exclusion criteria: having advanced or metastatic breast cancer, Unwillingness or inability to participate in group psychotherapy sessions, Having other medical and psychiatric disorders

##### Intervention groups

Intervention group: Acceptance and commitment therapy (ACT) is one of the third wave therapies and its main purpose is to focus on the psychological connection of the person with his thoughts and feelings. Women with uterine cancer and breast lumpectomy surgery will undergo ACT intervention during 8 sessions of 90 minutes (two sessions per week) for 1 months. control group: This group will not receive any intervention. In order to observe ethics in research, after the end of

intervention, two training sessions on psychological skills will be provided for this group

##### Main outcome variables

body image concern, women's Sexual Self-Schema, marital intimacy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200117046165N1**

Registration date: **2020-08-16, 1399/05/26**

Registration timing: **retrospective**

Last update: **2020-08-16, 1399/05/26**

Update count: **0**

##### Registration date

2020-08-16, 1399/05/26

##### Registrant information

##### Name

Narges Zarei

##### Name of organization / entity

The University of Allameh Tabatabaiei

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3726 1836

##### Email address

nargeszareei57@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-10, 1398/12/20

##### Expected recruitment end date

2020-04-08, 1399/01/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of acceptance and commitment group therapy on body image, sexual self-schema and marital intimacy in women with uterine cancer and breast lumpectomy surgery

**Public title**

The effect of acceptance and commitment group therapy on body image, sexual self-schema and marital intimacy

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Aged between 21 to 51 years Having at least a high school diploma Willingness to participate in the study Not receiving psychological treatment since diagnosis Having uterine cancer Having breast lumpectomy surgery

**Exclusion criteria:**

Having advanced or metastatic breast cancer Unwillingness or inability to participate in group psychotherapy sessions Having other medical and psychiatric disorders

**Age**

From **21 years** old to **51 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization in this study will be based on a simple random method. Therefore, a random number is assigned to each patient by the table of random numbers, according to which if the number is odd, the patient will be in the intervention group, and if it is an even number, the patient will be in the control group

**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 Hakim Sabzevari University

**Street address**

Hakim Sabzevari University Campus, Tovhid Town

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617976487

**Approval date**

2020-02-15, 1398/11/26

**Ethics committee reference number**

IR.HSU.REC.1398.026

## Health conditions studied

1

**Description of health condition studied**

Uterine cancer

**ICD-10 code**

C53

**ICD-10 code description**

Malignant neoplasm of cervix uteri

## Primary outcomes

1

**Description**

Body Image Concern

**Timepoint**

Before the intervention, 30 days after the intervention

**Method of measurement**

The Littelton Body Image Concern Inventory (2005)

2

**Description**

women's Sexual Self-Schema

**Timepoint**

Before the intervention, 30 days after the intervention

**Method of measurement**

The Cyranowski women's Sexual Self-Schema Scale (1994)

3

**Description**

Marital Intimacy

**Timepoint**

Before the intervention, 30 days after the intervention

**Method of measurement**

The Bertommen Marital Intimacy Questionnaire (1995)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Women with uterine cancer and breast lumpectomy surgery will undergo acceptance and commitment group therapy intervention during 8 sessions of 90 minutes (two sessions per week) for 1 months which is based on the acceptance and commitment therapy book of Hayes (1999). The summary of the content of each session is as follows: 1) Introduction and general description of therapeutic approach and explaining the rules and expectations; 2) Assessing patient problems; 3) Elimination of inefficient control of negative events; 4) Separating assessments from personal experiences and observing thoughts without judgment; 5) Contact now and considered self as a context and teaching techniques of mindfulness; 6) Extracting value of patients' life and evaluation on the basis of their importance; 7) Providing practical solutions to overcome barriers and planning for commitment to pursue the great values of life; 8) A brief description of concepts discussed in each session

#### Category

Treatment - Other

### 2

#### Description

Control group: This group will not receive any intervention. In order to observe ethics in research, after the end of intervention, two training sessions on psychological skills will be provided for this group

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Reza Radiotherapy and Oncology Center

##### Full name of responsible person

Samira Keramati

##### Street address

Reza Radiotherapy and Oncology Center, 19 Rafsanjani St., Haftom Azar Sq., Rafsanjani Hwy., International Fair Blvd.

##### City

Mashhad

##### Province

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##### Postal code

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#### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hakim Sabzevari University

##### Full name of responsible person

Ahmed Farzaneh Kord

##### Street address

Hakim Sabzevari University Campus, Tovhid Town

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farzaneh@hsu.ac.ir

##### Web page address

<http://www.hsu.ac.ir>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hakim Sabzevari University

#### 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

Bojnourd University

##### Full name of responsible person

Samira Keramati

##### Position

Consultant

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Full name of responsible person**

Narges Zarei

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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nargeszareei57@yahoo.com

**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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable