

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

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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

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Sabzevar

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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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