

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effectiveness of compassion-focused therapy on perceived stress, body image anxiety, valuing body and psychological distress in the women suffering from breast cancer

Protocol summary

Study aim

Treatment of perceived stress, concerns of body image and psychological distress in women with breast cancer

Design

A clinical trial involving a control group included all 20-60 year old breast cancer patients. 30 female patients with breast cancer were selected and simple randomization using random numbers table in intervention and control groups. For the intervention group, Based Compassion-Focused Therapy and control group, Treatment-as-usual(TAU) was used.

Settings and conduct

compassion-focused therapy was used in 8 treatment sessions of 90 minutes , one session each week and consecutive for the treatment of perceived stress, concerns of body image and psychological distress in women with breast cancer. Sampling and treatment was done in Isfahan Ala' cancer prevention and control center. Blinding is not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a breast cancer disease by diagnosing an oncologist, From 20 years old to 60 years old, Have at least a diploma degree, Having a physical and cognitive ability to participate in the study, Not having another psychotherapy record Informed consent and willingness to participate in research. Exclusion criteria: having psychiatric disorders (based on DSM-5), advanced cancer and other cancers.

Intervention groups

The intervention group received 8 compassion-focused therapy sessions in a two and a half months at a weekly 90-minute session. The control group also used the current treatment (TAU).

Main outcome variables

Perceived Stress, Body Image Anxiety, Valuing Body and Psychological Distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190118042403N1**

Registration date: **2019-02-20, 1397/12/01**

Registration timing: **retrospective**

Last update: **2019-02-20, 1397/12/01**

Update count: **0**

Registration date

2019-02-20, 1397/12/01

Registrant information

Name

Razieh Purhoseini

Name of organization / entity

Islamic Azad University, Isfahan (Khorasgan) Branch

Country

Iran (Islamic Republic of)

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+98 31 3535 4001

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-30, 1397/03/09

Expected recruitment end date

2018-07-31, 1397/05/09

Actual recruitment start date

2018-06-14, 1397/03/24

Actual recruitment end date

2018-08-23, 1397/06/01

Trial completion date

2018-12-07, 1397/09/16

Scientific title

Effectiveness of compassion-focused therapy on perceived stress, body image anxiety, valuing body and psychological distress in the women suffering from breast cancer

Public title

The effect of compassion focused therapy on perceived stress, body image anxiety, valuing body and psychological distress.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a breast cancer disease by diagnosing an oncologist From 20 years old to 60 years old Have at least a diploma degree Having a physical and cognitive ability to participate in the study Not having another psychotherapy record Informed consent and willingness to participate in research

Exclusion criteria:

Having psychiatric disorders (based on DSM-5) Advanced cancer disease Affected by a variety of other cancers

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 30 patients with breast cancer were selected based on the inclusion and exclusion criteria. Through a Simple randomization method, 15 people were assigned to the intervention group and 15 were assigned to the control group using the random numbers table. In the use of random numbers table, first, how to read the numbers in the table were determined. Then the even numbers for the intervention group and the odd numbers for the control group were considered.

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 Islamic Azad University Of Khorasgan

Street address

East Gey Street ., Arghavanieh., University Blvd

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Isfahan

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Isfahan

Postal code

8155139998

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.111

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

c50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Perceived Stress Score in Perceived Stress Questionnaire

Timepoint

Perceived stress questionnaire before intervention, after intervention and 45 days after intervention

Method of measurement

perceived stress questionnaire

2

Description

Psychological Distress Score in Psychological Distress Questionnaire

Timepoint

Psychological Distress questionnaire before intervention, after intervention and 45 days after intervention

Method of measurement

psychological distress questionnaire

3

Description

Body Image Anxiety Score in Body Image Anxiety Questionnaire

Timepoint

Body Image Anxiety questionnaire before intervention,

after intervention and 45 days after intervention

Method of measurement

Body Image Anxiety questionnaire

4

Description

Valuing Body

Timepoint

Valuing Body questionnaire before intervention, after intervention and 45 days after intervention

Method of measurement

Valuing Body questionnaire

Secondary outcomes

1

Description

therapeutic alliance

Timepoint

after intervention on experimental group

Method of measurement

Working Alliance Inventory-Short Revised (WAI-SR)

Intervention groups

1

Description

Intervention group: Group-Based Compassion-Focused Therapy was used for treatment in the intervention group. The treatment group performed a 90 minute session per week. The number of sessions according to the protocol was considered 8 sessions. Compassion-focused therapy aims to help promote mental and emotional healing by encouraging patients in treatment to be compassionate toward themselves and other people. Compassion, both toward the self and toward others, is an emotional response believed by many to be an essential aspect of well-being. The mentioned treatment goals were implemented in accordance with the protocol. Regarding the disease, participants received routine medical treatments for breast cancer.

Category

Behavior

2

Description

Control group: Routine therapies for breast cancer

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ala' cancer prevention and control center

Full name of responsible person

Razieh Porhoseini

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Ala' cancer prevention and control center., Ayatollah Saeedi Ave., Zeinabieh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University Of Khorasgan

Full name of responsible person

Asghar Aghayi Jashoughani

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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

Islamic Azad University Of Khorasgan

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

Islamic Azad University Of Khorasgan

Full name of responsible person

Razieh Porhoseini

Position

Consultant

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable