

# 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)

##### Phone

+98 31 3535 4001

##### Email address

m.porhoseini1361@gmail.com

##### 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

##### City

Isfahan

##### Province

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

##### **Street address**

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

##### **City**

Isfahan

##### **Province**

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##### **Postal code**

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##### **Phone**

+98 31 3552 2006

##### **Fax**

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##### **Email**

info@ala.org.ir

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Islamic Azad University Of Khorasgan

###### **Full name of responsible person**

Asghar Aghayi Jashoughani

###### **Street address**

East Gey Street., Arghavanieh., University Blvd

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###### **Postal code**

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###### **Phone**

+98 31 3535 4001

###### **Email**

aghaeipsy@gmail.com

##### **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**

Psychology

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

Islamic Azad University Of Khorasgan

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Razieh Porhoseini

**Position**

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**Latest degree**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**Latest degree**

Master

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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