

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effectiveness of Group Compassion-Focused Therapy on Severity of Pain, Emotion regulation, Body image, Interpersonal stress and Quality of Life Among women with Breast Cancer

Protocol summary

Study aim

The Effectiveness of Group Compassion-Focused Therapy on Severity of Pain, Emotion regulation, Body image, Interpersonal stress and Quality of Life Among women with Breast Cancer

Design

In this study, which has a control group with parallel and single-blind groups, 44 patients with breast cancer will be randomly divided into two treatment groups based on compassion and control through the site www.randomizer.com.

Settings and conduct

Compassion-focused group therapy is used in 8 sessions of 90 minutes each week. Sampling and treatment will be performed in Beheshti and Yathrebi hospitals in Kashan and it is single-blind for the participants.

Participants/Inclusion and exclusion criteria

Inclusion: Having a diagnosis of breast cancer- Min age 18 and max 55 years-Having at least one recent course of chemotherapy, radiation therapy or mastectomy-The same phase of the disease in both groups-No other physical illnesses-Lack of mental disorders requiring immediate treatment- Having at least the fifth elementary education level- Not receiving psychological interventions during the last year stage. Exclusion: Lack of satisfaction to participate in research- unwillingness to continue treatment-Absence from treatment for two sessions- Having a mental disorder that requires immediate treatment -Intense thinking about self-harm or suicide- Physical inability to perform exercises - Simultaneous participation in another treatment program-Having psychiatric side effects from medications such as tamoxifen and letrofen

Intervention groups

The intervention group will receive 8 sessions of compassionate therapy for two months, 90 minutes per week. The control group also benefits from conventional

therapy (TAU).

Main outcome variables

Severity of pain , Emotion regulation, Body image, Interpersonal stress and Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220318054327N1**

Registration date: **2022-03-30, 1401/01/10**

Registration timing: **prospective**

Last update: **2022-03-30, 1401/01/10**

Update count: **0**

Registration date

2022-03-30, 1401/01/10

Registrant information

Name

Nastaran Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effectiveness of Group Compassion-Focused Therapy on Severity of Pain, Emotion regulation, Body image, Interpersonal stress and Quality of Life Among women with Breast Cancer

Public title
The Effectiveness of Group Compassion-Focused Therapy on Severity of Pain, Emotion regulation, Body image, Interpersonal stress and Quality of Life Among women with Breast Cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having a diagnosis of breast cancer by a cancer specialist Minimum age 18 and maximum 55 years Having at least one recent course of chemotherapy, radiation therapy or mastectomy The same phase of the disease in patients of both groups No other physical illnesses Lack of mental disorders requiring immediate treatment such as substance and alcohol use disorders and psychotic disorders Having at least the fifth elementary education level (having literacy to perform cognitive tasks) Not receiving psychological interventions during the last year and related drug treatment at least one month before the baseline assessment stage until the end of the follow-up stage
Exclusion criteria:
Lack of motivation and satisfaction to participate in research Unfortunate events occur for the person or her unwillingness to continue treatment Absence from treatment for two sessions Having a mental disorder that requires immediate treatment such as substance and alcohol use disorders and psychotic disorders Intense thinking about self-harm or suicide Physical inability to perform exercises (for example, having a lot of pain) Simultaneous participation in another treatment program Having psychiatric side effects from breast cancer-related medications such as tamoxifen and letrozole

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, according to the inclusion and exclusion criteria, 44 patients with breast cancer are purposefully

selected. They will then be divided into two groups of 22 people with compassion-focused therapy (CFT) and control through random assignment using the Randomization Website at Psychological Experiments, Medical Trials, and Field Studies at www.randomizer.com.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, after the participants are selected, they are randomly assigned to the intervention or control group without knowing that there are two groups in this study. We start the treatment, but the treatment that is applied to them will be explained. The blindness of the participants in the treatment is that they do not know that there is another group. But after the end, they find out about the existence of another group and if they want, the treatment will be done for them. The researcher is aware of the existence of the intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Qutb Ravandi Blvd.

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Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.214

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

Severity of Pain

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

McGill Pain Revised Questionnaire

2

Description

Emotion regulation

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Difficulty in emotion regulation scale

3

Description

Body image

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Body image scale

4

Description

Interpersonal stress

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Interpersonal Stress Questionnaire

5

Description

Quality of Life

Timepoint

Before intervention, after intervention, two months after intervention

Method of measurement

Quality of Life Questionnaire for Cancer Patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Compassion-Focused Therapy-
Compassion-focused therapy is based on a neurological

transformation approach to mental health problems and focuses on four areas: past experiences, underlying fears, security strategies, and unintended consequences. In compassion-focused therapy, people learn not to avoid or suppress their painful feelings, so they can learn from their experience and feel compassion for it.

Category

Behavior

2

Description

Control group: The control group means the group that does not receive any treatment other than its own medication.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Hamid Amiri

Street address

Shahid Beheshti Hospital, Kashan University of Medical Sciences, Qutb Ravandi Blvd.

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Nastaran Mehrabi

Position

master student

Latest degree

Bachelor

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

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

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

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

Data Dictionary

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