Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 letrofem

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)

Phone

+98 71 4452 4558

Email address

nastaran1997mehrabi@kaums.ac.ir

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 letrofem

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.

City

Kashan

Province

Isfehan

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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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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
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Person responsible for updating data

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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