

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effectiveness of group consulting based on meta-cognitive therapy and trans-personal therapy on coping strategies , fear of recurrence and resilience, quality of life, anxiety, depression, hope in breast cancer survivors

Protocol summary

Study aim

Determining the effectiveness of group consulting based on meta-cognitive therapy on anxiety, depression, coping strategies, hope, resilience, quality of life and fear of recurrence of breast cancer survivors. Determining the effectiveness of group counseling based on transpersonal therapy on anxiety, depression, coping strategies, hope, resilience, quality of life and fear of recurrence of breast cancer survivors. Comparison the effectiveness of group consulting based on meta-cognitive therapy and interpersonal therapy on anxiety and depression, coping strategies, hope, resilience, quality of life and fear of recurrence of breast cancer survivors.

Design

Parallel randomized single blind controlled clinical trial.

Settings and conduct

After screening patients who had completed their treatments, 36 patients will be randomized into 3 groups using simple randomization. Then, 2 groups will receive meta cognitive and trans personal interventions, separately. Data collectors and data analyzers are unaware of the interventions

Participants/Inclusion and exclusion criteria

Pathology examination with definitive diagnosis of breast cancer Total accomplishment of breast cancer treatment Having no medical history of psychiatric diseases Using no psychiatric medications Using no alternative methods of treatments such as yoga and meditation Not attending in classes similar with the present intervention Having informed consent to participate in the study Exclusion criteria: Patients during treatment Absence for two consecutive sessions Lack of desire to continue participating in the research

Intervention groups

Counseling sessions will be conducted in 14 sessions of 2

hours for participants in tow intervention group. Also, Control group will be performed for participants.

Main outcome variables

Coping strategies, Fear of recurrence, Quality of Life, Anxiety and depression, Hope

General information

Reason for update

Increase study results

Acronym

IRCT registration information

IRCT registration number: **IRCT20200422047170N1**

Registration date: **2020-06-20, 1399/03/31**

Registration timing: **prospective**

Last update: **2020-12-22, 1399/10/02**

Update count: **1**

Registration date

2020-06-20, 1399/03/31

Registrant information

Name

Akram Sajadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8879 7246

Email address

assajadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01
Expected recruitment end date
2023-06-22, 1402/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of group consulting based on meta-cognitive therapy and trans-personal therapy on coping strategies , fear of recurrence and resilience, quality of life, anxiety, depression, hope in breast cancer survivors

Public title
Effect of psychotherapy on the side effects of breast cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pathology examination with definitive diagnosis of breast cancer Total accomplishment of breast cancer treatment local residency in Tehran and suburb Have ability to participate in meta-cognitive and trans-personal classes Having no medical history of psychiatric diseases Using no psychiatric medications Using no alternative methods of treatments such as yoga and meditation Not attending in classes similar with the present intervention Having informed consent to participate in the study

Exclusion criteria:

Patients who are during their treatment Absence for two consecutive sessions Lack of desire to continue participating in the research The incidence of in-situ metastasis (carcinoma in-situ) in patients Patients who out of access during the intervention

Age
From **25 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Breast cancer survivors are invited to participate in several medical centers after complete treatment. Then, at the first visit to the follow-up clinic, those who completed the informed consent are registered and randomly assigned to one of the three study groups, with using a table of random numbers. Use of random numbers table Individual randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In general, this study will be blinded to individuals who are participated in data collection, outcome assessment and data analyzing, which means that they will not be aware of the intervention and the control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kharazmi University

Street address

No.146, Gandi Ave, Vanak Sq. Tehran.Iran.

City

Tehran

Province

Tehran

Postal code

1517964311

Approval date

2020-01-12, 1398/10/22

Ethics committee reference number

IR.KHU.REC.1398.057

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

Coping strategies ,fear of recurrence, quality of life, anxiety& depression, hope

Timepoint

Before the intervention, and at the end of the intervention and 2 months later, 4 months later, 8 month later,12 months later

Method of measurement

Coping strategies, cancer recurrence , Quality of Life Eortc30, Br23, HASD Anxiety and Depression, Beck

Depression, Life expectancy Questionnaire

2

Description

Resilience

Timepoint

Before the intervention, and at the end of the intervention and 2 months later, 4 months later, 8 month later, 12 months later

Method of measurement

Resilience Questionnaire

Secondary outcomes

1

Description

Mean square of coping, mean square of fear of recurrence, mean square of quality of life, mean square of anxiety and depression, mean square of life expectancy.

Timepoint

Before , after intervention and 2 month, 4month, 8month, 12month later.

Method of measurement

Questionnaire

2

Description

Resilience

Timepoint

Before , after intervention and 2 month, 4month, 8month, 12month later.

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Group 1: Patients with breast cancer who who have completed their treatments and have lower average scores of coping, fear of recurrence and resilience. After careful information and having informed consent, 30 participants will be randomly assigned to a receive counseling group based on meta cognitive therapy for 14 sessions. Questionnaires of coping strategies, and fear of recurrence, quality of life, anxiety and depression, hope will be filled out before and after the intervention and after 2,4,8,12 months of follow-up. The information will then be entered into the software and data analysis will be performed and reported.

Category

Behavior

2

Description

Intervention Group 1: Patients with breast cancer who

who have completed their treatments and have lower average scores of coping, fear of recurrence and resilience. After careful information and having informed consent, 30 participants will be randomly assigned to a receive counseling group based on meta cognitive therapy (including spiritual therapy, meditation and yoga) for 14 sessions. Questionnaires of coping strategies, and fear of recurrence, quality of life, anxiety and depression, hope will be filled out before and after the intervention and after 2,4,8,12 months of follow-up. The information will then be entered into the software and data analysis will be performed and reported.

Category

Behavior

3

Description

Control group: Patients with breast cancer who who have completed their treatments and have lower average scores of coping, fear of recurrence and resilience. After careful information and having informed consent, 30 participants will be randomly assigned to the control group for 14 sessions. Questionnaires of coping strategies, and fear of recurrence ,quality of life, anxiety and depression, hope will be filled out before and after the intervention in two intervention group, and after 2,4,8,12 months later. The information will then be entered into the software and data analysis will be performed and reported. They will be explained that they are in the control group and no intervention will be made for this group. However, if they wish to have counseling sessions, they will have them after accomplishment of the interventions and follow-up process.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Motamed Cancer Institute

Full name of responsible person

Akram Sajadian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Akram Sajadian

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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

Iranian academic center for education culture and research

Proportion provided by this source

100

Public or private sector

Private

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

Iranian academic center for education culture and research

Full name of responsible person

Akram Sajadian

Position

Assistant professor

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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