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)

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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

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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

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

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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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Position
Assistant professor

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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