Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of aromatherapy and acupressure on depression and quality of life in women with breast cancer

Protocol summary

Study aim
Comparison of effect of interventions on the side effects of chemotherapy in women with breast cancer will be studied.

Design
a clinical trial with a control group; with factorial group, randomized on 96 women with breast cancer

Settings and conduct
The field of breast cancer study will be conducted in Baqiyatullah and Shahid Chamran Hospitals. Participants will be divided into two groups: test and control Two groups of the test group, one group will be subjected to lavender aroma therapy and the other group will be subjected to acupressure at point p6. The quality of life and depression questionnaire will be filled by the three groups before and four weeks after the intervention.

Participants/Inclusion and exclusion criteria
Entry study: suffering from breast cancer for 1-3 years; having mild and moderate depression based on the Beck depression questionnaire, not taking antidepressants, anti-anxiety drugs, psychoactive substances, alcohol, tobacco;Reading and writing literacy; Marriage, lack of mental problems according to the statement of the person or family member; lack of olfactory disorders, eczema and hives or allergies to flowers, plants and respiratory problems; 60-18 years Exit criteria: Avoiding further participation in the study at any stage; reaction to aromatherapy or acupressure; Aggravation of the disease during the study.

Intervention groups
Dividing people by random allocation into three groups: aromatherapy, acupressure and control group In aroma therapy group, lavender scent will be used by inhalation for 3 days a week for four weeks. In acupressure group, pressure in the P6 area will be done with both hands three days a week for 4 weeks. For patients in the control group, no intervention is performed

Main outcome variables
Quality of life, depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230124057208N1**
Registration date: **2023-01-30, 1401/11/10**
Registration timing: **prospective**

Last update: **2023-01-30, 1401/11/10**
Update count: **0**

Registration date
2023-01-30, 1401/11/10

Registrant information

Name
Somaye Chyvaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 935 937 1672

Email address
schyvaee@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-28, 1401/12/09

Expected recruitment end date
2023-04-29, 1402/02/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of aromatherapy and acupressure on depression and quality of life in women with breast cancer

Public title

Comparison of the effect of aromatherapy and acupressure on depression and quality of life in women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Breast cancer for 1-3 years Suffering from mild and moderate depression according to the Beck depression questionnaire Not taking antidepressants and anti-anxiety drugs No consumption of psychoactive substances, alcohol and tobacco Reading and writing literacy to complete the questionnaire Married Absence of suffering from other mental problems according to the statement of the person or family member Absence of olfactory disorder according to the statement of the patient or a family member Not suffering from eczema and hives or allergies to flowers, plants and respiratory problems such as asthma 18-60 years old

Exclusion criteria:

Avoiding continuing to participate in the study at any stage Any reaction to aromatherapy or acupressure Aggravation of the disease during the study in such a way that prevents the continuation of the study.

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Dividing people by random allocation method into three aromatherapy groups, acupressure and control group In order to random allocation, block random allocation method with six blocks was used. In this way, the aromatherapy test group was assigned the letter A and acupressure the letter B, and the control group was assigned the letter C, and it was written in blocks of six with the letters A, B, and C, on separate sheets, and inside A container was thrown and randomly one of these sheets was taken out of the container and the composition written on it was noted and that sheet was again thrown into the container. Because the sample size in this study was 96 patients, this procedure was repeated 16 times and each time the composition written on each sheet was noted in the sequence of the composition written on the previous sheet. Then, each letter was assigned a number from one to eighty in the order of the letters memorized one after the other, and each letter was placed in an envelope and the number of that letter was written on the envelope. Each time a patient was selected, one of these envelopes was opened in the order of the number written on the envelope and it was determined that the patient should be placed in the test or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatullah University

Street address

Vank, Mulla Sadra St., Sheikh Bahai St., Baqiyatullah University

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2021-12-21, 1400/09/30

Ethics committee reference number

IR.BMSU.BAQ.REC.1400.056

Health conditions studied

1

Description of health condition studied

Depression in women with breast cancer

ICD-10 code

C00-D49

ICD-10 code description

Neoplasms of unspecified behavior

2

Description of health condition studied

Quality of life in women with breast cancer

ICD-10 code

C00-D49

ICD-10 code description

Neoplasms of unspecified behavior

Primary outcomes

1

Description
Depression score in Beck Depression questionnaire
Timepoint
before intervention and four weeks after intervention
Method of measurement
Beck's Depression Questionnaire II

2

Description
Quality of life
Timepoint
before intervention and four weeks after intervention
Method of measurement
Two questionnaires will be used:Quality of life questionnaire for Cancer patients Belongs to the European Organization for Research and Treatment of Cancer AND Quality of life questionnaire for Brest Cancer patients Belongs to the European Organization for Research and Treatment of Cancer

Secondary outcomes

1

Description
Depression score in Beck Depression questionnaire
Timepoint
before intervention and four weeks after intervention
Method of measurement
Beck's Depression Questionnaire II

2

Description
Quality of life
Timepoint
before intervention and four weeks after intervention
Method of measurement
Two questionnaires will be used:Quality of life questionnaire for Cancer patients Belongs to the European Organization for Research and Treatment of Cancer AND Quality of life questionnaire for Brest Cancer patients Belongs to the European Organization for Research and Treatment of Cancer

Intervention groups

1

Description
Intervention group: In the case of the aromatherapy group, 7 drops of lavender essential oil are dripped with a dropper on a 20x20 non-absorbable polyethylene napkin and attached to the patient's collar with a pin, and they are asked to wear it for 30 Breathe normally for a minute. This intervention will be carried out for 3 days a week for four weeks.
Category
Rehabilitation

2

Description
The second intervention group: In the acupressure group, pressure will be used in the P6 area. This point is located three fingers above the crease line of the wrist, on the inner surface of the forearm, on the midline (in the cavity between the last bones of the forearm). In this method, pressure of 3 to 4 kg will be done for 8 minutes with the thumb (three minutes at each point and two minutes of rest) in a circular manner and two rounds per second in both hands and three days a week for 4 weeks. . In order to check the reliability and validity of acupressure, choosing the right points to apply pressure and the amount of pressure force, the researcher will be trained and evaluated by a traditional medicine specialist of the University of Medical Sciences, and the correctness of performing acupressure at the designated point will be confirmed. It is fully presented so that they can continue the intervention at home and the patients will also be evaluated by the researcher so that the accuracy of their work is confirmed by the researcher. Patients will also be taught that the positive effect of massage is confirmed if the client feels warmth, heaviness, swelling or numbness at that point.
Category
Rehabilitation

3

Description
Control group: For patients in the control group, no intervention is performed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatullah Hospital
Full name of responsible person
somaye chivaee
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2

Recruitment center
Name of recruitment center
Shahid Chamran Hospital

Full name of responsible person
Somaye Chyvaee
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Gholam Hossein Alishiri
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Leila Karimi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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Somaye Chyvaee
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Student
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Bachelor
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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