Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of auriclotherapy on the level of stress, anxiety and depression after mastectomy in women with breast cancer

Protocol summary

Study aim
Investigating the effect of auriclotherapy on the level of stress, anxiety and depression after mastectomy in women with breast cancer

Design
A controlled clinical trial with parallel groups, double-blind, randomized by random selection from the envelopes corresponding to the numbers of the test and control groups on 70 patients.

Settings and conduct
in Isfahan breast cancer clinic. the test group will be treated with auriclotherapy (Relax, Mr. Shoulder, Long 2, Anxiety, Shenman and Thalamic points) up to ten weekly sessions and then Vaccaria Seed It is placed on the corresponding points. Then, patients are advised to press the pads for one minute every hour, and at the end of the week, the points will be stimulated again and seeds will be placed again. In the control group, auriclotherapy is not performed and only Vaccaria Seed patch is placed on the desired points every week. After the intervention sessions, the questionnaires will be given to the patients in two groups again.

Participants/Inclusion and exclusion criteria
Iranian nationality Not suffering from infectious diseases and other neurological diseases At least two weeks have passed since the mastectomy Not using antidepressants Reproductive age Obtaining a score of at least 19 in the 21-question DASS questionnaire before the intervention, Absence of infection and apparent abnormality in the ear

Intervention groups
subjects in the intervention group: breast cancer patients who undergo auriclotherapy up to ten sessions weekly, and after that, Vaccaria Seed is placed on the relevant points. subjects in the control group: the breast cancer patients who do not undergo auriclotherapy, but only Vaccaria Seed path is placed on the desired points every week. And it is not recommended to press the points.

Main outcome variables
stress, anxiety and depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091219002889N13**
Registration date: **2022-11-07, 1401/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-07, 1401/08/16**
Update count: **0**

Registration date
2022-11-07, 1401/08/16

Registrant information

Name
Mahboubeh Valiani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3651 4640

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-26, 1401/08/04

Expected recruitment end date
2022-12-25, 1401/10/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of auriclotherapy on the level of stress, anxiety and depression after mastectomy in women with breast cancer

Public title
Auriclotherapy on stress, anxiety and depression after mastectomy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian nationality At least two weeks have passed since the mastectomy Reproductive age Obtaining a score of at least 19 in the DASS questionnaire before intervention

Exclusion criteria:
Not suffering from infectious diseases and other neurological diseases such as MS Absence of infection and apparent abnormality in the ear Non-use of complementary medicine techniques during the last two months

Age
From **15 years** old to **54 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
At this stage, the trained person provides the sealed envelopes in which intervention and control groups are registered as number one and number two, respectively and hidden , and they are randomly assigned to two intervention and control groups. They find that neither the patients were previously aware of their choice nor the researcher has any knowledge in this field.

Blinding (investigator's opinion)
Double blinded

Blinding description
The questionnaire will be distributed among the patients by another trained person and will be completed and delivered by the patients. The trained person will determine the score of the questionnaire. Then the people who have obtained a score of 19 and above from the three scales of stress, anxiety and depression of the DASS questionnaire and meet the inclusion criteria will be included in the study. At this stage, the trained person provides the sealed envelopes in which intervention and control groups are registered as number one and number two, respectively and hidden , and they are randomly assigned to two intervention and control groups. They find that neither the patients were previously aware of their choice nor the researcher has any knowledge in this field.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2022-01-15, 1400/10/25

Ethics committee reference number
IR.MUI.NUREMA.REC.1400.202

Health conditions studied

1

Description of health condition studied
stress, anxiety and depression

ICD-10 code
F43

ICD-10 code description
Reaction to severe stress, and adjustment disorders

Primary outcomes

1

Description
Score of stress, anxiety and depression in DASS questionnaire

Timepoint
Before and after intervention

Method of measurement
The depression anxiety stress scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They undergo ten weekly sessions of auriclotherapy (Relax, Mr. Shoulder, Long 2, Anxiety, Shen Man and Thalamic points) and then Vaccaria seeds is placed on the corresponding points. Then, the patients are advised to press the pads for one minute every hour, and at the end of the week, they will come back and be stimulated again and the pads will be applied.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
مراکز و کلینیک های سرطان پستان شهر اصفهان

Full name of responsible person
دکتر محبوبه والیانی

Street address
خیابان آپادانا اول ، معاونت درمان علوم پزشگی اصفهان

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr Gholamreza Asgari

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mahboubeh Valiani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Isfahan University of Medical Sciences - Faculty of Nursing and Midwifery - Department of Midwifery and Reproductive Health

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Person responsible for scientific inquiries

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the data, such as the information related to the main outcome, will be published in the articles resulting from this study and the final report.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Secondary data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
Data will only be available for use in meta-analysis studies.

From where data/document is obtainable
To receive the data, contact the responsible person in this study via email.

What processes are involved for a request to access data/document
After sending the request from the academic person, the email will be checked and after confirming the purpose of accessing the data, the person responsible for the study will respond to the request as soon as possible.

Comments