

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

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

Protocol summary

Study aim

Investigating the effect of auricloththerapy 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 auricloththerapy (Relax, Mr. Shoulder, Long 2, Anxiety, Shenman and Thalamie 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, auricloththerapy 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 auricloththerapy 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 auricloththerapy, 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

Mahboubbeh Valiani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3651 4640

Email address

valiani@nm.mui.ac.ir

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

Isfahan

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 auriculotherapy (Relax, Mr. Shoulder, Long 2, Anxiety, Shen Man and Thalamie 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 پزشکی اصفهان

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valiani@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Asgari

Street address

Hezar jereb Street, Isfahan University of Medical Sciences

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research@mui.ac.ir

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

Mahboubah Valiani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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

Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Street address

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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

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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