Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study of the effect of aromatherapy and music therapy on physiological indices and preoperative anxiety of mastectomy candidates

Protocol summary

Study aim

In this study, aromatherapy and music therapy as a non-invasive intervention will be compared and evaluated to reduce women's preoperative anxiety before mastectomy surgery.

Design

Randomized trial with a control group, with parallel groups, on 99 patients. The statistical website www.randomizer.org was used for randomization.

Settings and conduct

Study population is female mastectomy candidates at Imam Khomeini Hospital in Tehran. Anxiety data are collected first, along with physiological measurements. Aromatherapy involves placing a cotton ball containing three drops of 20% rose essential oil 15 to 20 cm from the nasal airway. Patients breathe normally for 30 minutes. After 30 minutes, aromatherapy will end. Music therapy involves listening to selected music through headphones for 30 minutes. After 30 minutes, music therapy ends. The parameters are collected 10 minutes after both interventions are completed. In the control group, only routine nursing care is used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent for participation, female sex, 18 to 65 years old age, stage 3 or 4 of breast cancer, performing surgery on the same day for the first time, Anxiety score at least 5, not using sedatives, painkillers, or other affecting drugs, mentally healthy and literacy in Persian reading and writing. Exclusion criteria: Olfactory, auditory and visual impairment, history of allergies, eczema and respiratory diseases, reluctance in listening to music and or aromatherapy and rose essential oil.

Intervention groups

Aromatherapy: Inhaling 20% rose essential oil for 30 minutes. Music therapy: Listening to the selected music for 30 minutes. Control: Routine nursing cares.

Main outcome variables

This medicine can be used in nursing interventions more frequently if it proves effective due to its increasing popularity, ease of use, and fewer side effects than other methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230221057482N1**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

Faezeh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A comparative study of the effect of aromatherapy and music therapy on physiological indices and preoperative anxiety of mastectomy candidates

Public title
Comparing the effects of aromatherapy and music therapy on preoperative anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the study Female sex 18 to 65 years old age Stage 3 or 4 of breast cancer Performing surgery for the first time Having surgery on the same day Anxiety score of 5 or higher according to the NVAAS tool Not using sedatives and painkillers (at least in the last 24 hours) Not using drugs or corticosteroid products and other central nervous and endocrine system affecting drugs (according to medical records) Having a mental health condition Literacy in Persian reading and writing

Exclusion criteria:
Olfactory dysfunction (for the aromatherapy group) Auditory impairment (for the music therapy group) Visual impairment (to measure anxiety using the NVAAS scale) History of allergies, eczema and respiratory diseases Reluctance and disinterest in listening to music Reluctance and disinterest in aromatherapy and rose essential oil

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
In the first stage, samples are selected by convenience sampling. In this way, the samples that met the conditions for entering the study are chosen. In the second stage, the random assignment of samples is done by the random sequence created on the statistical website www.randomizer.org with a ratio of 1:1:1 to three groups of aromatherapy, music therapy and control so that in each group, 33 people are included.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Imam Khomeini Hospital Complex Research - Tehran University of Medical Sciences

Street address
Room 604, 6th Floor, Central Building of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd., Secretariat of Ethics Committee in Biomedical Research University of Tehran

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2023-02-14, 1401/11/25

Ethics committee reference number
IR.TUMS.IKHC.REC.1401.389

Health conditions studied

1

Description of health condition studied
Breast Cancer

ICD-10 code
C50-C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Anxiety score on the numerical visual analogue anxiety scale

Timepoint
At the beginning of the study and 10 minutes after the intervention has ended

Method of measurement
Numerical Visual Analogue Anxiety Scale

Secondary outcomes

1

Description
Physiological indices (systolic and diastolic blood pressure, heart rate, respiratory rate, arterial blood oxygen saturation and salivary cortisol level)

Timepoint
At the beginning of the study and 10 minutes after the

intervention has ended

Method of measurement

Monitor device, pulse oximetry, laboratory kit (by ELISA method)

Intervention groups

1

Description

First intervention group: Aromatherapy; The aims and methods of this study will be explained to all eligible patients at the beginning of the study. Next, the researcher will complete the demographic and clinical characteristics questionnaire by interviewing the patients and referring to their medical records. Before performing any intervention, the base levels of state anxiety and measurable physiological indicators of systolic and diastolic blood pressure, heart rate, respiration, and arterial blood oxygen saturation will be measured with the Numeric Visual Analogue Anxiety Scale (NVAAS) and monitoring device, respectively. The data will be recorded immediately. To measure the baseline level of salivary cortisol, patients are instructed to throw away the remaining saliva in their mouth and then empty their saliva into the laboratory tube by spitting, a non-invasive and non-stimulating method. They first sit calmly for two minutes in a sitting position. After that, while slightly bent forward, they spit their saliva in a covered laboratory tube for a maximum of five minutes, three to five cc. The test tube is immediately placed in an ice box. To prepare for the intervention, a sterile cotton ball containing three drops of 20% rose essential oil (Rosa damascena) of Barij company will be prepared and attached to the patient's collar with a pin to maintain a distance of 15-20 cm from the nasal airway. 15 minutes later, this procedure is repeated. For privacy, patients are advised to lie comfortably in their beds and usually breathe for 30 minutes. During this period, patients are placed in their rooms without the presence of a nurse or caregiver and without care or treatment intervention. The patient is assured that the researcher is present and available in case of any problems or questions. After 30 minutes, aromatherapy will end. In order to make the intervention effective, 10 minutes after the completion of aromatherapy, the researcher will collect the post-intervention data, which includes state anxiety, measurable physiological indicators and salivary cortisol parameters.

Category

Other

2

Description

Second intervention group: Music therapy; The aims and methods of this study will be explained to all eligible patients at the beginning of the study. Next, the researcher will complete the demographic and clinical characteristics questionnaire by interviewing the patients and referring to their medical records. Before performing any intervention, the base levels of state anxiety and measurable physiological indicators of systolic and diastolic blood pressure, heart rate, respiration, and arterial blood oxygen saturation will be measured with the Numeric Visual Analogue Anxiety Scale (NVAAS) and monitoring device, respectively. The data will be recorded immediately. To measure the baseline level of salivary cortisol, patients are instructed to throw away the remaining saliva in their mouth and then empty their saliva into the laboratory tube by spitting, a non-invasive and non-stimulating method. They first sit calmly for two minutes in a sitting position. After that, while slightly bent forward, they spit their saliva in a covered laboratory tube for a maximum of five minutes, three to five cc. The test tube is immediately placed in an ice box. To prepare for the intervention, the room conditions are the same as those of the aromatherapy group. The patients listen to the selected music for 30 minutes using headphones and MP3 players. Headphones are used to block out the sounds of the environment and allow the patient to concentrate better. At first, patients are provided with four pieces of music (traditional, classical, elemental, ambient genres) selected in the field of music therapy with 60-80 beats per minute. For each music, the patient is exposed to a maximum of 15 seconds. The patient chooses a piece that is closely related and feels more relaxing. Then he listens to the music for 30 minutes through headphones. Patients have the option to listen to the next piece of music or just select the same piece during music therapy. The patient adjusts the sound according to their comfort.

Category

Other

3

Description

Control group: In the control group, routine nursing care is used. In this group, data collection and room and patient conditions are maintained as in the two intervention groups. However, no intervention is performed and only routine nursing care is used.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Esmaeil Mohammadnejad

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Sponsors / Funding sources

1

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Full name of responsible person
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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
Tehran 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
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Full name of responsible person
Faezeh Samadi
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All non-identifiable data can be provided if required.
When the data will become available and for how long
The access period starts 1 month after the results are published
To whom data/document is available
All researchers working in scientific institutions and universities who send requests
Under which criteria data/document could be used
When the copyright law is followed and data serves a relevant research purpose, the data can be used
From where data/document is obtainable
Email Ms. Faezeh Samadi at f-samadi@razi.tums.ir
What processes are involved for a request to access data/document
Within one month of reviewing the application and the applicant's conditions, the data will be sent
Comments