Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of aromatherapy and music therapy on the level of anxiety of patients undergoing general surgery

Protocol summary

Study aim
Comparison of the effect of aromatherapy and music therapy on the level of anxiety of patients before general surgery

Design
This clinical trial is a randomized controlled trial with a parallel design. The study is single-blind and will be performed on 236 patients. Random blocking is used for randomization.

Settings and conduct
In the music therapy group, music is played for 30 minutes. In the aromatherapy group, three drops of 25% rosemary essential oil are used. In the music therapy and aromatherapy group, patients will receive a combination of music and aromatherapy at the same time. Aromatic distilled water is used in the control group. The interventions are performed one hour before the surgery. Before and after the intervention, a trait-mode questionnaire will be completed by all patients. Only the statistics consultant will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having preoperative anxiety, consent to participate in the study, and a healthy sense of smell and hearing. Exclusion criteria: history of mental illness, use of psychotropic drugs from one week before the study, and having thyroid diseases.

Intervention groups
Study groups include music therapy, aromatherapy, a combination of aromatherapy and music therapy, and control. In the music therapy group, patients listen to the "Song of Bidad" through headphones. In the aromatherapy group, three drops of 25% rosemary essential oil are used. In the third group, patients will receive a combination of music therapy and inhalation aromatherapy simultaneously. In the control group, only aromatic distilled water is used.

Main outcome variables
anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100913004736N26**
Registration date: **2022-03-09, 1400/12/18**
Registration timing: **prospective**

Last update: **2022-03-09, 1400/12/18**
Update count: **0**

Registration date
2022-03-09, 1400/12/18

Registrant information

Name
Alireza Khatony

Name of organization / entity
Kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 83 3827 9394

Email address
akhatony@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of aromatherapy and music therapy on the level of anxiety of patients undergoing general surgery

Public title
Comparison of the effect of aromatherapy and music therapy on anxiety of surgical patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate of General Surgery Willingness to participate in the study 18 years and older Having preoperative pain and anxiety No history of allergies Healthy sense of smell Healthy sense of hearing No drug addiction
Exclusion criteria:
Having a history of mental illness Taking psychoactive drugs (anti-anxiety and anti-depressant drugs) from one week before the study Having thyroid diseases
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **236**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be enrolled in the study using the convenience method and will be assigned to one of the groups of music therapy, aromatherapy, a combination of aromatherapy and music therapy, and control, using random blocking method. Each block contains numbers from one to eight. Each patient is assigned a number from one to eight. Each group is assigned a letter (M to the music group, A to the aromatherapy group, AM to the group combining aromatherapy and music therapy, and C to the control group). A sequence is created for a sample size of 236 patients. For the random allocation concealment process, 30 opaque envelopes and 236 cards will be prepared. Inside each envelope, eight cards are placed in order. The number of blocks is written on each envelope. Patients are assigned to one of the study groups based on these letters. Random blocks will be generated by the statistics consultant. The process of randomly assigning patients to study groups will be performed by the researcher. To create a random sequence, permuted block randomization is used by generating eight blocks for four groups. Random sequences will be generated online through sealed www.envelope.com.
Blinding (investigator's opinion)
Single blinded
Blinding description
The statistical advisor will not be aware of the names of the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Shahid Beheshti Blvd.,
City
Kermanshah
Province
Kermanshah
Postal code
6714634698
Approval date
2022-02-08, 1400/11/19
Ethics committee reference number
IR.KUMS.REC.1400.803

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Anxiety score in the State-Trait Anxiety Inventory
Timepoint
At the beginning of the study (before the intervention) and immediately after the intervention
Method of measurement
The State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In this group, one hour before surgery and for 30 minutes, inhalation aromatherapy with three drops of 25% rosemary essential oil (produced by Zardband Company-Iran) is performed. For this purpose, three drops of this essential oil are instilled onto a piece of cotton ball and attached to the patient's collar. The patient is then asked to breathe normally for 30 minutes.
Category
Prevention

2

Description
Second intervention group: In this group, one hour before the surgery, a traditional song without words (song of Bidad), composed by Parviz Meshkatian, will be played for 30 minutes through headphones.
Category
Prevention

3

Description
Third intervention group: In this group, one hour before surgery and for 30 minutes, a combination of aromatherapy and music therapy is used. For this purpose, three drops of this essential oil are instilled onto a piece of cotton ball and attached to the patient's collar. The patient is then asked to breathe normally for 30 minutes. Simultaneously with inhaling the rosemary scent, traditional music without words (song of Bidad), composed by Parviz Meshkatian is played through headphones.
Category
Prevention

4

Description
Control group: In this group, aromatic distilled water is used. For this purpose, a very small amount of rosemary essential oil (in micrograms) is added to the distilled water. Three drops of this solution are instilled onto a piece of cotton ball and attached to the patient's collar. Then the patient is asked to breathe normally for 30 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Alireza Khatony
Street address
Nurse Blvd., Imam Reza Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6714634698
Phone
+98 83 3827 9394
Email
Akhatony@kums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Reza Khodarahmi
Street address
Shahid Beheshti Blvd., Kermanshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6714634698
Phone
+98 83 3837 0541
Email
rkhodarahmi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Alireza Khatony
Position
Professor

Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nurse Blvd., Imam Reza Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6714634698
Phone
+98 83 3827 9394
Email
Akhatony@kums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Alireza Khatony
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nurse Blvd., Imam Reza Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6714634698
Phone
+98 83 3827 9394
Email
Akhatony@kums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Alireza Khatony
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nurse Blvd., Imam Reza Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6714634698
Phone
+98 83 3827 9394
Email
akhatony@kums.ac.ir

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