

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 analyster

**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](http://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

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#### 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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Alireza Khatony

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**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

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Professor

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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