

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of music therapy and aromatherapy on anxiety and physiological parameters of patients undergoing surgery

#### Protocol summary

##### Study aim

Comparison of the effect of music therapy and aromatherapy on anxiety and physiological parameters of patients undergoing surgery

##### Design

Randomized control clinical trial, Parallel design, Single-blind and on 92 patients. Random blocking is used for randomization.

##### Settings and conduct

The study is performed on surgical patients admitted to the intensive care unit. In the music therapy group, traditional non-verbal music is played to patients through headphones for half an hour. In the aromatherapy group, 25% rosemary essential oil is used by inhalation for half an hour. For the combined group, traditional music without words, and aromatherapy with 25% rosemary essential oil are performed simultaneously for half an hour. In the control group, silent headphones and aromatherapy with aromatic distilled water (a combination of distilled water and a very small amount of 25% of rosemary essential oil) are used. Blinding is done only for the statistician and he will not be informed of the names of the groups until the analysis is completed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the study, healthy hearing  
Exclusion criteria: Patient request

##### Intervention groups

Study groups include music therapy, aromatherapy, combination of music therapy and aromatherapy, and control.

##### Main outcome variables

Anxiety, Physiological indexes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100913004736N27**

Registration date: **2022-06-02, 1401/03/12**

Registration timing: **prospective**

Last update: **2022-06-02, 1401/03/12**

Update count: **0**

##### Registration date

2022-06-02, 1401/03/12

##### 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

2022-07-23, 1401/05/01

##### Expected recruitment end date

2023-07-23, 1402/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of music therapy and aromatherapy on anxiety and physiological parameters of patients undergoing surgery

## Public title

The effect of music therapy and aromatherapy on anxiety and physiological parameters

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Consent to participate in the study No history of allergies  
Age over 18 years and under 65 years level of consciousness 15 based on the Glasgow Coma Scale  
Healthy sense of hearing Not having thyroid disease No drug addiction No psychiatric illness

### Exclusion criteria:

Patient request to leave the study Changing the level of consciousness Transferring the patient to another ward

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **92**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are admitted to the study by convenience methods and randomly assigned to one of the study groups based on random blocking. Random sequences will be generated online through sealed www.envelope.com. Study groups include music therapy (A), aromatherapy (B), combination of music therapy and aromatherapy (C), and control (D). For the allocation concealment, 12 opaque envelopes and 92 cards will be prepared. Inside each envelope, 8 cards are placed. The number of blocks is written on each envelope.

Abbreviation code (A, B, C and D) of each group is written on each card. Patients are placed in one of the study groups based on the codes on each card. This process is performed by the researcher.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The study is single-blind, and the statistician is unaware of the equivalence of each code for each group from the beginning, and this ignorance will continue until the end of the data analysis.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of Arak University of Medical Sciences

##### Street address

Pasteur Street

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2022-04-24, 1401/02/04

#### Ethics committee reference number

IR.ARAKMU.REC.1401.032

## 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

### 2

#### Description of health condition studied

Physiological indicators

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Anxiety Score in Spielberger Questionnaire

#### Timepoint

Before and after the intervention

#### Method of measurement

Spielberger Questionnaire

### 2

#### Description

Heart rate per minute

#### Timepoint

Before and after the intervention

#### Method of measurement

The value on the monitor

### 3

#### Description

Percentage of oxygen saturation  
**Timepoint**  
Before and after the intervention  
**Method of measurement**  
The value on the monitor

#### 4

**Description**  
Temperature  
**Timepoint**  
Before and after the intervention  
**Method of measurement**  
The value on the monitor

#### 5

**Description**  
Blood pressure  
**Timepoint**  
Before and after the intervention  
**Method of measurement**  
The value on the monitor

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**  
First intervention group: In the music group, non-verbal music is played through headphones for 30 minutes.  
**Category**  
Prevention

#### 2

**Description**  
Second intervention group: In the aromatherapy group, three drops of 25% rosemary essential oil are poured on a piece of cotton ball and attached to the patient's collar. The patient is asked to breathe normally for 30 minutes.  
**Category**  
Prevention

#### 3

**Description**  
Third intervention group: In this group, a combination of aromatherapy and music therapy is used. For this purpose, similar to the aromatherapy group, 25% rosemary essential oil is used for 30 minutes. Simultaneously with aromatherapy, non-verbal music is played to patients through headphones for 30 minutes.  
**Category**  
Prevention

#### 4

**Description**

In this group, headphones without sound playback, and aromatherapy with aromatic distilled water are used simultaneously. For aromatherapy, a very small amount (in micrograms) of 25% rosemary essential oil is added to distilled water and acts similarly to the aromatherapy group.

#### **Category**

Placebo

### Recruitment centers

#### 1

##### **Recruitment center**

**Name of recruitment center**  
Ayatolah Taleghani hospital  
**Full name of responsible person**  
Alireza Khatony  
**Street address**  
Shahid Beheshti Blvd.,  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6715847167  
**Phone**  
+98 83 3836 7984  
**Email**  
Akhatony@kums.ac.ir

#### 2

##### **Recruitment center**

**Name of recruitment center**  
Imam Reza hospital  
**Full name of responsible person**  
Alireza Khatony  
**Street address**  
Parastar Blvd.,  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6714634698  
**Phone**  
+98 83 3427 6301  
**Email**  
Akhatony@kums.ac.ir

### Sponsors / Funding sources

#### 1

##### **Sponsor**

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Alireza Kamali  
**Street address**  
Basij square, University of Medical Sciences

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3532

**Email**

Alikamaliir@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Parastar Blvd, Imam Reza Hospital

**City**

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**Province**

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**Postal code**

6714634698

**Phone**

+98 83 3427 6301

**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**

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

Kermanshah University of Medical Sciences

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**Postal code**

6714634698

**Phone**

+98 83 3427 6301

**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