

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)

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+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

Ayatollah Taleghani hospital

Full name of responsible person

Alireza Khatony

Street address

Shahid Beheshti Blvd.,

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2

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

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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

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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

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

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

Kermanshah University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

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Other areas of specialty/work

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

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Position

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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