Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity
Kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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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

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2

Recruitment center

Name of recruitment center

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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

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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
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Person responsible for updating data

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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