

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of traditional music with and without words on the level of anxiety of patients undergoing general surgery

Protocol summary

Study aim

Comparison of the effect of traditional music with and without words on the level of anxiety of patients undergoing general surgery

Design

A controlled clinical trial, with parallel groups, randomized, on 102 surgical patients. Random blocking is used for randomization.

Settings and conduct

One of the non-pharmacological methods to reduce patients' anxiety is music. The study will be performed on patients who are candidates for general surgery. Samples will be divided into two intervention groups and one control group (34 patients in each group) based on random blocking. The intervention time is one hour before the surgery and the duration of the intervention is 15 minutes. Traditional music with words and without words will be used for intervention groups. For the control group, headphones connected to the mute player will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria include general surgery candidate, willingness to participate in the study, 18 years and older, having pain and anxiety, interest in traditional music, no drug addiction, no thyroid diseases, no history of psychiatric illness, and a healthy sense of hearing. Exclusion criteria include unwillingness to continue cooperation and receiving sedatives and narcotics during the intervention.

Intervention groups

The study groups consist of three groups: traditional music with words, traditional music without words, and control. For the group of traditional music without words, the music of "Bidad" by Parviz Meshkatian will be played for 15 minutes. In the traditional music group with words, the song "Ei Namat" by Alireza Eftekhari will be played for 15 minutes. In the control group, headphones connected to the mute player will be used for 15 minutes.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100913004736N25**

Registration date: **2022-03-04, 1400/12/13**

Registration timing: **prospective**

Last update: **2022-03-04, 1400/12/13**

Update count: **0**

Registration date

2022-03-04, 1400/12/13

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

2022-05-05, 1401/02/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of traditional music with and without words on the level of anxiety of patients undergoing general surgery

Public title
The effect of music on the level of anxiety of patients undergoing surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 General surgery candidate Having pain and anxiety
 Willingness to participate in the study A healthy sense of hearing Interest in traditional music
Exclusion criteria:
 Drug addiction History of mental illness Having thyroid diseases Use of psychotropic drugs (anti-anxiety and anti-depressant drugs) from one week before the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **102**

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 non-verbal traditional music, traditional verbal music, and control by random blocking method. Each block contains numbers from one to six. Each patient is assigned a number from one to six. Each group is assigned a letter (A to the non-verbal traditional music group, B to the traditional verbal music group, and C to the control group). A sequence is created for a sample size of 102 people. For the random allocation concealment process, 17 opaque envelopes and 102 cards will be prepared. Inside each envelope, six 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.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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.1400.804

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

Pain

ICD-10 code

F45.4

ICD-10 code description

Pain disorders related to psychological factors

Primary outcomes

1

Description

Anxiety score in Spielberger questionnaire

Timepoint

At the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement

Spielberger Anxiety Questionnaire

Secondary outcomes

1

Description

Pain score according to Visual Analogue Scale

Timepoint
At the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group 1: In this group, traditional music without words will be played for 15 minutes. For this purpose, the music of "Bidad" by Parviz Meshkatian is played through headphones.

Category
Prevention

2

Description
Second intervention group: In this group, traditional music with words will be played for 15 minutes. For this purpose, the song "Ei Namat" by Alireza Eftekhari is played through headphones.

Category
Prevention

3

Description
Control group: In this group, headphones connected to a muted player will be used for 15 minutes.

Category
Prevention

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

2

Recruitment center

Name of recruitment center
Taleghani Hospital
Full name of responsible person
Alireza Khatony
Street address
Shahid Beheshti Blvd., Taleghani Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6715847167
Phone
+98 83 3836 7984
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

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Akhatony@kums.ac.ir

Person responsible for updating data

Contact

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Professor

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Street address

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Province

Kermanshah

Postal code

6714634698

Phone

+98 83 3827 9394

Fax

+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