

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of music on the anxiety and some physiological indices of patients before Coronary Arteries Bypass Surgery in the hospital of Dr. Heshmat Hospital in Rasht, 1998-97

Protocol summary

Study aim

The effect of music on anxiety and some physiological parameters of patients before coronary artery bypass graft surgery

Design

Clinical trials with control group; with parallel groups; double blind; randomized blocked

Settings and conduct

This study is an experimental study of double-blind clinical trial. Patient satisfaction form is completed and filled by them. Then, the patients are randomly assigned into two groups of control and test. Then, patients awaiting cardiovascular surgery, go to the rescue room for an hour before the operation, and for the patients in the test group, slow-sounding music will be played back by the MP3 player for 20 minutes before operation, but for The control group does not play music. After 20 minutes, the anxiety level was again measured by Spielberger's questionnaire and physiological parameters in both groups. For masking this study, two-dimensional, for all patients in two groups of MP3 player devices are placed on the patients ear. For the group Music therapy is distributed and no music is distributed to the control group. The degree of anxiety is unknown to the study group.

Participants/Inclusion and exclusion criteria

Entry criteria: complete consciousness; ability to read and write; have hemodynamic stability; no history of surgery; score higher than 20 in the questionnaire; exit criteria: unwillingness to participate in the study; having neuropsychiatric disorders

Intervention groups

Patients awaiting cardiopulmonary resuscitation will go to the rescue room one hour before the operation, and for the patients in the test group, slow-sounding music will be played back by the MP3 player for 20 minutes before the operation, but for the group Witness, music

will not be played. After 20 minutes, the anxiety level was measured by Spielberger questionnaire and physiological parameters in both groups.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181126041762N1**

Registration date: **2019-02-14, 1397/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-14, 1397/11/25**

Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name

Samere Rasouli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3467 2372

Email address

samereh.rasoli928@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of music on the anxiety and some physiological indices of patients before Coronary Arteries Bypass Surgery in the hospital of Dr. Heshmat Hospital in Rasht, 1998-97

Public title

The effect of music therapy on anxiety

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Full readability 2. Ability to read and write 3. Hemodynamic stability 4. Undesirable use of anxiolytic drugs 5. No history of surgery 6. A score higher than 20 in the questionnaire.

Exclusion criteria:

1. Unwilling to participate in the study 2. Having mental illness 3. Lack of interest in music

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 62

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly selected randomly and randomly assigned to two groups of control and test.

Blinding (investigator's opinion)

Double blinded

Blinding description

For mocking up this study, the double-blind, for all patients, is placed in two groups of MP3 player devices on the ears of the patients. For the music therapy group, music is not distributed and the control group does not play any music. The anxiety estimator of the study group is not known.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazums University of Medical Sciences

Street address

17 km of Farah Abad road

City

sari

Province

Mazandaran

Postal code

4464155343

Approval date

2019-02-12, 1397/11/23

Ethics committee reference number

IR.MAZUMS.REC.1397.184

Health conditions studied**1****Description of health condition studied**

Anxaiaety

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

Primary outcomes**1****Description**

Anxaiaety

Timepoint

An hour before study

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients awaiting cardiopulmonary resuscitation, one hour before surgery, accompanied the researcher to the closed room, and for the intervention group, the quiet soft music of standard music files approved by the Psychiatric Association for a while 20 minutes will be played by an MP3 player. Then, their anxiety levels will be measured by the Spielberger Questionnaire. Their vital signs will also be recorded by the evaluator.

Category

Prevention

2

Description

Control group: Patients awaiting cardiopulmonary resuscitation, one hour before the start of the procedure, accompanied the researcher to the room and the headphones have been placed, but no music is played. After 20 minutes, their anxiety is caused by The Spielberg questionnaire will be measured. Their vital signs will also be recorded by the evaluator.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat Hospital Heart Research Center

Full name of responsible person

Heydar Dadkhah

Street address

15 KHordad Street

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ebrahim Nassiri

Street address

17 km of Farah Abad road

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Sari

Province

Mazandaran

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4847191971

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Email

samereh.rasoli928@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Samere Rsouli

Position

Master's degree student operating room

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Samere Rasouli

Position

Master student of the operating room

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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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