Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Instrumental Music and Quranic Voices on Sleep Quality and Anxiety in Patients Admitted to Coronary Care Units (CCU)

Protocol summary

Study aim
Comparison of the Effect of Invalid Music and Quranic Voices on Sleep Quality and Anxiety in Patients Admitted to Coronary Care Units (CCU)

Design
Clinical trial with control group, two intervention groups, parallel, one blind, randomized

Settings and conduct
The present study is a clinical trial that will be conducted in patients with acute coronary syndrome admitted to CCU department of Hajar hospital in Shahrekord. After ensuring the inclusion criteria, Informed consent form, demographic information questionnaire, Spielberger Anxiety Inventory and Sleep Quality Questionnaire in St. Mary's Hospital will be completed after 24 hours after hospitalization. Afterwards, the patients will be randomly assigned to three groups of Quran (32 students), speechless music (32) and control (32 people). After at least 2 successive sessions by headphones, a questionnaire related to the quality of sleep and anxiety will be filled out by the Voice of the Ocean group, the Quran voice group and the control group at the student's level.

Participants/Inclusion and exclusion criteria
log in: Completion of informed consent form Being aged 18 to 65 years old Not having a history of mental illness Deaf hearing loss Having a sleep disorder Stability of vital signs Non arrival: Unwillingness to participate in the plan Deafness Disorders of consciousness Having mental illnesses that lead to taking medication Not having sleep disorder during the first 24 hours

Intervention groups
In the Qur'an, the patients will listen to the sound of the Qur'an using headphones. In the non-verbal musical group, patients will listen to the ocean by using headphones. In the control group, headphones will be used without sound.

Main outcome variables
Sleep quality, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190222042798N1**
Registration date: **2019-04-19, 1398/01/30**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-19, 1398/01/30**
Update count: **0**

Registration date
2019-04-19, 1398/01/30

Registrant information

Name
Masomeh Mohammadpoor

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3620 1497

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st-mohammadpoor.m@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-14, 1397/12/23

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Instrumental Music and Quranic Voices on Sleep Quality and Anxiety in Patients Admitted to Coronary Care Units (CCU)

Public title

The Effect of Instrumental Music and Quranic Voices on Sleep Quality and Anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Completion and signing the informed consent form Aged between 18 and 65 and full vigilance Not having a history of psychiatric illness leading to admission or taking neurological drugs and screening for psychiatric disorders Loss of hearing Sleep disturbance with the St. Mary's Sleep Quality Questionnaire is fully confirmed after 24 hours of admission and is greater than 11. Stability of vital signs (blood pressure, pulse, respiration and temperature).

Exclusion criteria:

Unwillingness to participate in the study Disorders of consciousness Deafness Having mental illnesses that lead to taking medication Not having sleep disorder during the first 24 hours

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, individuals are selected based on simple random sampling. The researcher then selects the research environment and selects all patients who have the criteria for entering the study. After selecting the samples, their random allocation In three groups, using the card method inside the envelope, there are 32 plain memorization cards and 32 cards of the Qur'an and 32 control cards inside the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

All of the participants in each of the three groups use headphones and are not aware that each of the headphones plays a different sound.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Shahr kurd University of Medical Sciences

Street address

Street of Shohadaye Sufeh

City

Esfahan

Province

Isfehan

Postal code

8174785754

Approval date

2019-03-14, 1397/12/23

Ethics committee reference number

IR.SKUMS.REC.1397.297

Health conditions studied

1

Description of health condition studied

Acute cronery syndrom

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality

Timepoint

24 hours after admission and the 4th day after admission

Method of measurement

Sleep quality questionnaire in St. Mary's Hospital

2

Description

Anxiety

Timepoint

24 hours after admission and day 4 after admission

Method of measurement

Spillberger's Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the Qur'anic voice group, the patients stayed for 20 minutes when the CCU lights were turned off in order to rest and sleep at night by using headphones to sound the Qur'an (verses 78 to the end of the Sura al-Asra) with the voice of Master Saadal-Ghamedi in the form of a trilate And in Nahavand style) will listen.
Category
Rehabilitation

2

Description
Intervention group: In the non-verbal musical group, patients will listen to the ocean sound using headphones for at least 20 minutes when they turn off the CCU lights for rest and night sleep.
Category
Rehabilitation

3

Description
Control group: In the control group, patients will use a non-sounding headset for at least 20 minutes when CCU lights are turned off for rest and night sleep.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Hagar Hospital, Kurdish
Full name of responsible person
Ali mohammad Hasheminia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Kamal Solati
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Web page address
https://fa.irct.ir/user/trial/38316/update/sponsor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Hasheminia Alimohammad
Position
Trainer
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
No more information

When the data will become available and for how long
No more information

To whom data/document is available
No more information

Under which criteria data/document could be used
No more information

From where data/document is obtainable
No more information

What processes are involved for a request to access data/document
No more information

Comments
No more information