

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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)

Phone

+98 31 3620 1497

Email address

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

Isfahan

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 coronary 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-Ghamed in the form of a trilite 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

Street address

Rahmatieh

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8174785754

Phone

+98 31 3620 1497

Email

aria.mohammadpoor@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Kamal Solati

Street address

Rahmatieh

City

Sahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8174785754

Phone

+98 31 3620 1497

Fax

+98 31 3624 9035

Email

st-mohammadpoor.m@skums.ac.ir

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

Master

Other areas of specialty/work

Nursery

Street address

Rahmatieh

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8174785754

Phone

+98 31 3620 1497

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Hasheminia Alimohammad

Position

Trainer

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Rahmatieh

City

Shahricord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8174785754

Phone

+98 31 3620 1497

Email

st-mohammadpoor.m@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammadpoor Masomeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shohadaye Soffeh

City

Esfahan

Province

Isfahan

Postal code

8174785754

Phone

+98 31 3620 1497

Email

aria.mohammadpoor@gmail.com

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