Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of music on the agitation on the basis of Richmond in intubated patients admitted to the Medical ICU

Protocol summary

Study aim
The effect of music on the agitation on the basis of Richmond in intubated patients admitted to the Medical Intensive Care Unit(ICU)

Design
Determination of control group and the intervention by random allocation (simple randomization).For both groups, the headphones are placed for 20 minutes each day for 3 days.In the intervention group, music is played but not in the music control group.Richmond is evaluated before and after intervention in each group.At the end of the third day, the results are evaluated and compared

Settings and conduct
Patients admitted to the ICU in Shahid Rajaee Hospital who have criteria for entering the study are in the intervention group and ICU 2 in the control group.For both groups, the headphones are placed for 20 minutes each day for 3 days.In the intervention group,non word music approved by the association will be played but in the control group will not be played.Richmond is evaluated before and after intervention in each group.

Participants/Inclusion and exclusion criteria
Entry Criteria: Having a tracheal tube from entry or on the first day of hospitalization in the unit, mechanical ventilation, Age between 16 and 70 years, Informed consent; Non-entry criteria: Psychological disorder, Hemodynamic disorders, Addiction, Deafness and hearing problems, The ability to communicate verbally

Intervention groups
For both intervention and control groups, the headphones are placed for 20 minutes each day for 3 days.In the intervention group,non word music approved by the association will be played but in the control group will not be played.Richmond is evaluated before and after intervention in each group.

Main outcome variables
Agitation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180918041060N1**
Registration date: **2019-05-19, 1398/02/29**
Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**
Update count: **0**

Registration date
2019-05-19, 1398/02/29

Registrant information

Name
Narges Seyfi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3460 0724

Email address
n.seyfi@abzums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-02, 1397/07/10

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of music on the agitation on the basis of Richmond in intubated patients admitted to the Medical ICU

Public title
Music in agitation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having a tracheal tube from entry or on the first day of hospitalization in the unit mechanical ventilation Age between 16 and 70 years Informed consent
Exclusion criteria:
Psychological disorder Hemodynamic disorders Addiction Deafness and hearing problems The ability to communicate verbally
Age
From **16 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Alborz University of Medical Sciences and Health Services
Street address
safariyan estreet, 45 yards of Golshahr
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2018-08-05, 1397/05/14
Ethics committee reference number
IR.ABZUMS.REC.1397.063

Health conditions studied

1

Description of health condition studied
Restlessness and agitation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
agitation
Timepoint
before and 20 minutes after intervention
Method of measurement
Richmond

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, the headphones are placed for 20 minutes each day for 3 days and non word music approved by the association will be played.The Richmond scale is evaluated before and after intervention.
Category
Treatment - Other

2

Description
Control group: The routine care
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei
Full name of responsible person
Narges Seyfi
Street address
Shahid Rajaei Hospital, Shahid Beheshti, Hesarak
City
Karaj
Province
Alborz
Postal code

3197635141

Phone
+98 26 3457 0030

Fax

Email
narges.seyfi.1986@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
DR Mohammad Noorisepehr

Street address
Shahid Rajaei Hospital, Shahid Behshti Ave,Hesarak

City
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narges.seyfi.1986@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Karaj 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
Karaj University of Medical Sciences

Full name of responsible person
Narges Seyfi

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Rajaei Hospital, Shahid Behshti Ave, Hesarak

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable