Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing The Effect Of Nature-Based Sound On Quality Of Sleep Among Hospitalized Patients In Intensive Care Units

Protocol summary

Summary

1)Aim: Investigate the effect of nature-based sound on quality of sleep among patients admitted intensive care units.2) Design: The study is a randomized clinical trial with both control and intervention group.3) Setting and conduct: Participants randomly will divide to 3 groups(receive sounds of nature with headphone , receive no sound of nature through headphone (silence), control). 4)Participants: Patients in intensive care units.5) Intervention: In the sounds of nature group for two days and up to 30 minutes will get the sounds of nature and in silence group for two days and up to 30 minutes will receive no audio through headphone.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015121325394N2**
Registration date: **2016-03-02, 1394/12/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-03-02, 1394/12/12

Registrant information

Name

Maryam Nasari

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 4422 2951

Email address

nasari.m@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University Of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing The Effect Of Nature-Based Sound On Quality Of Sleep Among Hospitalized Patients In Intensive Care Units

Public title

The Effect Of Nature-Based Sound On Quality Of Sleep

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: At least 18 years old, Being in ICU at least for two nights, Do not have sleeping disorders, Do not have mental and auditory disorders, Not taking anti-depressants and anesthesia drugs, Recognizing time and place and people, Not taking addictive drugs 5 or 6 hours before intervention. Exclusion criteria: Appearance of sever problems such as hemodynamic instability and unconsciousness, Cardiac pulmonary arrest during the study, Emergency prescribed drugs such as anti-depressants and anesthesia drugs, Leaving hospital before 3 days intervention.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway , Tehran
City
Tehran
Postal code
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
IR.IUMS.REC.1394.9311449008

Health conditions studied

1

Description of health condition studied
Nonorganic Sleep Disorders
ICD-10 code
F51
ICD-10 code description
Nonorganic Sleep Disorders

Primary outcomes

1

Description
Quality of Sleep
Timepoint
Before and After study
Method of measurement
Richards Campbell Sleep Questionnaire

Secondary outcomes

1

Description
Blood Pressure
Timepoint
Before and After Study
Method of measurement
Manometer

Intervention groups

1

Description
Listen to natural sound with headset for two days (30 minutes in any session)
Category
Other

2

Description
Putting headphone without receiving any sound for two days (30 minutes any time)
Category
Other

3

Description
There is no intervention in control group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Maryam Nasari
Street address
Firoozgar Hospital, Beh Afarin Street, Karim Khane Zand Street,Valiasr Street, Tehran
City
Tehran

2

Recruitment center

Name of recruitment center
Sahahid Rajaei Heart Education, Research And Therapy Center

Full name of responsible person
Maryam Nasari

Street address
The Intersection Niayesh, Valiasr Street

City
Tehran

3

Recruitment center

Name of recruitment center
Hazrate Rasool Hospital

Full name of responsible person
Maryam Nasari

Street address
Hazrate Rasool Hospital, Niyayesh Street, Sattarkhan Street, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor For Research, Iran University of Medical Sciences

Full name of responsible person
Naser Bakht

Street address
Iran University Of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor For Research, Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
School of Nursing & Midwifery of Iran University

Full name of responsible person
Maryam Nasari

Position
MSc Student of Nursing

Other areas of specialty/work

Street address
School of Nursing & Midwifery, Rashid Yasemi Street, Valiasr Street, Tehran

City
Tehran

Postal code
7971754739

Phone
+98 76 4422 2951

Fax
+98 76444222951

Email
maryamnasari65@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School Of Nursing & Midwifery of Iran University

Full name of responsible person
Tahere Najafi

Position
Ph.D In Nursing

Other areas of specialty/work

Street address
School Of Nursing & Midwifery, Rashid Yasemi street, Valiasr street, Tehran

City
Tehran

Postal code
1996713883

Phone
+98 218888288500

Fax
+98 21 8820 1978

Email
Najafi.t@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Nursing & Midwifery of Iran University

Full name of responsible person
Maryam Nasari

Position
MSc Student of Nursing

Other areas of specialty/work

Street address

School of Nursing & Midwifery, Rashid Yasemi Sreett, Valiasr street, Tehran

City

Tehran

Postal code

Phone

+98 76 4422 2951

Fax

Email

maryamnasari65@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty