Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of nature-based sounds’ intervention on physiological signs of anxiety and agit

Protocol summary

Summary

The purpose of this study was to investigate the effect of nature-based sounds’ intervention on physiological signs of anxiety and agitation in patients under mechanical ventilator support in intensive care units of selected hospitals in Tehran. This study is a randomized controlled trial, 60 patients undergoing mechanical ventilator were randomly assigned to the control and experimental groups. All participants were provided with information about the intervention. The patients in the experiment group were given nature-based sounds through an audiotape via fixed earphones. The patients assigned to the control group were asked to wear the foam-lined headphone and rest in silence for a similar time frame as the intervention group. Two groups are assessing without earphones, 30 minutes after finishing the procedure.The intensity of anxiety and agitation expressed by the participants were measured using the visual analogue Richmond Agitation Sedation Scale (RASS) and and Faces Anxiety Scale (FAS) for four times. (after intervention,30 minutes after intervention, 60 minutes after intervention, 90 minutes after intervention, 30 minutes after finish of the intervention)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207277529N2**
Registration date: **2012-08-17, 1391/05/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-08-17, 1391/05/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2012-01-05, 1390/10/15

Expected recruitment end date

2012-07-05, 1391/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nature-based sounds’ intervention on physiological signs of anxiety and agit

Public title

effect of nature-based sounds’ intervention on anxiety and agitation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The patients were aged between 18 and 65 years; who were under mechanical ventilation support for 48 hours in an ICU ; had Glasgow Coma Scale Point 9 or above; were able to hear and see ; were not drug-addicted; were not receiving beta blocker and

inotropic support were not taking any neuromuscular blocker agent and antihypertensive drug; had no facial signs of being scared; had no currently using a N-BS intervention; had no psychiatric or neurological illnesses Exclusion criteria: Subjects were extubations from mechanical ventilation; need emergency dose- stat sedative ; Patient withdraws from study.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahed University

Street address
Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran

City
Tehran

Postal code

Approval date
2012-05-08, 1391/02/19

Ethics committee reference number
4/148499

Health conditions studied

1

Description of health condition studied
Generalized anxiety disorder

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
agitation

Timepoint
after intervention,30 minutes after intervention, 60 minutes after intervention, 90 minutes after intervention(end intervention), 30 minutes after finish of the intervention

Method of measurement
The visual analog scale Richmond Agitation Sedation Scale(RASS)

Secondary outcomes

1

Description
agitation

Timepoint
after intervention,30 minutes after intervention, 60 minutes after intervention, 90 minutes after intervention(end intervention), 30 minutes after finish of the intervention

Method of measurement
Faces Anxiety Scale (FAS)

Intervention groups

1

Description
In interventional group who received the N-BS intervention consisted of 90 minutes of listening to the N-BS (birds' song, soothing rain sounds, river stream)subjects were assessed in the last thirty minutes without headphones and sounds playing. The nature sounds were played using a MP3 media player (Leono Inc., Guangzhou, China) through disposable foam-lined headphones The average sound pressure level was set to 25-50 dB. For all samples is recording physiological parameters of agitation and anxiety score hemodynamic

Category
Other

2

Description
In the control group which received only The patients assigned to the control group were asked to wear the foam-lined headphone and rest in silence for a similar time frame as the intervention group to minimize unpleasant environmental noises or stimuli. This group is assessed in the last thirty minutes without headphones and sounds playing.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghiatallah University of Medical Sciences
Full name of responsible person
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Vice Chancellor for Research of Shahed University
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Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
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

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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