Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compare the effect of music therapy and foot reflexology on physiological parameters and pain in patients with non traumatic loss of consciousness in intensive care unit at Imam Ali Hospital, Zahedan 2015

Protocol summary

Summary

This randomized clinical trial will be conducted to compare the effect of music therapy and foot reflexology on physiological parameters and pain in patients with non-traumatic loss of consciousness in intensive care unit. The study population was the ventilated patients in intensive care unit at Imam- Ali Hospital, Zahedan 2014 .90 patients were selected according to inclusion criteria and then were randomly allocated through permuted blocks into three groups of music therapy, foot reflexology and control. The main inclusion criterion is GCS between 5-8 and having intubation. The exclusion criterion is having any fracture or trauma. In music therapy group, patients listen to music through headphones for 30 minutes per day during three consecutive days between 16 to 18 hours. In the second intervention group, foot reflexology will be done 15 minutes for each foot and totally 30 minutes per day during three consecutive days between 16 to 18 hours.The pain score and vital sign (pulse rate, respiration, blood pressure, arterial oxygen saturation) of patients will record 5 minutes before and immediately after the each intervention. Measuring of pain and vital signs will be done with the same interval in the control group. Pain and vital sign record after intervention as primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051722300N1**
Registration date: **2016-01-09, 1394/10/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-09, 1394/10/19

Registrant information

Name

Sarah Sheikh

Name of organization / entity

Zahedan Univercity Of Medical Science, School of Nursing & Midwifery

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of music therapy and foot reflexology on physiological parameters and pain in patients with non traumatic loss of consciousness in intensive care unit at Imam Ali Hospital, Zahedan 2015

Public title

Compare the effect of music therapy and foot reflexology

on physiological parameters and pain in patients with non traumatic loss of consciousness in intensive care unit at Imam Ali Hospital, Zahedan 2015

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: the level of consciousness of the patient based on the GCS between 5 and 8 and able to respond to painful stimuli; The patient's hemodynamic status is stable water and electrolytes; Lake of hearing defect ; Age over 18 years; The first is a history of hospitalization in ICU; patient doesn't have neuromuscular disorders and sensory-motor paralysis or does not receive the paralysis drug; Patient has been healthy feet, especially in the feet and toe; Lack of chronic pain in other parts of the body such as migraine and backache; Exclusion criteria: any fracture or trauma; Fixed invasive catheters except endotracheal tubes and IV; The patient is awake and extubated during the study; The type and dose analgesic is change by doctors; Transfer to the operating room for surgery; substantial drop in the level of consciousness; The patient's guardian does not consent to continue participating in the study; Received anti-hypertensive and pressor drugs;

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences

Street address
Pardis Zahedan Univercity Of Medical Science, Doctor Hesabi Square

City
Zahedan

Postal code
9816743463

Approval date
2015-05-24, 1394/03/03

Ethics committee reference number
IR.ZAUMS.REC.1394.52

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52-R52.9

ICD-10 code description
Pain, not elsewhere classified-Pain, unspecified

Primary outcomes

1

Description
Behavioral pain scale

Timepoint
5 minutes before and immediately after the intervention

Method of measurement
Measuring tools BPS (Behavioral pain scal)

2

Description
Systolic blood pressure

Timepoint
5 minutes before and immediately after the intervention

Method of measurement
observation of Monitoring

3

Description
Diastolic blood pressure

Timepoint
5 minutes before and immediately after the intervention

Method of measurement
observation of Monitoring

4

Description
pulse

Timepoint
5 minutes before and immediately after the intervention

Method of measurement
observation of Monitoring

5

Description
respiratory rate

Timepoint
5 minutes before and immediately after the intervention

Method of measurement
observation of Monitoring

6

Description
Arterial oxygen saturation(sao2)
Timepoint
5 minutes before and immediately after the intervention
Method of measurement
observation of Monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Listening to music with headphones. Intervention time during three consecutive days for 30 minutes at 16 to 18
Category
Behavior

2

Description
Reflexology on the feet of the patient by the investigator. Intervention for 3 consecutive days for 30 minutes at 16-18
Category
Behavior

3

Description
Resting in bed for 30 minutes without any intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ebne Abitaleb Hospital
Full name of responsible person
Mohammad Nasir Tabatabai
Street address
Ali Ebne Abitaleb Hospital, khalije Fars Blvd
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Science
Full name of responsible person
Hoshang Rafighdost
Street address
Pardis Zahedan Univercity Of Medical Science, Doctor Hesabi Square,
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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
Zahedan University of Medical Science
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
Zahedan University of Medical Science, School of Nursing & Midwifery
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Sarah Sheikh
Position
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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