Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of natural voice and family voice on pain and physiological indices in unconscious patients

Protocol summary

Study aim
Comparison the effect of natural voice and family voice on pain and physiological indices in unconscious patients

Design
Clinical trial,Control group, With parallel groups,One blind, with random

Settings and conduct
Place of study in special wards of Imam Khomeini hospital in Tehran After sampling and randomization in three control groups and two intervention groups, in the intervention group Patients' Voice, one patient acquaintance's voice recorded for 15 minutes by the headphones for two weeks in the morning. And the evening is done. In the upper group of nature, the recorded sound of nature is played by the headphones for 15 minutes for the patient. This is done for two weeks in both morning and evening. Pain and physiological parameters are recorded before and after the intervention. The control group did not receive any intervention. Finally, the collected data will be analyzed by SPSS 16 software Blindness is such that participants and caregivers are unaware of random assignment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Minimum enrollment age is 18 years No previous history of intensive care unit admission Patient with low level of consciousness (Glasgow coma score of 5-9) Lack of hearing (hearing loss) in the person No bandage or ear surgery Lack of paralysis in four organs of the body No hearing aids Pain in the patient based on CPOT instrument (minimum score of 1) No high-dose painkillers and sedatives No use of neuromuscular blockers Non-fracture in diseased organs

Intervention groups
In the intervention group, the voice of the patient's acquaintances was recorded by a patient's voice recorder for 15 minutes with the headphones on. In the intervention group, the voice of nature was muted by the headphones for 15 minutes. The control group did not receive any intervention.

Main outcome variables
pain and physiological indices in unconscious patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190908044729N1**
Registration date: **2019-09-21, 1398/06/30**
Registration timing: **prospective**

Last update: **2019-09-21, 1398/06/30**
Update count: **0**

Registration date
2019-09-21, 1398/06/30

Registrant information

Name
Kaveh Ebadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6105 4000

Email address
k-ebadi@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-12, 1398/07/20

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of natural voice and family voice on pain and physiological indices in unconscious patients

Public title
effect of nature phonics and voice of patient acquaintances on pain and vital criteria in patients with decreased consciousness

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum enrollment age is 18 years Patient with low level of consciousness (Glasgow coma score of 5-9) Lack of hearing (hearing loss) in the person No bandage or ear surgery Lack of paralysis in four organs of the body No hearing aids Pain in the patient based on CPOT instrument (minimum score of 1)

Exclusion criteria:
-fracture in diseased organs use of neuromuscular blockers high-dose painkillers and sedatives previous history of intensive care unit admission Unstable hemodynamic status

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling is done in two stages. In the first step, the samples will be included in the study based on inclusion criteria in a continuous method. The second step, namely assigning the samples to the three groups, will be randomized as starting from letter A for the nature sound group, and letter B for the familiar voice group and letter c for the control group. Then write all the permutations of the letters A, B, and C, which are 6 different combinations, on the six cards: 1- ABC 2- ACB 3- BAC 4- BCA 5- CAB 6- CBA Then we ask the nurse number 1 to randomly select a card. For example, if card number 2 is selected, the concept is that the first one is assigned to the voice of nature, the second to the control group, and the third to the familiar voice, and this is continued. Allow the sample size to reach quota

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants themselves are not randomly assigned to randomization due to reduced level of consciousness. Clinical caregivers (nurses, physicians, physiotherapists, etc.) are not in the process of being randomized.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Organizational Committee of School of Nursing and Midwifery and Rehabilitation

Street address
School of Nursing Midwifery ,Tehran University of Medical Sciences Nosrat st. Tohid sq. Tehran I.IRAN

City
Tehran

Province
Tehran

Postal code
141973317

Approval date
2019-09-08, 1398/06/17

Ethics committee reference number
IR.TUMS.FNM.REC.1398.103

Health conditions studied

1

Description of health condition studied
unconscious patients

ICD-10 code
R40.2

ICD-10 code description
Coma

Primary outcomes

1

Description
pain: A pain score, which is measured by the CRITICAL-CARE PAIN OBSERVION TOOL criterion, ranging from 0 to 8. Its value is measured before and after the intervention.

Timepoint
Immediately before and after the intervention for two weeks in the morning and evening

Method of measurement
CRITICAL-CARE PAIN OBSERVION TOOL Pain Assessment Tool

2

Description
Physiological indices: Physiological indices in this study are systolic and diastolic blood pressure, mean arterial blood pressure, heart rate, respiratory rate and arterial blood oxygen level, measured by monitoring device before and after intervention in the experimental and control groups.

Timepoint
Immediately before and after the intervention for two weeks in the morning and evening

Method of measurement
Cardiovascular Monitoring Machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: family voice, in this intervention, physiological indices such as respiratory rate, heart rate, blood pressure and arterial blood oxygenation were measured using a monitoring device, and the patient's pain level was calculated using the CPOT instrument, and then the familiarity sound A patient who has a closer and more intimate relationship with the voice of a family member (the person whose voice is recorded by family members and chosen by the principal's opinion) and its content including (the individual (family member) after Introduce yourself to the patient, talk about the patient and the patient's location and the reason for their hospitalization. It starts by defining a memory that the patient is expected to be interested in) via the mp3 plyer, using a headphone for 15 minutes, and immediately afterwards physiological indices including respiratory rate, number Heart rate, blood pressure, and arterial blood oxygen are measured using a monitoring device and the patient's pain level is calculated using the CPOT tool. This is done twice in the morning and in the evening for 2 weeks. That is, pain levels and physiological indices were measured daily for 2 weeks before the intervention and also after the intervention in the morning and evening.

Category
Other

2

Description
Intervention group: natural voice, he Voice of Nature group first measured physiological indices including respiratory rate, heart rate, blood pressure, and arterial blood oxygen level using a monitoring device, and the patient's pain score was calculated using the CPOT instrument. And then the sound of nature (one of the sounds of the Divine) is transmitted to the patient via mp3 plyer using headphones for 15 minutes and immediately thereafter the physiological indices including respiratory rate, heart rate, blood pressure and arterial blood oxygen level. It is measured using a monitoring device and the patient's pain score is calculated using the CPOT tool. This is done twice in the morning and in the evening for 2 weeks. That is, pain levels and physiological indices were measured daily for 2 weeks before the intervention and also after the intervention in the morning and evening.

Category
Other

3

Description
Control group: Does not receive any intervention

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Tehran

Full name of responsible person
Kaveh Ebadi

Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Square

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 6192 7171

Email
k-ebadi@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Mohamad Ali Sahraeiyan

Street address
Deputy of Research and Technology, Sixth Floor, Central Organization ofTehran University of Medical Sciences, Ghods St, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1419733171

Phone
+98 21 8163 3619

Email
nmcrc@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Kaveh Ebadi
Position
MSc Medical Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
k-ebadi@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mojdeh Navidhamidi
Position
Ph.D. of Medical Physiology
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4307
Email
m-navid@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Kaveh Ebadi
Position
MSc Medical Surgical Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Nosrat St., Tohid Square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
k-ebadi@razi.tums.ac.ir

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

make this available