

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 pleyer, 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 pleyer 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 of Tehran 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