Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of hearing stimuli (familiar sounds and preferred music) on intracranial blood pressure level, level of consciousness, cortisol level and vital signs of severe head injury patients.

Protocol summary

Study aim
Determine the effect of auditory stimuli (preferred music and familiar sounds) on vital symptoms (pulse rate, blood pressure, mean arterial blood pressure, temperature) blood cortisol hormone level, level of consciousness, intracranial pressure in intensive care unit patients Shahid Rajaee Hospital of Shiraz.

Design
A randomized controlled clinical trial with parallel groups, single blind

Settings and conduct
The study was performed at Shahid Rajaee Hospital in Shiraz twice daily between 7 am and 6 pm, For two weeks with blinded data collection, the researcher used the hands free for patients during 30 minutes.

Participants/Inclusion and exclusion criteria
Inclusion criteria; Aged over 17 and under 60, Informed consent of the patient's family, GCS of 3 to 8, vital signs stable, presence of ICP transducer in patient's head, 4 hour after receiving narcotic Exclusion criteria; History of cardiovascular disease , Hypertension, Infection, Epilepsy, Prior Stroke or concussion history, Endocrine disorder, Cushing, Diabetes, Liver Failure, Kidney Failure, Brain Tumor, Alcoholism, Syncope, Hearing loss,, Major Fractures such as Limbs, Abdomen, Chest, Injury to the patient's ears by accident, Patient's family dissatisfaction at each stage of intervention, Narcotic Addiction, otorrhea, Severe smokers,Taking drugs that lead to anesthesia, taking corticosteroids, Drug and food poisoning Concurrent with a severe head injury, Blindness, bilateral eyelid inflammation or ptosis

Intervention groups
control group, patients receive routine care, Preferred Music Group:Patient Preferred Music Band based on the patient's family history, they receive music of their interest and familiar group: the patient receives the voice of the most intimate member of his or her family or friends.

Main outcome variables
Vital symptoms, intracranial pressure, blood cortisol level, level of consciousness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191230045944N1**
Registration date: **2020-03-26, 1399/01/07**
Registration timing: **retrospective**

Last update: **2020-03-26, 1399/01/07**
Update count: **0**

Registration date
2020-03-26, 1399/01/07

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2013-09-23, 1392/07/01

Expected recruitment end date
2014-04-21, 1393/02/01

Actual recruitment start date

2013-09-23, 1392/07/01

Actual recruitment end date

2014-09-23, 1393/07/01

Trial completion date

2014-10-07, 1393/07/15

Scientific title

The effect of hearing stimuli (familiar sounds and preferred music) on intracranial blood pressure level, level of consciousness, cortisol level and vital signs of severe head injury patients.

Public title

The effect of hearing stimuli (familiar sounds and preferred music) on intracranial blood pressure level, level of consciousness, cortisol level and vital signs of severe head injury patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People between 18 and 60 years Informed consent of the patient's family, Glasgow coma score between 3 and 8, Vital signs are constant, Intracranial pressure transducer in patient's head, It's been 4 hours since the last time a patient was given a painkiller,

Exclusion criteria:

History of cardiovascular disease Hypertension, Infection, Epilepsy, Prior Stroke or concussion history, Endocrine disorder, Cushing, Diabetes, Liver Failure, Kidney Failure, Brain Tumor, Alcoholism, Syncope, Hearing loss, Major Fractures such as Limbs, Abdomen, Chest, Injury to the patient's ears by accident, Patient's family dissatisfaction at each stage of intervention, Narcotic Addiction, otorrhea, Severe smokers, Taking drugs that lead to anesthesia, taking corticosteroids, Drug and food poisoning Concurrent with a severe head injury, Blindness, bilateral eyelid inflammation or ptosis

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **54**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Fifty-four patients were divided into three groups of 18 (control, preference music, and familiar voice) using simple randomization via dice throwing. Dice numbers 1 and 2 were used for the control group, 3 and 4 for the familiar group, and 5 and 6 for the preferred music group. The throw of the dice continued until the end of the sampling. For whatever reason, if the patient were removed from any group, the dice would be thrown again. And by inserting headphones and MP3 for the patient by the researcher, blinding the outcome collector was done.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data collector was not aware of the type of groups, and the accuracy of the MPTRIs and Freemasons geometry was verified by the researcher.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman Medical Sciences

Street address

Kerman, Beginning of the Axis of the Seven Gardens of Alavi, Campus of the University of Medical Sciences

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kerman

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7616913555

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

10/40/3815

Health conditions studied

1

Description of health condition studied

Patients with severe head injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The level of blood cortisol levels

Timepoint

The first morning before and after the intervention.

Method of measurement

Due to the patient's rights and the high cost of this trial, it was measured twice in only one intervention.Blood sampling was performed by the same collector of outcomes in the Same way. The blood samples were immediately sent to the laboratory of Shahid Rajaee

Hospital in Shiraz and put in a centrifuge. The centrifuge was set for five minutes and thirty rounds. After centrifuging the samples, the serum was removed by blood sampling. Serum samples were kept at -20 ° C until the end of the study. At the end of sampling, patients' serum samples were transferred to another laboratory due to lack of laboratory facilities at Shahid Rajaee Hospital in Shiraz. And all patient serum samples in a laboratory were measured by one person using a device with identical kits.

2

Description
The level of intracranial pressure
Timepoint
Before, during, and after the intervention twice daily for three days
Method of measurement
An S1800-ER monitoring device was used to measure intracerebroventricular pressure in patients with severe head trauma admitted to critical care units. It has TFT color display.Patient-related parameters were measured momentarily and updated. Intracerebral pressure was measured using a ventriculostomy implanted by a neurosurgeon within the patient's brain ventricle. Which, due to its aggressive procedure, was used only in patients who, according to their own medical needs, were diagnosed by a neurosurgeon in order to monitor intraocular pressure,The other end of the ventriculostomy was connected to the monitoring device by a transducer

3

Description
The level of consciousness
Timepoint
Before, during, and after the intervention twice daily for twelve days
Method of measurement
Using the Glasgow Coma Scale, the level of consciousness of patients with severe head injury was measured.

4

Description
blood pressure
Timepoint
Before, during, and after the intervention twice daily for twelve days
Method of measurement
Monitoring model S1800-ER was used to measure blood pressure in patients with severe head injury admitted to intensive care units.

5

Description
heart rate
Timepoint
Before, during, and after the intervention twice daily for twelve days
Method of measurement
The S1800-ER monitoring device was used to measure heart rate in patients with severe head injury admitted to intensive care units.

6

Description
Temperatures
Timepoint
Before, during, and after the intervention twice daily for twelve days
Method of measurement
The S1800-ER monitoring device was used to measure the armpit temperature of patients with severe head injury in intensive care units.

7

Description
Mean arterial pressure
Timepoint
Before, during, and after the intervention twice daily for twelve days
Method of measurement
The S1800-ER monitoring device was used to measure mean arterial pressure in patients with severe head injury admitted in intensive care units.

8

Description
Cerebral perfusion pressure
Timepoint
Before, during, and after the intervention twice daily for three days.
Method of measurement
We reduced the mean arterial pressure from intracranial pressure.

Secondary outcomes

1

Description
Level of consciousness, intracranial pressure level, blood cortisol level, vital signs
Timepoint
Before, during and after the intervention twice daily for two weeks
Method of measurement
Using the Glasgow Coma Scale, intracranial blood pressure transducer, cardiovascular monitoring device, blood sampling and sending to the laboratory

Intervention groups

1

Description
First intervention group: Familiar voices were heard for

thirty minutes. Which, based on the patient's family history, recorded the most intimate voice of the patient in a quiet environment. And there was no whimper or cryingwhen recording the sound.While talking to the patient several times, they called the patient by the name they were calling home and in their intimate surroundings. And the person who was recording his voice introduced himself to the patient in his own cultural language at the beginning of the recording. She told the patient what had happened to her and was admitted to the intensive care unit. And he assured the patient to keep track of his treatment and return to health. And they talked about what was going on in the last month and what they were going to do after the patient recovered.

Category

N/A

2

Description

Control group: These patients were receiving routine care in the intensive care unit, and no other new work was being done in the twelve days they were monitored. The headphone was used for thirty minutes for this group of patients who did not make any noise to ensure that the outcome collector was not aware of the control group.

Category

N/A

3

Description

Preferred Music group:The patient's favorite music sound was played for thirty minutes based on the patient's family history of using the headphones.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaee Hospital of Shiraz

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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http://research.sums.ac.ir/fa/index.html#

Grant name
It is done at a personal cost

Grant code / Reference number
0

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

Title of funding source
Shiraz 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Bam University of Medical Sciences

Full name of responsible person
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Latest degree
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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information about the main outcome can be shared

When the data will become available and for how long
Access started 6 months after printing.

To whom data/document is available
All interested people in academic, scientific and industrial institutions have permission to use.

Under which criteria data/document could be used
Systematic review and ongoing research in this field

From where data/document is obtainable
parvin delavari; parvin.delavari@yahoo.com

What processes are involved for a request to access data/document
Apply via e-mail

Comments