Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of auditory stimulation with job sound on consciousness level in comatose traumatic brain injury patients

Protocol summary

Study aim
Determining the effect of auditory stimulation with job sound on changes in consciousness level in patients with traumatic brain damage

Design
Controlled clinical trial with parallel group, double-blind, randomized

Settings and conduct
Patients in the control group receive ICU routine sounds (common sensory stimuli, staff voice, device alarms, accompanying voice during a visit, etc.). Patients in the intervention group, in addition to receiving ICU routine sounds, twice a day for 10 days (20 times in total) at 11 am and 17 pm each time for 15 to 20 minutes each day for their own work-related sounds by the patient's family at work The person is picked up using headphones using a single voice recorder. The recorded sound level level will be adjusted using the acoustic meter so that all recorded and used audio levels have a sound level of 60-70 dB.

Participants/Inclusion and exclusion criteria
Entry requirements: • Having a traumatic brain injury condition • GCS score of eight and less • Age from 15 to 65 years • The patient was employed before the incident • Hemodynamic stability of the patient • No history of previous brain damage • Lack of disturbance or loss of previous hearing • Lack of blood or cerebrospinal fluid from the ear and nose • Non-sedating medicines • Absence of a skull fracture, bleeding (according to CT scan reports), or temporal area surgery.

Intervention groups
Patients in the control group receive routine ICU auditory stimuli. Patients in the intervention group received in addition to routine ICU sounds, their own work-related sounds through headphone.

Main outcome variables
level of consciousness

General information

Reason for update

Acronym
TBI

IRCT registration information
IRCT registration number: **IRCT20171209037801N1**
Registration date: **2019-04-01, 1398/01/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-01, 1398/01/12**
Update count: **0**

Registration date
2019-04-01, 1398/01/12

Registrant information

Name
Mohammad Goudarzi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3774 0815

Email address
goodarzi77@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-05-21, 1398/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of auditory stimulation with job sound on consciousness level in comatose traumatic brain injury patients

Public title
The effect of auditory stimulation with job sound on consciousness level in comatose traumatic brain injury patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
• Status of traumatic brain coma • GCS score of eight and less • Age from 15 to 65 years • Being employed before the accident • Hemodynamic stability of the patient
Exclusion criteria:
Blood or cerebrospinal fluid out of the ear or nose History of previous brain damage Disturbance or loss of previous hearing The presence of a skull fracture, bleeding (according to CT scan reports), or temporal surgery Get sedative medications
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Traumatic brain comatose patients, on admission list after reviewing and conditions of the study, using a randomized block, divided into two experimental and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients and outcome evaluators are blinded to study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical
Street address
Nosrat st. Tohid sq. Tehran I.IRAN
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2019-03-17, 1397/12/26
Ethics committee reference number
IR.TUMS.FNM.REC.1397.216

Health conditions studied

1

Description of health condition studied
Traumatic Brain Injury
ICD-10 code
S06.0-S06.
ICD-10 code description
Concussion- Traumatic cerebral oedema- Diffuse brain injury- Focal brain injury- Epidural haemorrhage- Traumatic subdural haemorrhage- Traumatic subarachnoid haemorrhage- Intracranial injury with prolonged coma- Other intracranial injuries- Intracranial i

Primary outcomes

1

Description
Level of consciousness traumatic brain comatose patients
Timepoint
Twice a day for 10 days before and after the intervention.
Method of measurement
Glasgow Coma Scale-Full Outline of Un Responsiveness

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to receiving ICU routine sounds, they received auditory stimulation with headphones twice a day for 10 days (20 times in total) at 11 am and 17 pm each time for 15 to 20 minutes with their own job sounds.Job sound is collected by the patient's family in the work environment of patient using a single voice recorder.
Category
Rehabilitation

2

Description
Control group: Patients in the control group receive ICU routine sounds (common sensory stimuli, staff voice, device alarms, accompanying voice during a visit, etc.).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Forghani hospital
Full name of responsible person
Masoumeh Zakerimoghadam
Street address
Qom, Nekouei Square
City
Qom
Province
Ghoum
Postal code
3715873355
Phone
+98 25 3133 1175
Fax
+98 25 3721 1069
Email
Nekoeihospital@muq.ac.ir
Web page address
http://nekuei.muq.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masoumeh Zakerimoghadam
Street address
Nosrat st. Tohid sq
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6691 4368
Fax
+98 21 6105 4170
Email
nursing_intl@tums.ac.ir
Web page address
http://www.fnm.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of Research of 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
Masoumeh Zakerimoghadam
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nosrat st. Tohid sq
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6691 4368
Fax
+98 21 6105 4170
Email
zakerimo@sina.tums.ac.ir
Web page address
http://www.fnm.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masoumeh Zakerimoghadam
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery

Street address
Nosrat st. Tohid sq
City
Tehran
Province
Tehran
Postal code
141973317
Phone
+98 21 6691 4368
Fax
+98 21 6105 4170
Email
zakerimo@sina.tums.ac.ir
Web page address
http://www.fnm.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masoumeh Zakerimoghadam
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Nosrat st. Tohid sq
City
Tehran
Province
Tehran
Postal code
141973317
Phone
+98 21 6691 4368
Fax
+98 21 6105 4170
Email
zakerimo@sina.tums.ac.ir
Web page address
http://www.fnm.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
Undecided - It is not yet known if there will be a plan to make this available
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