

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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 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

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Qom, Nekouei Square

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Ghous

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghadam

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nursing_intl@tums.ac.ir

Web page address

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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

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Contact

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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