Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of music on the level of consciousness of Traumatic brain injury patients

Protocol summary

Study aim
The results of this study may increase the level of alertness of head injured patients in the intensive care unit and promote the use of non-pharmacological treatments, such as music in special units

Design
A clinical trial design with a control group, single blind, randomized

Settings and conduct
The study will be conducted in Shahid Rajaee and razi hospitals in Qazvin for 7 days.

Participants/Inclusion and exclusion criteria
Patients aged 18-65 years old. The level of consciousness based on Glasgow coma scale is less than 8. The patient is admitted with a diagnosis of trauma brain injury including subdural , epidural, intracerebral, ventricular and subarachnoid hemorrhage. The setation is based on the Richmond criteria in the range of 2+ to 2. 48 hours from the time of admission. exclusion criteria: discontent of the patient's companions to continue the study. Patients with vegetable status according to doctor's diagnosis. Patients with severe previous head injury. The history of alcohol use and pre-incident drug use according to family statements. Loss of consciousness is suddenly more than 3 scores based on the Glasgow coma scale during the intervention.

Intervention groups
In the intervention group, smooth and unconventional beach walking, Stein will be selected from the Top-Hits zum Entspannen Vol.1 album. This music will be played in the intervention group with a beat of 60 to 80 beats per minute with MP3 PLAYER for 15 minutes. Music selected once a day ,Music will be at 16-18 pm, Music will be played through headphones for 7 days.The control group will only receive the usual activities of the department

Main outcome variables
level of consciousness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190106042259N1**
Registration date: **2019-02-19, 1397/11/30**
Registration timing: **prospective**

Last update: **2019-02-19, 1397/11/30**
Update count: **0**

Registration date
2019-02-19, 1397/11/30

Registrant information

Name
saeedeh doust mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3523 9125

Email address
s.doustmohammadi@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of music on the level of consciousness of Traumatic brain injury patients

Public title
The Impact of Music on the Level of consciousness the traumatic brain injury patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-65 years old The level of consciousness based on Glasgow coma scale less than 8 The patient is admitted with a diagnosis of. traumatic brain injury including subdural , epidural, intracerebral, ventricular and subarachnoid hemorrhage. The sedation is based on the Richmond critera in the range of 2+ to 2 24 hours after vital signs are stable No previous hearing loss is reported by the family No Dressing in the ear According to the orthopedics doctor, patients should have at least one healthy hearing position
Exclusion criteria:
Dissatisfaction the companions of the patient to continue participating in the study Patients with vegetable status according to doctor's diagnosis The history of alcohol use and pre-incident drug use according to family statements. Loss of consciousness is suddenly more than 3 scores based on the Glasgow coma scale during the intervention.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **54**
More than 1 sample in each individual
Number of samples in each individual: **27**
The research units will include patients who have entered the research criteria and will enter the study in two groups of control and Intervention. 54 patients (women and men) will be placed in two groups of intervention and control, each of which will contain 27 samples. Satisfaction will be taken from executor patient. Patients with an alertness level of less than 8 scores based on the Glasgow coma scale will be selected
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are selected by convenient sampling method. Using simple random sampling method, two groups of intervention and control using separate drawings of two red and white balls (without placement) will be performed, so that the white ball indicates the control group And the red ball indicates the intervention group
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Shafa hospital,Fakuri street,Takestan,Qazvin-
City
Qazvin
Province
Qazvin
Postal code
3481993656
Approval date
2019-01-06, 1397/10/16
Ethics committee reference number
IR.QUMS.REC.1397.276

Health conditions studied

1

Description of health condition studied
Level of consciousness in traumatic brain injury
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
level of consciousness
Timepoint
The level of consciousness will be measured for 7 days 5 minutes before the performance and 10 minutes after the completion of the music
Method of measurement
level of consciousness will be measured based on Glasgow coma scale

Secondary outcomes

empty

Intervention groups

1

Description
Music intervention in the intervention group will be

performed through a part of the work of Arend Stein for 7 sessions and 15 minutes through the headphones.

Category
Rehabilitation

2

Description
Control group: The control group will receive routine care only

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaei and Razi Hospital in Qazvin city

Full name of responsible person
Saeedeh doust mohammadi

Street address
Shafa hospital,Fakouri street,Takestan,Qazvin

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3481993656

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saeedeh.dm6475@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
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Shafa hospital,Fakuri street,Takestan,Qazvin

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Grant name

Grant code / Reference number

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

Title of funding source
Qazvin University of Medical Sciences

Proportion provided by this source
50

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
Qazvin University of Medical Sciences

Full name of responsible person
Saeedeh doust mohammadi

Position
Nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
saeedeh doust mohammadi

Position
nurse

Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

Contact

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Position

nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Not applicable

Title and more details about the data/document

Information on the main consequence of sharing is possible

When the data will become available and for how long

One year after the start of sampling

To whom data/document is available

All people

Under which criteria data/document could be used

In order to use in traumatic care units to increase the level of consciousness in patients with truamatic brain injury

From where data/document is obtainable

Qazvin University of Medical Sciences

What processes are involved for a request to access data/document

The data will be collected by the researcher after receipt of the clinical trial code and the written consent of the patient.

Comments