Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of music on the vital signs and agitation of Traumatic brain injury patients admitted to traumatic intensive care units of selected hospitals in Qazvin

Protocol summary

Study aim
The results of this study may reduce the restlessness and hemodynamic improvement of the 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, Not blind, randomized

Settings and conduct
The study will be conducted in Shahid Rajaee and razi hospitals in Qazvin .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.The control group will receive routine care only

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
vital signs and agitation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190106042259N2**
Registration date: **2019-04-20, 1398/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-20, 1398/01/31**
Update count: **0**

Registration date
2019-04-20, 1398/01/31

Registrant information

Name
saeedeh doust mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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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 vital signs and agitation of Traumatic brain injury patients admitted to traumatic intensive care units of selected hospitals in Qazvin

Public title
Investigating the effect of music on the vital signs and agitation of Traumatic brain injury patients

Purpose
Health service research

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 72 hours after admission 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 Physician satisfaction for the study

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**

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
2019-03-03, 1397/12/12

Ethics committee reference number
IR.QUMS.REC.1397.388

Health conditions studied

1

Description of health condition studied
vital signs and agitation in traumatic brain injury

ICD-10 code
S06.9

ICD-10 code description
head injury NOS

Primary outcomes

1

Description
vital signs and agitation

Timepoint
vital signs and agitation will be measured for 7 days 5 minutes before the performance and 10 minutes after the completion of the music

Method of measurement
Restlessness based on the Richmond criteria and vital signs will be monitored by the monitoring device.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 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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saeedeh.dm6475@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Amir Peimani
Street address
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
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Person responsible for updating data

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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 Improve hemodynamics and restlessness 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 and Accept permission from the patient physician.

Comments