

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Rajaei 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 setting 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)

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 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 criteria 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 dust mohammadi

Street address

Shafa hospital,Fakouri street,Takestan,Qazvin

City

Qazvin

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3481993656

Phone

+98 28 3523 9125

Email

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

City

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

Leili Yekehfallah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Saeedeh Duost Mohammadi
Position
Nurse
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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