

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of the combined music program with family reminiscence on level of consciousness and cognitive function of Patients With Traumatic Brain Injury In Intensive Care Unit

Protocol summary

Study aim

Determination The effect of the combined music program with family reminiscence on level of consciousness and cognitive function of Patients With Traumatic Brain Injury In Intensive Care Unit

Design

The present study is a randomized clinical trial with parallel, three-blind, and control group that was conducted on 30 patients With Traumatic Brain Injury admitted to the ward of Shahid Kamyab Hospital in Mashhad. Patients were randomly divided into two groups by software before the intervention stage

Settings and conduct

A research project in the intensive care unit of Shahid Kamyab Hospital in Mashhad, a researcher-specialized center in Mashhad University of medical sciences in the field of accidents and trauma During the study a research project in the intensive care unit of Shahid Kamyab Hospital in Mashhad, a researcher-specialized center in Mashhad University of medical sciences in the field of accidents and trauma

Participants/Inclusion and exclusion criteria

Patients admitted to the intensive care unit after traumatic brain injury with level of consciousness of less than 8 and sustained hemodynamic status in terms of water and electrolyte were enrolled. At the end of the study, patients whose their hodynamic status were unstable in terms of water and electrolyte were excluded.

Intervention groups

Patients in the intervention group receive the combined music program with family reminiscence. This combined music program with family reminiscence featuring frequent reminders of events and good experiences of the patient's past personal life is recounted and broadcasted through the headphone. The control group will be the patients who, apart from the usual sounds of

environment and possibly GCS that check the patients, do not receive any other stimuli.

Main outcome variables

Level of consciousness in patients with Traumatic Brain and their cognitive function

General information

Reason for update

Acronym

MPWFR

IRCT registration information

IRCT registration number: **IRCT20180602039947N1**

Registration date: **2018-08-07, 1397/05/16**

Registration timing: **prospective**

Last update: **2018-08-07, 1397/05/16**

Update count: **0**

Registration date

2018-08-07, 1397/05/16

Registrant information

Name

Hamid Hoseini

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of the combined music program with family reminiscence on level of consciousness and cognitive function of Patients With Traumatic Brain Injury In Intensive Care Unit

Public title
Investigating the Effect of Music Composition Program with Family Memory Remedies on the Level of consciousness and cognitive function

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Hospital less than 3 days Age (60-14) Brain trauma patients with GCS less than 8 Not having a history of delirium, dementia and admission to a mental hospital Stable hemodynamic status of patients in terms of water and electrolyte Not having hearing impairment that prevents you from hearing music through the headphones Satisfied to participate in the study. Not having a skull fracture or bleeding or surgery in the temporal region Not having aethera or reneur No swelling of both eyelids or both eyes
Exclusion criteria:
Incomplete or corrupted patient records Sending the patient to other treatment centers Unwillingness to continue cooperation in the study The hemodynamic status of patients in terms of water and electrolyte is unstable

Age
From **14 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are entered into the study on the basis of entry criteria, and then divided into two intervention and control groups based on random block assignment (quadruple blocks). The number of samples in this study will be 30 people

Blinding (investigator's opinion)
Triple blinded

Blinding description

The blinding process will be such that the researcher or researcher does not know about the allocation of patients to the two intervention and control groups. Also, patients will be unaware from that in which one of the study groups Also, the statistics consultant who is responsible for analyzing information is unaware of the allocation of individuals to study groups

Placebo

Not used

Assignment

Parallel

Other design features

Considering that coma is one of the traces of traumatic brain injury and patients suffering from changes in level of consciousness and functional skills for a period of time Therefore, non-medical interventions can be used to stimulate patients in coma after severe brain damage, as non-invasive, low-risk, low-cost interventions for patients with coma Among these non-medical interventions that enhance awareness and arousal of the patient in coma, live performance and playback of music In this way, a music program with family memories that includes a frequent reminder of past events and past experiences of the patient's personal life is recounted and mused by the family, then the headache is traumatized to the patient Ultimately, the patient's alertness will be measured using the Glasgow table and cognitive function using the RLA.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committe of Mashhad University of Medical Sciences

Street address

Ahmadabad Ave Faculty of Nursing and Midwifery of Mashha

City

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Approval date

2018-08-03, 1397/05/12

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.016

Health conditions studied

1

Description of health condition studied

Traumatic Brain Injury

ICD-10 code

So6

ICD-10 code description

Incranial injury

Primary outcomes

1

Description

Level of consciousness in patients with traumatic brain injury

Timepoint

Patient Level of consciousness using Glasgow's coma table 5 minutes before and 10 and 30 minutes after the combined music program with family reminiscence is performed Will be measured

Method of measurement

By Glasgow coma scale (GCS)

2

Description

Level of Cognitive Function of Patients

Timepoint

Using Rancho Los Amigos Scale, the cognitive function of patients 5 minutes before and 10 and 30 minutes after the combined music program with family reminiscence is performed Will be measured

Method of measurement

By Rancho Los Amigos Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Patients in the intervention group the combined music program with family reminiscence, in which a music program featuring family memories frequent reminders of events and past experiences of the patient's personal life is recounted and mused by the family, then a head trauma is traumatic to the patient

Category

Other

2

Description

Control group:The control group will be patients who, apart from the usual sounds of the environment and possibly GCS that check the patient, do not receive any other stimuli

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care unit of Shahid Kamyab Hospital in Mashhad

Full name of responsible person

Razieh Frootan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Razieh Frootan

Position

Faculty trainer

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of secondary data analysis

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available