Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Music therapy for cognitive and emotional rehabilitation in mild traumatic brain injury: a randomized controlled trial

Protocol summary

Study aim

To evaluate the effectiveness of listening to instrumental Western classical music on improving cognitive function and mood, and reducing post-concussion symptoms in patients with mild traumatic brain injury.

Design

A phase II randomized, double-blind, parallel-group controlled clinical trial in 100 patients; allocation to music therapy or control groups using variable block randomization.

Settings and conduct

After informed consent, patients ≥18 years old with mild traumatic brain injury admitted to Imam Hossein Hospital will be enrolled and randomly assigned to music therapy or control groups using variable block randomization. The intervention group will listen to instrumental classical music for 1 hour daily until 14 days after discharge, while the control group will receive standard care only. Assessments will be performed at admission and at 2 weeks, 1, 3, 6, and 12 months after discharge.

Participants/Inclusion and exclusion criteria

Patients ≥18 years old with an initial diagnosis of mild traumatic brain injury admitted to general wards. Inclusion criteria: ability to understand and follow study instructions, access to a music player and headphones, and willingness to participate in follow-up. Exclusion criteria: prior TBI, major neurological disease, severe psychiatric disorder, significant hearing impairment, active substance or alcohol abuse, or inability to complete questionnaires.

Intervention groups

Intervention group: In addition to standard care, patients will listen to instrumental Western classical music with headphones for 1 hour daily from day 2–3 of hospitalization until 14 days after discharge and record it. Control group: Patients will receive standard care only

Main outcome variables

The Cambridge Neuropsychological Test Automated Battery (CANTAB)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120910010800N17**
Registration date: **2026-05-19, 1405/02/29**
Registration timing: **prospective**

Last update: **2026-05-19, 1405/02/29**
Update count: **0**

Registration date

2026-05-19, 1405/02/29

Registrant information

Name

Dariush Abtahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-20, 1405/02/30

Expected recruitment end date

2027-05-20, 1406/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Music therapy for cognitive and emotional rehabilitation in mild traumatic brain injury: a randomized controlled trial

Public title

The role of music therapy in cognitive and emotional rehabilitation in mild traumatic brain injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The ability to understand and implement study instructions Access to a music player and headphones Consent to participate in the study

Exclusion criteria:

Previous history of moderate or severe TBI Major neurological disorders (e.g., stroke, epilepsy, Parkinson's, MS) Previous severe psychiatric disorders Deafness or significant hearing problems that prevent listening to music Active substance or alcohol abuse Inability to complete the questionnaires (even with assistance)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent and conducting baseline assessments, eligible participants will be randomly assigned to either the music therapy or the control group. The random allocation sequence will be generated using variable block randomization with block sizes of 4 and 6. This sequence will be created by an independent statistician using a computerized random number generator. To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes will be used. Outcome assessors will remain blinded to the patients' group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind, randomized controlled clinical trial, both the participants (patients) and the researchers interacting with the patients (including the investigators providing the training and those conducting clinical follow-ups) will be unaware of group allocation, while the control group receives no intervention other than standard treatment. To achieve this, despite the control group not receiving any intervention, in order to blind the participants, all patients in both groups will be told that "you may be assigned to one of the study groups (music therapy group or comparison group) in the future," without informing the control group that they will not receive any intervention. Additionally, researchers interacting with the patients will not be informed of group allocation, and only an independent individual outside the research team will know which group each patient belongs to. To maintain blinding, all assessment and follow-up sessions will be conducted by researchers who are neither aware of the patient's group nor have had any role in the allocation or intervention implementation process. Finally, the success of blinding will be assessed by asking participants and involved researchers about their guess regarding group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

Street address

Emam Hossein Hospital, Shahid Madani St.

City

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Province

Tehran

Postal code

1617763141

Approval date

2025-11-09, 1404/08/18

Ethics committee reference number

IR.SBMU.RETECH.REC.1404.736

Health conditions studied

1

Description of health condition studied

Cognitive and Emotional Rehabilitation of Patients with Traumatic Brain Injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

cognitive function

Timepoint
At the time of hospital admission (baseline, before initiation of the intervention or allocation), and subsequently at 2 weeks, 1 month, 3 months, 6 months, and 12 months after hospital discharge.

Method of measurement
The Cambridge Neuropsychological Test Automated Battery (CANTAB) is an innovative computerized tool designed to assess brain function with precision and reliability.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in this group, in addition to receiving standard care, will listen daily for one hour (preferably at a fixed and quiet time of the day) to a standardized playlist of instrumental Western classical music using headphones. This intervention will begin on the second or third day of hospital admission and will continue at home for 14 days after discharge. Participants will be provided with a daily logbook to record the time and duration of music listening. The quality of the audio files and the suitability of the headphones will be checked.

Category
Treatment - Other

2

Description
Control group: Participants in this group will receive only the usual standard care for mild traumatic brain injury, which may include recommendations regarding rest, symptom management, and a gradual return to activities. No structured music intervention will be provided to them. To control for the attention effect, participants in this group may also be given logbooks to record their daily activities (other than music).

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital Emam Hossein

Full name of responsible person
Dariush Abtahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshhin Zarghi

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dariush Abtahi

Position
Associate Professor

Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Some portions of the data, such as information related to the primary outcome and similar variables, may be available for sharing.
When the data will become available and for how long
One year after the publication of the article
To whom data/document is available
All professions involved in this research
Under which criteria data/document could be used
All non-personal patient information (anonymously) can be accessed by contacting the responsible author.
From where data/document is obtainable
email to: drdariushabtahi@yahoo.com
What processes are involved for a request to access data/document
Sending email and review by the responsible author.
Comments