

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effects of calm music on physiological indexes (Oxygen saturation,heart rate,respiratory rate, systolic, diastolic blood pressure,main arterial pressure, Pulse pressure and central temperture) of patients with traumatic brain injuries in intensive care units of shahid beheshti medical university hospitals in 2011

Protocol summary

Summary

The purpose of this research is evaluation of light music on physiological parameters of patients with traumatic brain injuries at intensive care units of teaching hospitals affiliated with Shaheed Beheshti Medical University. This research is a quasi-experimental study in which 35 patients with traumatic brain injuries will be enrolled. Physiological parameters and level of consciousness (LOC) of subjects will be measured and compared at 5 minute before and after the end 10 minutes of listening to light music.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012145392N1**

Registration date: **2011-05-16, 1390/02/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-16, 1390/02/26

Registrant information

Name

Marzieh Maleki

Name of organization / entity

Shaheed Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 21 2224 3293

Email address

mmaleki@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shaheed Beheshti University of Medical Sciences

Expected recruitment start date

2011-05-02, 1390/02/12

Expected recruitment end date

2011-06-22, 1390/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of calm music on physiological indexes (Oxygen saturation,heart rate,respiratory rate, systolic, diastolic blood pressure,main arterial pressure, Pulse pressure and central temperture) of patients with traumatic brain injuries in intensive care units of shahid beheshti medical university hospitals in 2011

Public title

Music therapy in patients with head injuries

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: presence of traumatic brain injuries at intensive care units (ICU), GCS between 8 to 10, stable hemodynamic situation (e.g. fluid and electrolytes), no any auditory defects, not receiving continues IV sedative drugs, age 18 to 49 years old, no admission more than

one month Exclusion criteria: imbalance hemodynamic or death, GCS decreased to less than 8 or increased more than 10 during the intervention phase

Age

From **18 years** old to **63 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shaheed Beheshti University of Medical Sciences

Street address

Shaheed Beheshti University of Medical Sciences,
beside the Taleqani hospital, Yaman St, Shaheed
Chamran highway

City

Tehran

Postal code

1985717443

Approval date

2011-05-02, 1390/02/12

Ethics committee reference number

89-01-86-7473-5471

Health conditions studied

1

Description of health condition studied

head Injuries

ICD-10 code

S00

ICD-10 code description

Injures to head

Primary outcomes

1

Description

Respiratory rate

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

Observation the chest movements(up and down movements) in rate per minute

2

Description

Heart rate

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

Radial pulse palpation, in rate per minute

3

Description

Pripheral arterial oxygen saturation(SPO2)

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

pulse oxymeter in percent

4

Description

Systolic blood pressure

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

Sphyngomanometer in mmhg

5

Description

Diastolic blood pressure

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

Sphyngomanometer in mmhg

6

Description

Central body temperture

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

Tympanic thermometer in centigrad degree

7

Description

Mean Arterial Pressure

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

Physiological Parameters form

8

Description

Pulse pressure

Timepoint

5 minute before music listening, at the end of music listening And 10 minute after that

Method of measurement

Physiological Parameters form

Secondary outcomes

1

Description

level of consciousness

Timepoint

before and after music listening

Method of measurement

Glasgow Coma Scale (GCS)

Intervention groups

1

Description

Light Music : The patient will listen to light music for sequence of 3 days at 16 to 18 o'clock for 15 minutes each session through headphones.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadye Tajrish Hospital

Full name of responsible person

Mahnaz Nik Peyma(MSN)

Street address

Tajrish Square

City

Tehran

2

Recruitment center

Name of recruitment center

Hakim Loqman Hospital

Full name of responsible person

Fatemeh Goodarzi (MSN)

Street address

Hakim Loqman Hospital, Kamal St, Lashkar crossroads, South Kargar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences. nursing midwifery college

Full name of responsible person

Mohammad Ghaderi

Street address

Nursing midwifery college, crossroads valieaser with niaiesh, valieaser St.

City

Tehran

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. nursing midwifery college

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nursing midwifery college, Shaheed Beheshti Medical Sciences university.

Full name of responsible person

Marzieh Maleki

Position

MSN, team leader in clinical skills

Other areas of specialty/work

Street address

Nursing midwifery college, crossroads valieaser with niaiesh, valieaser St

City

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax

-

Email

mmaleki@sbmu.ac.ir,mmaleki5@yahoo.com

Web page address

sbnmf@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shaheed Beheshti nursing midwifery Coleage

Full name of responsible person

Marzieh Maleki

Position

MSN ,team leader in clinical skills

Other areas of specialty/work

Street address

Nursing midwfery college, crossroads valieaser with niaiesh, valieaser St.

City

Tehran

Postal code

1985717443

Phone

+98 218865536671

Fax

Email

mmaleki5@yahoo.com, mmaleki@sbmu.ac.ir

Web page address

sbnmf@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shaheed Beheshti nursing midwifery College

Full name of responsible person

Mohammad Ghaderi

Position

Master nursing student

Other areas of specialty/work

Street address

Nursing midwfery college, crossroads valieaser with niaiesh, valieaser St

City

Tehran

Postal code

9698113879

Phone

+98 53 3622 4610

Fax

-

Email

ghaderi.mohammad1@gmail.com

Web page address

-

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty