

# 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 temperature) 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 temperature) 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**

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-

**Email**

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

**Web page address**

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## 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**

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## 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**

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-

**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*