

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of music therapy on comfort of open heart surgery patients

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of music therapy on the comfort of patients undergoing coronary artery bypass surgery. In this clinical trial study, 62 patients who will undergo coronary artery bypass surgery and are hospitalized in hospitals affiliated to Tehran University of Medical Science, after the purposive sampling will be assigned randomly to experiment and control groups. Before the commence of the intervention, patients' comfort will be measured by using a questionnaire derived from the idea of kolcaba general comfort questionnaire with three physical, environmental and psychological dimensions. While patients in the control group will be at rest for half an hour in bed, patients in the experiment group will listen to their preferred music that is instrumental and relaxing for half an hour. Finally, once again patients' comfort will be measured and compared.

#### General information

##### Acronym

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##### IRCT registration information

IRCT registration number: **IRCT201310234443N6**

Registration date: **2013-12-04, 1392/09/13**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-04, 1392/09/13

##### Registrant information

###### Name

Masoumeh Zakerimoghadam

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2286 2160

##### Email address

zakerimo@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2013-11-22, 1392/09/01

##### Expected recruitment end date

2014-02-20, 1392/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of music therapy on comfort of open heart surgery patients

##### Public title

Effect of music therapy on comfort of patients undergoing open heart surgery

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study; Undergoing non-emergency open heart surgery for the first time; Age between 30 to 75 years old; Stable hemodynamic condition such as systolic blood pressure higher than 90 mmHg, lack of life threatening dysrhythmia and a heart rate between 60 and 100 bpm; Having no mental disorders; Understanding Persian language; Not drug and alcohol addicted; Willingness to hear music; Having no hearing impairment that prevents using headphones; Being conscious and oriented to time, place and person; Undertaking a routine surgical procedure in the operating room such as saphenous vein

graft without unexpected events such as severe bleeding or prolong operation; Having no underlying chronic disease that disturb patient comfort such as discopathy. Exclusion criteria: Suffering from acute complications associated with surgery such as bleeding more than 200cc/h of chest tubes, cardiac tamponade, life threatening dysrhythmias or any emergency condition that requires immediate intervention; Willingness to quit from the study; Death during the study.

**Age**

From **30 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **62**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

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**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

**Street address**

Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd

**City**

Tehran

**Postal code**

1419733171

**Approval date**

2013-11-09, 1392/08/18

**Ethics committee reference number**

92/130/1772/5

**Health conditions studied****1****Description of health condition studied**

Heart surgery

**ICD-10 code**

I97.1

**ICD-10 code description**

Other functional disturbances following cardiac surgery

**Primary outcomes****1****Description**

Comfort

**Timepoint**

Immediately before and after the clinical trial

**Method of measurement**

kolcaba General Comfort Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention: Playing instrumental and relaxing music through headphones for half an hour.

**Category**

Other

**2****Description**

Control: Resting on bed for half an hour.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Elyas Soltani

**Street address**

Imam Khomeini Hospital, Dr Mirkhani St, Tohid Sq

**City**

Tehran

**2****Recruitment center****Name of recruitment center**

Shariati Hospital

**Full name of responsible person**

Elyas Soltani

**Street address**

North Kargar St

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mr Madadi

**Street address**

Keshavarz Blvd, Central Organization of Tehran  
University of Medical Sciences

**City**

Tehran

**Grant name**

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**Grant code / Reference number**

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**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Elyas Soltani

**Position**

M.s of Critical Care Nursing

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Masoumeh Zakerimoghadam

**Position**

Phd Student

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## Person responsible for updating data

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## 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*