Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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; Stabile 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

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/د

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
--
Grant code / Reference number
--
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
School of Nursing and Midwifery, Dr Mirkhani St, Tohid Sq
City
Tehran
Postal code
1419733171
Phone
+98 21 6694 3187
Fax
+98 21 6690 4252
Email
soltani_75@yahoo.comsoltani.chenar@gmail.com
Web page address
--

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masoumeh Zakerimoghadam
Position
Phd Student
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Dr Mirkhani St, Tohid Sq
City
Tehran
Postal code
1419733171
Phone
+98 21 6693 7120
Fax
+98 21 6690 4252
Email
zakerimo@gmail.com
Web page address
--

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elyas Soltani
Position
Master of Science in critical care Nursing
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Dr Mirkhani St, Tohid Sq
City
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
+98 21 6690 4252
Email
soltani_75@yahoo.comsoltani.chenar@gmail.com
Web page address
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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