Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Music on the Quality of Sleep in Patients with Heart Failure

Protocol summary

Study aim
Determining the effect of music on quality of sleep in patients with heart failure

Design
Randomized controlled clinical trial with control group design of 38 patients in each group. Blocked randomization with quadruple blocks of patients and the formation of random strings and sampling based on it.

Settings and conduct
The research community included patients with heart failure and the research environment is the cardiac ward of the selected hospital of the Social Security Organization in Tehran. Research samle: Patients with heart failure admitted to the cardiac ward of the selected hospital of Social Security Organization in Tehran that are studied according to entry criteria and are examined.

Participants/Inclusion and exclusion criteria
A confirmed diagnosis of HF(EF<40%); HF functional class II to IV according to New York Heart Association classification; Poor sleep quality according to Pitsburge sleep quality index; Age above 18 years; Stable situation of disease; No taking hypnotic drugs or medication with sleep complications when entering the study; No habit of listening to nature sound music for sleep; No existence of intra cardiac defibrillator; No sever neurologic disorder such as Parkinson's or Alzheimer's

Intervention groups
Intervention is the music box of the sounds of nature with the combination of classical nonverbal music. Patients in the intervention group, in addition to receiving regular care, listen to the music through headphones and for 30 minutes during 7 nights before bedtime. Patients in the control group receive only the usual care of the ward.

Main outcome variables
Evaluation of sleep quality in patients with heart failure; The Effect of Music on Improving Sleep Quality in Patients with Heart Failure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100725004443N25**
Registration date: **2019-01-09, 1397/10/19**
Registration timing: **retrospective**

Last update: **2019-01-09, 1397/10/19**
Update count: **0**

Registration date
2019-01-09, 1397/10/19

Registrant information

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Masoumeh Zakerimoghadam

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2018-06-05, 1397/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Music on the Quality of Sleep in Patients with Heart Failure

Public title
The Impact of Music on Sleep in Heart Failure
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
A confirmed diagnosis of HF by cardiologist HF functional classification I to IV according to New York Heart Association Age above 18 years Poor sleep quality according to pitsburge sleep quality index Stable situation of disease
Exclusion criteria:
Cancellation of participation in research Entry into the acute phase of disease Reduce level of consciousness Deafness The habit of listening to nature sound music for sleep Existence of intra-cardiac implantation defibrillator(ICD) Discharge earlier than 3 days Sever neurologic disorders such as Parkinson's or Alzeimer's
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization type is blocked randomization. Foursquare blocks of intervention group(A) and control(B) are defined on cards 1-6 (AABB,ABAB,ABBA,BBAA,BABA,BAAB), the cards are placed inside the envelope. Then the cards are selected randomly and then random string is created from the sequence of selected cards. Patients in the intervention and control group are included in the study according to this sequence. During the intervention, the curtains around the patient's unit are pulled.
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
Ethics committee of Tehran university of medical sciences
Street address
Office building of Tehran University of medical Sciences, Keshavarz St, Tehran.
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2018-01-23, 1396/11/03
Ethics committee reference number
IR.TUMS.FNM.REC.1396.4352

Health conditions studied

1

Description of health condition studied
Heart Failure
ICD-10 code
I50.2
ICD-10 code description
Systolic (congestive) heart failure

Primary outcomes

1

Description
Poor sleep quality score in Pittsburgh sleep quality questionnaire
Timepoint
Measurement of sleep quality before intervention and 7 days after listening to the nature sounds music
Method of measurement
Pittsburgh Sleep Quality Index Past Week Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in addition to receiving the usual care of the ward, they listen to the music box sounds of nature with the combination of classical music through headphones for 30 minutes before night sleep, during 3 days of hospitalization.
Category
Treatment - Other

2

Description
Control group: patients receive usual care of the ward.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad hospital
Full name of responsible person
Masoumeh Zakerimoghadam
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Sponsors / Funding sources

1

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Web page address
Grant name
Tehran University of Medical Sciences
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
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
Tehran University of Medical Sciences
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Position
Nursing education PHD, Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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