

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 sample: 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 Pittsburgh 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 severe 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

##### 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

##### 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 pittsburge 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 Alzheimer'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

**Street address**

No.12734,near by Iran university of medical science,Hemat Highway, Tehran

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**Postal code**

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**Email**

www.miladhospital@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadali Sahraian

**Street address**

Research deputy of Tehran University of Medical Sciences, No. 21, Qods St., Keshavarz Blvd., Tehran Town,

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**Fax****Email**

msahrai@tuma.ac.ir

**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

**Full name of responsible person**

Zakerimoghadam Masoumeh

**Position**

Nursing education PHD, Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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Eastern Nosrat street, Tohid square

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing midwifery faculty of Tehran university of medical sciences

**Full name of responsible person**

Zakerimoghadam Masoumeh

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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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