

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The Effect of music on sleep quality of hemodialysis patients

Protocol summary

Summary

Main aim: To determine the effect of music on sleep quality in patients undergoing hemodialysis. Inclusion criteria: The age of the patients between 60-18 years, At least 6 months treated with hemodialysis, At least 2 times a week and a maximum of 3 times a week hemodialysis, The patient's history according to the sleep disorder is not a major handicap, hearing, cognitive or neurological disorders, sensory experience or not, have advanced heart disease and pulmonary edema, The patient is not suffering from mental disorders, The patient is not addicted to drugs, willingness to participate in the study and use of music have . Exclusion criteria: Cooperation in study discontinuation for any reason, during the study of major physical or mental patient for the accident happens, The patient is unwilling to continue the collaboration. Study design: Block randomization method using two intervention group and a control group of population are divided. Case study: All hemodialysis patients referred to the Hospital of hemodialysis Shiraz University of medical sciences. The sample size $n = 105$. Studied interventions: Before the start of the intervention of the questionnaire to all patients completed the Pittsburgh sleep quality. for a month for the two groups (Group during dialysis and group home before bedtime) music Play through headphones. One week after the end of the fourth week the Pittsburgh sleep quality questionnaire again for patients complete. During this period the control group received routine care

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050217546N5**

Registration date: **2016-05-15, 1395/02/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellery for research affairs

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of music on sleep quality of hemodialysis patients

Public title

The Effect of music on sleep quality of hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The age of the patients between 60-18

years, At least 6 months treated with hemodialysis, At least 2 times a week and a maximum of 3 times a week hemodialysis, The patient's history according to the sleep disorder is not a major handicap, hearing, cognitive or neurological disorders, sensory experience or not, have advanced heart disease and pulmonary edema, The patient is not suffering from mental disorders, The patient is not addicted to drugs, willingness to participate in the study and use of music have . Exclusion criteria: Cooperation in study discontinuation for any reason, During the study of major physical or mental patient for the accident happens, The patient is unwilling to continue the collaboration.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

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

Single 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 Shiraz University of Medical Sciences

Street address

Shiraz, 7th floor, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Postal code

1978-71345

Approval date

2016-04-24, 1395/02/05

Ethics committee reference number

IR.SUMS.REC.1395.19

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

chronic renal failure

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

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

sleep quality

Timepoint

before intervention, one week after finishing the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

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

The control group receives routine care

Category

N/A

2**Description**

For a month for the two groups (Group during dialysis and group home before bedtime) music playback through headphones.

Category

Lifestyle

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

Shiraz Namazi Hospital, Mamasani Vali-e-Asr Hospital

Full name of responsible person

Mohsen ranjbar

Street address

Fars, Mamasani Vali-e-Asr Hospital

City

Mamasani

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Vice chancellery for research affairs

Full name of responsible person

Dr Sayed Baser Hashemi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellery for research affairs

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**

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh momennasab

Position

Assistant professor

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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