Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Name of organization / entity
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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 afterfinishing 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
Street address
Shiraz, 7th floor, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
City
Shiraz
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
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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