

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of natural sounds on fatigue and sleep quality of hemodialysis patients.

Protocol summary

Study aim

This study was designed with the aim of determining the effect of nature sounds on sleep quality and fatigue in hemodialysis patients.

Design

This research is a randomized interventional study with a control group and Single blind. It will be conducted on 82 patients. For randomization, minimization method and sealed envelope will be used..

Settings and conduct

This research is a Single blind study (The outcome assessor will not know about the allocation of samples in the studied groups). which will be performed on patients referred to the dialysis department of Ali Ibn Abi Talib Hospital and Rafsanjan Special Medical Center. After obtaining the code of ethics, one of the researchers will refer to the research environment and explain the objectives of the research and how to do the work to the qualified patients. And the patients will complete a written informed consent form if they wish to participate in the research.

Participants/Inclusion and exclusion criteria

Being over 18 years old Not having a medication regimen that affects the quality of sleep Absence of hearing impairment Obtaining a score above 5 on the PSQI scale

Intervention groups

In the intervention group, the sounds of nature will be played for 4 weeks, every night for 30 minutes, before going to bed. These people will be taught to lie down in a comfortable position while listening to music in a quiet environment with low light and a suitable and balanced temperature. Close your eyes and breathe regularly. For the control group, they should be placed in a quiet environment, with low light and suitable and balanced temperature, lie down in bed and in a comfortable position. Close your eyes and breathe regularly

Main outcome variables

sleep quality, fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230619058529N1**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

Registration date

2024-03-02, 1402/12/12

Registrant information

Name

Amin Saharkhiz

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2025-04-04, 1404/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of natural sounds on fatigue and sleep quality of hemodialysis patients.	
Public title	Investigating the effects of natural sounds on fatigue and sleep quality of hemodialysis patients
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Being over 18 years old No alcohol addiction or smoking Having enough mental and cognitive power to answer questions and use hands-free or the presence of family members to help the patient to play music and use hands-free Not experiencing a crisis during the past 6 months Obtaining a score above 5 on the PSQI scale Awareness of place, time and person Not having a medication regimen that affects the quality of sleep Exclusion criteria: having hearing impairment unwillingness to cooperate
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Outcome assessor
Sample size	Target sample size: 82
Randomization (investigator's opinion)	Randomized
Randomization description	Eligible samples will be placed in two intervention and control groups in a random minimization method (based on the classes of the sleep quality score of the basic measurement). The randomization units will be entered into the study individually, the first sample will be randomly drawn through a sealed envelope, and the next sample will be assigned to the next group with the same sleep quality class as the baseline measurement. This process will continue until reaching the desired sample size of the study.
Blinding (investigator's opinion)	Single blinded
Blinding description	This research is a randomized intervention study with a control group and a Single blind, (The outcome assessor will not know about the allocation of samples in the studied groups).
Placebo	Not used
Assignment	Other
Other design features	
Secondary Ids	empty

Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Rafsanjan University of Medical Sciences
Street address	NO 7717758764, School of Nursing and Midwifery, Nursing Boulevard, Rafsanjan, Kerman
City	rafsanjan
Province	Kerman
Postal code	7717758764
Approval date	2023-03-12, 1401/12/21
Ethics committee reference number	IR.RUMS.REC.1401.252
Health conditions studied	
<u>1</u>	
Description of health condition studied	The subject of study is not a disease
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	Sleep quality: the number of people who scored more than 6 from the Petersburg sleep quality questionnaire.
Timepoint	On the first day of the intervention, the pre-test will be performed. And within two days after the end of the intervention, sleep quality questionnaire will be filled again for both groups.
Method of measurement	Petersburg Sleep Quality Questionnaire
<u>2</u>	
Description	Fatigue: Fatigue is described as a lack of mental and physical energy, and in this research, fatigue is the score obtained by patients from the multidimensional fatigue evaluation scale.
Timepoint	On the first day of the intervention, the pre-test will be performed. And within two days after the end of the intervention, a fatigue questionnaire will be filled again for both groups.
Method of measurement	Multidimensional fatigue questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, the sounds of nature will be played for 4 weeks, every night for 30 minutes, half an hour before sleep. The sounds of nature used in this study will be the artwork "Sounds of Nature" by Dr. Arendstein, recorded in 2011. These sounds include birds chirping, sea waves, river and forest sounds and the sound of rain. The audio will be played in MP3 format. Before listening to the sounds of nature, these people will be taught to lie down in bed in a comfortable position, in a quiet room without anyone's traffic, with a suitable and balanced temperature and low light, while listening to the sounds of nature, adjust the volume to a level that they feel comfortable, not to worry about turning off the music, not to talk to anyone while listening, close their eyes while listening to the sounds of nature, and focus on them and breathe regularly.

Category

Treatment - Other

2

Description

Control group: It is also recommended for the control group to be placed in a quiet environment, with low light and a suitable and balanced temperature, to lie down in bed and in a comfortable position, similar to the intervention group. Close your eyes and breathe regularly.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafsanjan University of Medical Sciences, Ali Ibn Abi Talib Hospital, Dialysis Department

Full name of responsible person

Tayyaba Naghban Banabi

Street address

NO 7717758764, School of Nursing and Midwifery, Nursing Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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NO 7717758764, School of Nursing and Midwifery, Nursing Boulevard,

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Tayyaba Naghban Banabi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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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

Not applicable

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