Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of Aromatherapy and Music on the sleep quality in hemodialysis patients

Protocol summary

Study aim
This study will aim to compare the effectiveness of aromatherapy and music on sleep quality in hemodialysis patients.

Design
Unblinded, parallel-group, randomized, crossover clinical trial on 60 patients undergoing hemodialysis. Simple randomization using sealed envelopes will be used for randomization.

Settings and conduct
For patients in the music group, silent music will be played for 10 minutes right when the patient is in bed, using a smartphone without headphones or a headset for one month. For patients in the aromatherapy group, lavender scent will be inhaled in the form of a small gauze soaked in lavender essential oil, which will be pinned to the patient's collar right at the beginning of going to bed, for one month. Then, both groups will have a washout for one month, and then the intervention used by the patients will be changed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18, history of at least 3 months of hemodialysis, score of 5 or higher on the Pittsburgh Sleep Quality Questionnaire, and having a smartphone (yours or a partner living with you) to transfer the desired music file. Exclusion criteria: Having a smell problem (olfactory health test with lemon juice), having a known allergy to lavender, having a history of addiction or dependence on sleeping/tranquilizing drugs, and having a history of alcohol or drug addiction

Intervention groups
The one intervention group received aromatherapy (pure lavender essential oil; 100%). The latter intervention group received selected music (Baran Eshghe by Naser ChashmAzar) in accordance with Iranian culture.

Main outcome variables
Patients' sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120109008665N17**
Registration date: **2025-08-12, 1404/05/21**
Registration timing: **prospective**

Last update: **2025-08-12, 1404/05/21**
Update count: **0**

Registration date
2025-08-12, 1404/05/21

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-16, 1404/05/25

Expected recruitment end date
2025-11-16, 1404/08/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of Aromatherapy and Music on the sleep quality in hemodialysis patients

Public title
Comparison of the effects of Aromatherapy and Music on the sleep quality in hemodialysis patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Over 18 years old History of at least 3 months of hemodialysis Score of 5 or higher on the Pittsburgh Sleep Quality Questionnaire Having a smartphone (yours or someone you live with) to transfer the desired music file
Exclusion criteria:
Having a smell problem (olfactory health test with lemon juice) Having a known allergy to lavender Having a history of addiction or dependence on sleeping/tranquilizing drugs Having a history of alcohol or drug addiction

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of samples (to two experimental groups) will be done by simple random method using sealed envelopes. 60 envelopes with one of the letters A or M in them (30 envelopes each) will be prepared, and the selection of the envelope will be done randomly by the patients. In this method, the letter A represents the aromatherapy group, and the letter M represents the music group. In this way, the number of samples of both groups will be random and equal.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Semnan University of Medical Sciences
Street address
Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran
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3519899951

Approval date
2025-07-21, 1404/04/30

Ethics committee reference number
IR.SEMUMS.REC.1404.110

Health conditions studied

1

Description of health condition studied
Sleep quality in hemodialysis patients

ICD-10 code
F 51.0

ICD-10 code description
بی‌خوابی غیر ارگانیک

Primary outcomes

1

Description
Sleep quality

Timepoint
In four stages: at the beginning of the study, one month after the initial intervention, after the washout period, and at the end of the study.

Method of measurement
Sleep quality will be measured using the Pittsburgh Sleep Quality Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For patients in the music group, the intervention includes playing a wordless piece of music (Rain of Love by Naser Chashm Azar) for 10 minutes every night for a month, right when the patient has just gone to bed and is ready for their night's sleep. This will be done using a smartphone and without the use of headphones or hands-free devices, in the form of direct audio streaming into the space.

Category
Prevention

2

Description
Intervention group: For patients in the aromatherapy group, the intervention includes the use of pure (100%) lavender essential oil provided by Zardband Company along with medical gauze and a pin that will be provided to the patients. Patients are asked to pour 3 drops of the essential oil on a small piece of medical gauze (2 x 2 cm) every night before going to bed for a month, then pin the gauze soaked in the essential oil to their collar, breathe normally throughout the night, and remove it from their collar in the morning after waking up.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
بیمارستان شهید دکتر رهنمون یزد

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Hassan Babamohamadi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
Not applicable
Data Dictionary
Not applicable