Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of audible guided imagery and self -selected instrumental music on comfort and well-being index amounts in hemodialysis patients

Protocol summary

Study aim
Comparison of the level of comfort and well-being in hemodialysis patients after the use of auditory guided imagery and selected instrumental music

Design
A clinical trial with 2 control groups involving 90 patients, randomized using the Random allocation 2 software

Settings and conduct
The study location is Shahrvand Dialysis Center in Sari city; the study population consists of patients undergoing three hemodialysis sessions per week; and blinding will not be performed in this study

Participants/Inclusion and exclusion criteria
Inclusion criteria: Hemodialysis for at least 6 months; undergoing three hemodialysis sessions per week; hemodynamic stability during dialysis sessions; age over 18 years; full consciousness with the ability to communicate and possess comprehension and understanding of the Persian language. Exclusion criteria: Use of psychotropic medications; use of sedative medications; use of narcotic substances; use of alcohol; pregnancy; use of music in the home or ward

Intervention groups
Intervention group 1: Auditory Guided Imagery, in which a guided imagery audio file will be played to the patient for 20 minutes using headphones; Intervention group 2: Self-Selected Instrumental Music, in which each individual will first select their favorite album and then listen to the tracks on that album for 20 minutes using headphones; Control group: The Control Group will receive no intervention and will undergo the standard dialysis program

Main outcome variables
Level of comfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N48**
Registration date: **2025-12-12, 1404/09/21**
Registration timing: **prospective**

Last update: **2025-12-12, 1404/09/21**
Update count: **0**

Registration date
2025-12-12, 1404/09/21

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-19, 1404/10/29

Expected recruitment end date
2026-05-19, 1405/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparing the effect of audible guided imagery and self -selected instrumental music on comfort and well-being index amounts in hemodialysis patients

Public title
The effect of music and auditory guided imagery on the level of comfort and well being in hemodialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Undergoing hemodialysis for at least 6 months Having three hemodialysis sessions per week Having hemodynamic stability during dialysis sessions Age over 18 years Full consciousness and ability to communicate Having the ability to understand and comprehend the Persian language Sufficient hearing ability to listen to music and guided visualization instructions, and to use headphones

Exclusion criteria:
Use of psychotropic medications Use of sedative medications Use of narcotic substances Alcohol consumption Pregnancy Having any other incurable diseases Having a history of known psychiatric disorders Use of music in the home or ward

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
To assign participants into three groups, a stratified block randomization method will be used. Randomization will be conducted in blocks of three participants. The group assignment for each individual will be determined using the Random Allocation Software version 2, employing Stratified Block Randomization based on gender. To construct each 3-member block, patients will be stratified according to gender. In total, there will be 30 blocks of three participants (15 blocks for males and 15 blocks for females). Based on the codes A, B, and C generated by the software, group allocation will be performed as follows: code A for the selected instrumental music group, code B for the auditory guided imagery group, and code C for the control group. Each envelope will be numbered from 1 to 90, and inside each envelope, the codes A, B, and C will be placed following the software-generated random sequence. Each block will be arranged randomly. Sampling will be performed according to the envelope numbers for the first patient who meets the inclusion criteria, and participants will thus be randomly assigned to one of the three groups.

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 Mazandaran University of Medical Science

Street address
Beginning of Valiasr Highway, Imam Square, Sari

City
Sari

Province
Mazandaran

Postal code
4736131167

Approval date
2025-09-08, 1404/06/17

Ethics committee reference number
IR.MAZUMS.REC.1404.345

Health conditions studied

1

Description of health condition studied
Chronic renal failure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Comfort

Timepoint
At the beginning of the study and then at the end of weeks 2 and 4.

Method of measurement
olcaba’s General Comfort Questionnaire (GCQ) for hospitalized patients

Secondary outcomes

1

Description

Well-being

Timepoint

At the beginning of the study and then at the end of weeks 2 and 4.

Method of measurement

WHO well-being index

Intervention groups

1

Description

Intervention Group 1: Auditory Guided Imagery Group: After randomization and determination of the patient's intervention group type, the inclusion and exclusion criteria are checked, and the necessary explanations regarding the study objectives are provided to the patient. Following the acquisition of written informed consent and completion of the demographic and medical information form, as well as the completion of the Inpatient Comfort Questionnaire and the WHO Well-being Questionnaire by the patient with the researcher's assistance, the intervention begins. Thirty minutes after connecting the patient to the dialysis machine and stabilizing their condition, an auditory guided imagery audio file will be played for the patient for 20 minutes via headphones connected to the researcher's mobile phone (the researcher is a master's student in critical care nursing). This will occur during dialysis sessions, 3 sessions per week , for a total duration of four weeks . The type and brand of the researcher's mobile phone is a Xiaomi Note 13 Pro, and the type and brand of the headphones are P39 2021. These sessions will involve guided auditory exercises using headphones for positive and soothing mental visualization. The content of the guided imagery audio file includes phrases and sentences that first invite the patient to practice breathing exercises and find a suitable and comfortable position. After the patient is prepared, they are guided to visualize a rainforest and mountain environment, focusing on the details to engage the patient in a calming adventure. The WHO 5-Item Well-being Questionnaire and the Kolcaba's Hospiece Comfort Questionnaire will be completed once before the intervention during the first session of the first week, and then at the end of the second and fourth weeks after the intervention, completed by the patient with the researcher's assistance. In total, each patient will be assessed 3 times.

Category

Other

2

Description

Second intervention group: Self-Selected Instrumental Music: considering the age range and diverse preferences of patients, 49 musical pieces across five albums of different styles will be used. These include 14 pieces from the traditional Mazandarani instrumental album titled Sor o Sama, 12 pieces of Santour instrumental music, 8 pieces of piano, 8 pieces of violin, and 7 pieces of setar. Each patient has the option to freely choose one of these five albums. The selected album cannot be changed during the same session. The list of tracks in the instrumental album Sor o Sama is as follows: 1-Te gereh te emsho boro, 2-Sama hal yek, 3-Sama hal do, 4-Rababe jan, 5-Rana, 6-Te mahale sang tarashon, 7-Bolbol nakhoon, 8-In denge sar oun denge sar, 9-Zahra mel mahale, 10-Sevari sama, 11-Majme sari, 12-Tayebeh jan, 13-Binje sama, 14-Parjai hal.The tracks in the piano album are as follows: 1-Spring Dance (Shahrdad Rohani), 2-Jan Maryam (Saeed Rehimi), 3-Idea 22 (Gibran Alcoser), 4-Secret and Prayer (Anoushiravan Rohani), 5-Tears of a Silent Heart (Michael Ortega), 6-Savior Homayoun (Anna Sophia), 7-Autumn (from the first Golden Autumn album by Fariborz Lachini), and 8-Reincarnation (from the second Golden Autumn album by Fariborz Lachini).The violin album includes the following tracks: 1-Kabuki (Babak Radmanesh), 2-Jan Maryam (Babak Radmanesh), 3-Zaman Negaram (Babak Radmanesh), 4-Laleh (Bijan Mortazavi), 5-Arshin Malalan (Farid Farjad), 6-Sarsabz (Bijan Mortazavi), 7-Orchids and Sickle (Bijan Mortazavi), and 8-Story of Love (Bijan Mortazavi).The Santour album includes: 1-Savior (Siamak Aghaei), 2-Shahr Ashoub (Majid Kiani), 3-Santour Solo by Kamkar Ensemble, 4-Rain over Sea (Siavash Kamkar), 5-Paradise (Faramarz Peyvar from the album Zarb Osoul), 6-New Spring Blossom (Kian Sedighi), 7-Colored Pencils (Amin Ahmadi), 8-Nava (Siavash Kamkar), 9-Mahour (Faramarz Peyvar), 10-Four Homayoun Strikes (Parviz Meshkatian), 11-Bidad (Parviz Meshkatian and Mohammadreza Rostamian), and 12-Celestial Circle (Soheil Hasanvi).The Setar album includes six pieces by Jalal Zolfonoun — From the Dawn of Time, If I Am Drunk, Delightful Spring, Mazandarani Song, Chahargah Song, and Saqi in Mahour Mode — plus one piece titled Homayoun by Iman Vaziri.Thirty minutes after the patient is connected to the hemodialysis machine and his condition stabilizes, the selected music will be played for the patient via headphones connected to the researcher's smartphone. The researcher's device is a Xiaomi Note 13 Pro, and the headphones used are P39 2021. Each session lasts approximately 20 minutes, held three times per week for four weeks. The patient may choose a different album and track in each session but may not switch selections during a single session.The WHO-5 Well-Being Questionnaire and the Kolcaba Comfort Questionnaire will be completed by each patient with the assistance of the researcher once before the intervention (in the first session of the first week) and again at the end of weeks two and four following the intervention. In total, each patient will be assessed three times.

Category

Other

3

Description

Control group: The Control Group will receive no intervention and will undergo the standard dialysis program; the World Health Organization's 5-item Well-Being Index questionnaire and the Kolcaba Comfort Scale for hospitalized patients will be completed by the patient

with the researcher’s assistance once before the first session of the first week, and subsequently at the end of the second and fourth weeks; patients in this group, similar to the other two groups, will be assessed and evaluated three times regarding their well-being and comfort variables

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized clinic of Shahrvand Kidney Patients Center

Full name of responsible person
Mansooreh Ezzati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Masoumeh Bagheri Nesami

Position
PhD in Nursing Education

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available