Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the impact of guided imagery on severity of restless leg syndrome in the elderly undergoing hemodialysis: A randomized controlled trial

Protocol summary

Study aim

Determining the effect of guided visualization on restless leg syndrome in the elderly undergoing hemodialysis in East Gilan

Design

The study group includes 72 elderly hemodialysis suffers with restless leg syndrome who will be examined in two intervention and control groups(36 people each). Randomization will be done by permutation block method with block 4. By entering the Randomization.com and entering the size and number of blocks, a random allocation sequence will be generated.

Settings and conduct

72 older people (36 in each group) in hemodialysis centers of East Guilan hospitals will be participated. Intervention group will undergo guided imagery training using training CD for 4 weeks and 4 sessions per week. After four weeks, the restless leg syndrome questionnaire will be administered again. Double blinding will be done which will include participants and analysts to prevent any deviation from the true results.

Participants/Inclusion and exclusion criteria

Inclusion criteria:60 years old or older, ability to understand and speak Persian, informed consent , having restless leg syndrome with mild-moderate and severe severity, adequate mental and cognitive ability, lack of Existence of a known mental illness, a history of at least six months of hemodialysis, no obvious hearing disorders, no use of drugs affecting the patient's mental state, no use of other methods sedation and patients resistant to routine treatments during the study. Exclusion criteria: Lacking of inclusion criteria

Intervention groups

"Intervention group": four weeks and four times per week will be guided visualization training using audio training CD. After four weeks and will complete the Restless Leg Syndrome questionnaire again. "Control group": will continue their routine treatments and guided visualization will not be performed on the their

Main outcome variables

Severity of restless leg syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231103059942N1**
Registration date: **2024-11-06, 1403/08/16**
Registration timing: **retrospective**

Last update: **2024-11-06, 1403/08/16**
Update count: **0**

Registration date

2024-11-06, 1403/08/16

Registrant information

Name

Ali Nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3344 4322

Email address

ali.nouri21@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of guided imagery on severity of restless leg syndrome in the elderly undergoing hemodialysis: A randomized controlled trial

Public title

Investigating the impact of guided imagery on restless leg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

60 years and older Ability to understand and speak Persian Informed consent to take part in the study A history of hemodialysis at least for 6 months Being developed to restless leg syndrome Appropriate mental and cognitive ability Resistance to routine treatments

Exclusion criteria:

Not using other relaxation methods such as yoga Absence of known mental illness such as schizophrenia Absence of hearing disorders Not using drugs affecting the patient's mental state

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by premutation block method with block size 4 and based on the generated sequence list, people will be assigned to 2 intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Using random sequence sealed opaque envelopes (SNOSE). After determining the random sequence using the block method, based on the sample size of the research, a number of envelopes with aluminum wrappers (in order to the contents of the envelopes unclear) are prepared and each of the generated random sequences is recorded on a card and the cards inside the letter envelopes are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box respectively. At the time of registration of the participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Guilan University of Medical Sciences

Street address

Namjoo Ave, Rasht

City

Rasht

Province

Guilan

Postal code

4477166595

Approval date

2023-09-13, 1402/06/22

Ethics committee reference number

IR.GUMS.REC.1402.327

Health conditions studied

1

Description of health condition studied

Restless Leg Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of restless leg syndrome

Timepoint

At the begining of the study and also after implementation of guided imagery

Method of measurement

Through a dedicated questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group" : First, elderly patients who meet the study entry criteria will be selected and examined after obtaining informed consent. Brief Cognitive Status Questionnaire (AMT), Demographic Information Questionnaire and Restless Leg Syndrome Severity Assessment Tool (RLSSG) will be completed by the patients and guided visualization by audio tapes will be prepared and presented to the elderly through headphones. The content of the CD used in the guided visualization will include the visualization of a combination of soothing nature scenes, comforting psychological sentences, and the use of translation of some verses of the Holy Quran to engage the minds of the participants through both traditional and modern methods."Intervention group": for four weeks and four sessions per week (two days a week, one session in the morning at the dialysis center and one session at night at home) under guided visualization training using an audio training CD prepared by the psychologist present in the study. They will sit and listen to it. In order to control disturbing factors such as noise in the ward, the intervention will be carried out in the morning shift in a quiet environment and every day with the presence of the researcher, and for the night shift it will be done at the patient's home. To ensure that the patient listens to the audio tape at home, the patient will be contacted by phone. After four weeks, both control.

Category

Treatment - Other

2

Description

"Control group" : First, elderly patients who meet the study entry criteria will be selected and examined after obtaining informed consent. Brief Cognitive Status Questionnaire (AMT), Demographic Information Questionnaire and Restless Leg Syndrome Severity Assessment Tool (RLSSG) will be completed by the patients. They will receive only routine care during the study period, at the end of the study they will receive a guided visualization CD to use if they wish.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Amini Hospital
Full name of responsible person
Parand Pourghane
Street address
Imam Khomeini Ave, Langroud
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research and Technology Deputy
Full name of responsible person
Mohammad Esmaeilpour-Bandboni
Street address
Zeynab School of Nursing and Midwifery, Yaghoub Sheikhi Ave, Leila Kooh Road, Langroud.
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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
Research and Technology Deputy
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
Rasht University of Medical Sciences
Full name of responsible person
Parand Pourghane
Position
Associate Professor
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
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