Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of reflexology and Swedish massage on sleep quality and restless leg syndrome among patients undergoing hemodialysis referred to Abu Ali Sina educational and medical center affiliated to Shiraz University of Medical Sciences in 2020

Protocol summary

Study aim

Comparison the effect of reflexology and Swedish massage on sleep quality and restless leg syndrome among patients undergoing Hemodialysis

Design

In the reflexology group, the researcher sits on a chair at the bottom of the patient's bed and performs a massage. This protocol will be performed on both legs for 20 minutes in 3 sessions. In the Swedish massage group, the researcher is placed at the bottom of the patient's legs, and first the patient is placed in an open arch position and a pillow is placed under the feet. The massage will be performed by the researcher for 20 minutes for 4 consecutive weeks. In the sham group, a simple knee-to-foot touch will be performed without compressing standard reflexology points with the same duration as the test group. There will be 30 people in each group to study.

Settings and conduct

The research environment will be Abu Ali Sina Educational-Therapeutic Hospital. After obtaining informed written consent from the patient, information related to demographic characteristics, sleep quality and restless legs syndrome will be obtained by interviewing in both intervention and control groups. a specific number to each of the individuals studied, the person evaluating the consequences of the interventions is blinded by not knowing which person or type of intervention was involved.

Participants/Inclusion and exclusion criteria

Age range 18 to 76 years At least 3 months of dialysis history At least 3 times a week under hemodialysis Intervention is prohibited in cases such as diabetic foot ulcers. Lack of cooperation in more than 2 sessions

Intervention groups

In the sham group, routine care will be provided as usual, and in the intervention group, the procedure will be performed using foot reflexology and Swedish massage.

Main outcome variables

sleep quality, restless legs syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200613047746N1**
Registration date: **2020-06-18, 1399/03/29**
Registration timing: **prospective**

Last update: **2020-06-18, 1399/03/29**
Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

Alireza Ghanbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3731 3346

Email address

alinurse1371@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of reflexology and Swedish massage on sleep quality and restless leg syndrome among patients undergoing hemodialysis referred to Abu Ali Sina educational and medical center affiliated to Shiraz University of Medical Sciences in 2020

Public title

Comparison the effect of reflexology and Swedish massage on sleep quality and restless leg syndrome among patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The age range is 18 to 76 years. At least 3 months have passed since the start of their dialysis. Have hemodialysis at least 3 times a week. Medically, there is no barrier to intervention.

Exclusion criteria:

Any medical prohibition to perform the intervention such as diabetic foot wound Lack of cooperation in more than 2 sessions of interventions

Age

From **18 years** old to **76 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method will be used to assign samples to three groups (Swedish massage, foot reflexology and control). Blocking will be done using online software (https://www.sealedenvelope.com/simple-randomiser/v1/lists). The size of the blocks will be 6. Using a lottery, each group will be assigned an A, B, and C label, and then samples will be assigned to each group based on a random block list.

Blinding (investigator's opinion)

Single blinded

Blinding description

By assigning a specific number to each of the individuals studied, the person evaluating the consequences of the interventions is blinded by not knowing which person has been subjected to which type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Beginning of the axis of Haft Bagh Alavi, Campus of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.KMU.REC.1399.147

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Sleep Quality

Timepoint

3 times a week for a month

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description

Restless Legs Syndrome

Timepoint

3 times a week for a month

Method of measurement
International Restless Legs Syndrome Questionnaire

Intervention groups

1

Description
Group 1: Hemodialysis patients under reflexology intervention. Massage at a slow pace with a regular or deep rhythm that would be tolerated by the patient. This protocol will be performed for 20 minutes on both feet (10 minutes for each foot) and in 3 sessions. Group II: Hemodialysis patients under Swedish massage intervention. Massage in this study will be performed once by dialysis for 20 minutes (10 minutes per foot) for 4 weeks (3 times per week) by the researcher.
Category
Rehabilitation

2

Description
Control group: In the sham or treatment group (control), by creating the same conditions as the test group, a simple touch of the knee to the sole of the foot without squeezing the standard reflexology points will be performed with the same duration of the test group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Abu-Ali Sina Hospital
Full name of responsible person
Alireza Ghanbari
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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
Kerman 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
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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
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The clinical report of this study will be presented in the form of an article.
When the data will become available and for how long
2 years
To whom data/document is available
researchers
Under which criteria data/document could be used
No specific conditions have been defined
From where data/document is obtainable
The author of the dissertation
What processes are involved for a request to access data/document
Satisfaction with the main researcher
Comments