

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

Street address

Sadra, Fars Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Research and Technology Dept. - Research Manager,
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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

Kerman University of Medical Sciences

Full name of responsible person

Alireza Ghanbari

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Parvin Mangolian Shahrabaki

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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