Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect Of Foot Reflexology Massage On Fatigue And Sleep Quality In Hemodialysis Patients: A Randomized Control Trial

Protocol summary

Study aim
Determining the effect of foot reflexology massage on fatigue and sleep quality of hemodialysis patients

Design
50 hemodialysis patients will be selected in two groups, control and intervention, using random allocation methods.

Settings and conduct
The research environment will be the hemodialysis department of Sina Hospital in Zarand city. After coordinating with the supervisor of the hemodialysis department, he will introduce the patients who meet the conditions to enter the study. The patients were divided into two control groups and three questionnaires of demographic information, Pittsburgh Sleep Quality Index (PSQI) and Piper Fatigue Scale will be completed by the patients of both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: at least 18 years old, dialysis treatment for at least 3 months, hemodialysis treatment 3 times a week and each time for 4 hours, no limb amputation or wound at the place of massage, no chronic diseases.(Heart Failure, Rheumatoid Arthritis, Lupus Erythematous) Exclusion criteria: age less than 18 years, dialysis treatment less than 3 months, having limb amputation or wound at the place of massage, suffering from chronic diseases (heart failure, rheumatoid arthritis, lupus erythematosus)

Intervention groups
Patients in the intervention group are placed on their stomachs in a relaxed and sleeping position during three 16-minute sessions per week for 4 weeks, and then the masseur applies pressure on the solar plexus points on the soles of the feet. Patients in the control group will receive only simple touch without pressure on the solar plexus points.

Main outcome variables
Mental or physical feeling affecting people's functioning, Enjoying a person's sleep with the highest functional level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231016059742N1**
Registration date: **2023-11-16, 1402/08/25**
Registration timing: **prospective**

Last update: **2023-11-16, 1402/08/25**
Update count: **0**

Registration date
2023-11-16, 1402/08/25

Registrant information

Name
Raheleh rajabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3342 5400

Email address
r.rajabi@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effect Of Foot Reflexology Massage On Fatigue And Sleep Quality In Hemodialysis Patients: A Randomized Control Trial

Public title
The Effect Of Foot Reflexology Massage On Fatigue And Sleep Quality In Hemodialysis Patients: A Randomized Control Trial

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
At least 18 years old Dialysis treatment for at least 3 months Treatment with hemodialysis 3 times a week and each time for 4 hours Not suffering from chronic and debilitating diseases (cancer, chronic respiratory failure, heart failure, rheumatoid arthritis, lupus erythematosus) No obvious physical disability or mental disorder that the person cannot take care of himself

Exclusion criteria:
Age less than 18 years Treatment with dialysis less than 3 months Having a limb amputation or wound at the massage site Suffering from chronic and debilitating diseases (cancer, chronic respiratory failure, heart failure, rheumatoid arthritis, lupus erythematosus) Physical disability or obvious mental disorder that makes the person unable to take care of themselves

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample number of 50 people (hemodialysis patients) will be selected by the available method and will be divided into two intervention and control groups (25 people in each group) using the minimization random allocation method.

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 Kerman University of Medical Sciences

Street address
Imam Khomeini street

City
zarand

Province
Kerman

Postal code
7616913555

Approval date
2023-10-07, 1402/07/15

Ethics committee reference number
IR.KMU.REC.1402.228

Health conditions studied

1

Description of health condition studied
Fatigue and sleep quality in hemodialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mental or physical feeling affecting people's functioning

Timepoint
Before the start of the intervention and at the end of the intervention

Method of measurement
Providing Piper s fatigue scale questionnaire to the participants

Secondary outcomes

1

Description
Enjoying a person's sleep with the highest functional level

Timepoint
Before the start and at the end of the intervention

Method of measurement
Providing PSQI questionnaires to people

Intervention groups

1

Description
Patients in the intervention group will receive foot

reflexology massage three sessions a week (for 3 weeks) and each session lasts 16 minutes (each foot massage lasts 8 minutes). At this stage, the patient is placed in a semi-sitting position and his sole The reflexologist is placed parallel to the chest, the patient is asked to close his eyes and be in a relaxed position. Then the masseur, who is the same gender as the patient, performs reflex massage on the solar retina and the pineal gland area on the inner upper part of the soles and big toes. In this way, 1 minute of general massage in each leg, 3 minutes of reflex massage in each area in each leg and 1 minute of rest in between.

Category

Rehabilitation

2

Description

For patients in the control group, the sham group will be considered and only simple touch will be done without putting pressure on specific points.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sinai Hospital

Full name of responsible person
Ali Soltani

Street address
Republic Blvd

City
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Province
Kerman

Postal code
7761819595

Phone
+98 34 3342 2600

Email
sina.hospital@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Deputy of research and technology

Street address
Haft Bagh Alavi square

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Province
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7616913555

Phone
+98 34 3132 5700

Email
kmu@kmu.ac.ir

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
raheleh rajabi

Position
faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Demographic data including age and gender and disease related information
When the data will become available and for how long
Start high-speed access after printing
To whom data/document is available
public
Under which criteria data/document could be used
Statistical analysis and use of questionnaires
From where data/document is obtainable
Applicants for project documentation should send a message to the responsible author, Mrs. Rahela Rajabi, by email r.rajabi@kmu.ac.ir and provide her with a summary of her project along with the demographics and after reading the relevant information. will take
What processes are involved for a request to access data/document
Sending an email of the abstract of the project along with the sampling method and statistical population to the responsible author of the study and approval of the qualification by the responsible author. After the project is completed, it is necessary to provide its details to the responsible author. One month after receiving the email from the project author, the responsible author will provide the necessary information to them.
Comments