

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 Erythematosus)
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		Ethics committees	
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		Ethics committee Name of ethics committee Ethics Committee of Kerman University of Medical Sciences	
Gender Both		Street address Imam Khomeini street	
Phase N/A		City zarand	
Groups that have been masked No information		Province Kerman	
Sample size Target sample size: 50		Postal code 7616913555	
Randomization (investigator's opinion) Randomized		Approval date 2023-10-07, 1402/07/15	
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.		Ethics committee reference number IR.KMU.REC.1402.228	
Blinding (investigator's opinion) Not blinded		Health conditions studied	
Blinding description Placebo Not used		1 Description of health condition studied Fatigue and sleep quality in hemodialysis patients	
Assignment Parallel		ICD-10 code ICD-10 code description	
Other design features		Primary outcomes	
Secondary Ids empty		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

zarand

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

City

kerman

Province

Kerman

Postal code

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

Name of organization / entity

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Full name of responsible person

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Position

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

Kerman University of Medical Sciences

Full name of responsible person

raheleh rajabi

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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