

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of foot massage on sleep quality in hemodialysis patients

Protocol summary

Summary

The present research is conducted for determining the effect of foot massage on sleeping in hemodialysis patients in Khoram abbad. Key criteria for entering the study including: willingness to cooperate and participate in research; having sleeping problems based on scores resulting from Pittsburg questionnaire; age above 18 years and below 65 years; not using hypnotic drugs and exclusion key criteria including: not wanting to continue working; referring to another facility for further treatment; having undiagnosed illnesses. This experimental clinical trial was conducted on 80 hemodialysis patients admitted to the hemodialysis units affiliated to Lorestan University of Medical Sciences, Iran (2013). Tools were included Pittsburg questionnaire and sleep log. The treatment was Stroke foot massage carried out during hemodialysis for 10 minutes three times a week, for four consecutive weeks in experimental group and in control group Alprazolam 0.5 mg/oral before sleeping for four consecutive weeks was used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031516983N1**

Registration date: **2014-09-08, 1393/06/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-08, 1393/06/17

Registrant information

Name

Farhad Ariamanesh

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 1423 3808

Email address

malekshahif@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences

Expected recruitment start date

2014-02-04, 1392/11/15

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot massage on sleep quality in hemodialysis patients

Public title

The effect of foot massage on sleep quality in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to cooperate and participate in research; giving informed consent; having sleep problems based on scores resulting from Pittsburg questionnaire; performing hemodialysis in the evening and night shifts; lack of amputation, injury, infection, wound and skin disease in the lower limbs; insensitive to massage and having endurance against massage by patient; not having clotting disorders, vascular, neuropathy and diabetes complications; age above 18 years and below 65 years; no history of psychiatric disorders or psychiatric hospitalization; not using

hypnotic drugs. Exclusion criteria: Not wanting to continue working; referring to another facility for further treatment; referring patients for kidney transplantation; having undiagnosed illnesses.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Lorestan University of Medical Sciences

Street address

4th kilometers, Khoram Abbad-Brojerd Road

City

Khoram Abbad

Postal code

6813833946

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

99149/200

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

F51.0

ICD-10 code description

Nonorganic insomnia

Primary outcomes

1

Description

Lack of sleep

Timepoint

Before intervention, a week later, two weeks later, three weeks later and four weeks later after beginning of intervention

Method of measurement

By using Pittsburg and Sleep Log

Secondary outcomes

1

Description

Improving sleep Quality

Timepoint

Weekly

Method of measurement

By using Pittsburg and Sleep Log

Intervention groups

1

Description

In this study, Stroke foot massage was conducted in experimental group. Intervention was 5 minutes Stroke foot massage, three times a week for four consecutive days in the evening and night shifts (because of closeness to the night sleeping hours) among male patients by researcher and female patients by trained female partner after declaration of patient readiness. Stroke foot massage performed in the sole of the foot with a mild to moderate pressure slowly and regularly in every direction.

Category

Treatment - Other

2

Description

In this study, in control group, Alprazolam 0/5 mg/oral before sleeping for four consecutive weeks was used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi hospital

Full name of responsible person

Farideh Malekshahi

Street address

Near Safavi bridge, Azadi square

City
Khoram Abbad

2

Recruitment center

Name of recruitment center
Shohada hospital

Full name of responsible person
Farideh Malekshahi

Street address
Enghlab street

City
Khoram Abbad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Lorestan University of Medical Sciences

Full name of responsible person
Farideh Malekshahi

Street address
4th kilometers Khoram Abbad- Brojerd road,
Kamalvand

City
Khoram Abbad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Lorestan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Lorestan University of Medical Sciences

Full name of responsible person
Farideh Malekshahi

Position
MD/Teacher of nursing college

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty