Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment the effect of foot reflexology massage on sleep quality in hemodialysis patients

Protocol summary

Summary

The aim of the present study is to determine the effect of reflexology massage on sleep quality in hemodialysis patients. The study population is all hemodialysis patients who refereed to hemodialysis center of Qazvin Bou-Ali hospital. 62 patients were randomly divided into control and intervention groups. Randomization in this study was conducted using a random numbers table. This study will implement in Bou-Ali Hospital Dialysis Center. The main inclusion criteria include having sleeping disorders and at least 3 months of dialysis. At first, demographic information of patients in both intervention and control groups will be recorded. Patients will asked do not use another treatment for their sleep disorder and also do not perform activities that affect sleep, such as exercise, yoga refrain during the study. In these patients, massage therapy will be done between dialysis sessions, three days a week (from 6 am to 8 pm) for 4 weeks totally 12 sessions of 30 minutes (15 minutes per leg) by trained colleagues. Massage of male patients will be done by male nurse and massage of female patients will be done by female nurse. Initial assessment of sleep quality will be measure at baseline, after the first, second, third weeks and final assessment of sleep quality will takes place after 12 sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122125642N1**
Registration date: **2016-02-15, 1394/11/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-15, 1394/11/26

Registrant information

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Ramin Farrokhian
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of foot reflexology massage on sleep quality in hemodialysis patients

Public title

Foot massage impact on sleep

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Sleep disorders; Having willingness to cooperate in the study and signed an informed consent form; Having at least 3 months of dialysis; Lack of skin

disease with involvement; Lack of acute infection; Lack of blood coagulation disorders (because of the risk of blood clots and thromboembolic); No history of drugs and tranquilizers; as well as having no history of psychological problems; No smoking and drugs; The use of other accessories and complementary therapies. Exclusion Criteria: The reluctance of patients to continue working during the study; Death of a spouse, close relatives; Referral for transplantation.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study randomization was conducted using a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Shahid Bahonar Boulevard, Qazvin University of Medical Sciences

City
Qazvin

Postal code
3419759811

Approval date
2015-12-09, 1394/09/18

Ethics committee reference number
IR.QUMS.REC.1394.240

Health conditions studied

1

Description of health condition studied
Renal failure

ICD-10 code
Renal fail

ICD-10 code description
Acute renal failure with tubular necrosis

Primary outcomes

1

Description
History of hemodialysis

Timepoint
Before Intervention

Method of measurement
The initial questionnaire, having a history of dialysis three months

2

Description
Sleep Qulality

Timepoint
Before and after intervention

Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, massage therapy will be done between dialysis sessions, three days a week (from 6 am to 8 pm) for 4 weeks totally 12 sessions of 30 minutes (15 minutes per leg) by trained colleagues. Massage of male patients will be done by male nurse and massage of female patients will be done by female nurse. Initial assessment of sleep quality will be measure at baseline, after the first, second, third weeks and final assessment of sleep quality will takes place after 12 sessions.

Category
Rehabilitation

2

Description
Control group: There is no intervention in this group.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis center of Qazvin Bou-Ali hospital

Full name of responsible person

Ms. Rostami

Street address

Dialysis center, Bou-Ali hospital

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Zinat Joorabchi

Street address

Nursing and Midwifery School, Qazvin University of Medical Sciences, Shahid Bahonar Boulevard

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Zinat Joorabchi

Street address

Nursing and Midwifery School, Qazvin University of Medical Sciences, Shahid Bahonar Boulevard

City

Qazvin

Grant name

Grant code / Reference number

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Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

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

Qazvin University of Medical Sciences

Full name of responsible person

Ramin Farrokhian

Position

M.Sc. in Critical Care Nursing Student

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