

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 referred 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

Name

Ramin Farrokhian

Name of organization / entity

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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 Bahrar 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 Quality

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
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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

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Web page address**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