

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of foot reflexology on fatigue & quality of sleep in Birjand haemodialysis patients.

Protocol summary

Summary

The research was conducted to evaluate the effect of foot reflexology on fatigue and sleep quality in haemodialysis patients. The sample consisted of 70 patients in total, 35 intervention and 35 control patients, receiving treatment in the haemodialysis units of two institutions in birjand (shaikh hadi hadavi & vali asr hospital). Patients included in the research were 18 years old or older; had full consciousness and orientation; did not have any communication problems; received haemodialysis three times a week; had been receiving haemodialysis for at least 6 months and agreement to participate in the study. Patients with current skin problems, deep vein thrombosis, peripheral neuropathy and transfer to intensive care units with any reason, were excluded from the study. reflexology application was performed by a researcher who received a certificate after completing a 50 h theoretical and applied education. Data were collected by using two questionnaire, Fatigue Severity Scale (FSS) and pittsburgh sleep quality index (PSQI) for measuring the severity of fatigue and sleep disorders. The intervention group received reflexology treatment for 3 weeks in three sessions following haemodialysis and The control group only received routine care. Foot reflexology was chosen, since all patients had fistula arms. Reflexology was applied for 16 min in total, 8 min for each foot. Parametric and nonparametric tests were used in data analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100530150N1**

Registration date: **2016-11-15, 1395/08/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-15, 1395/08/25

Registrant information

Name

Mahdi Hadavi

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3256 0418

Email address

mahdihadavi.526@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on fatigue & quality of sleep in Birjand haemodialysis patients.

Public title

Reflexology & nursing care

Purpose

Supportive

Inclusion/Exclusion criteria

Patients included in the research were 18 years old or

older; the minimum of literacy was elementary; had full consciousness and orientation; did not have any communication problems; received haemodialysis three times a week; had been receiving haemodialysis for at least 6 months; marked the level of severity of fatigue according to FSS scale; marked Pittsburgh Sleep Quality Index (PSQI) scores of five points or over; do not use of any drugs for sleeping; do not participate in relaxation & meditation period and volunteered to participate in the research. Patients with open foot wound, deep vein thrombosis, peripheral neuropathy, kidney transplantation, transfer to intensive care units with any reason, current skin problems, traveling to other city, experience of stressful condition and disagreement to continue were excluded from the study.

Age

From **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Shahid
Qhaffari street

City

Birjand

Postal code

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

IR.BUMS.REC.1395.69

Health conditions studied

1

Description of health condition studied

Haemodialysis patients

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes

1

Description

Sleep quality

Timepoint

Before intervention, after intervention & one week after
it

Method of measurement

Pittsburgh sleep quality index(PSQI)

2

Description

Fatigue

Timepoint

Before intervention, after intervention & one week after
it

Method of measurement

The FSS scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before and after the intervention

Method of measurement

Using piezometer, manual

2

Description

Sufficiency of dialysis

Timepoint

Before and after the intervention

Method of measurement

Using formula

3

Description

Hb

Timepoint

Before and after the intervention

Method of measurement

Laboratory test

4

Description

Hct
Timepoint
Before and after the intervention
Method of measurement
Laboratory test

Intervention groups

1

Description
foot reflexology in intervention group in solar plexus and locale of pineal node for 16 minutes in both legs was conducted.
Category
Other

2

Description
The control group only received routine care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The ward of heamodialysis, Shaikh Hadi Hadavi
Full name of responsible person
Mahdi Hadavi
Street address
The ward of heamodialysis, Shaikh Hadi Hadavi, Taleghani square
City
Qaen

2

Recruitment center
Name of recruitment center
Haemodialysis ward of Vali Asr hospital
Full name of responsible person
Mahdi Hadavi
Street address
Vali Asr hospital, Shahid Ghafari street
City
Qaen

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Gholam Reza Sharif Zadeh
Street address
Birjand University of Medical Sciences

City
Birjand
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Mahdi Hadavi
Position
MSc student of Nursing
Other areas of specialty/work
Street address
Birjand University of Medical Sciences, Shahid Qhafari street
City
Qaen
Postal code
Phone
+98 56 3256 0418
Fax
Email
mahdihadavi.526@bums.ac.ir;
nurseicu.61@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mahdi Hadavi
Position
MSc student of Nursing
Other areas of specialty/work
Street address
Birjand University of Medical Sciences, Shahid Qhafari street
City
Qaen
Postal code

9764133898

Phone

+98 56 3256 0418

Fax

Email

mahdihadavi.526@bums.ac.ir;

nurseicu.61@gmail.com

Web page address

9764133898

Phone

+98 56 3256 0418

Fax

Email

mahdihadavi.526@bums.ac.ir;

nurseicu.61@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

birjand university of medical science

Full name of responsible person

Mahdi Hadavi

Position

MSc student of Nursing

Other areas of specialty/work

Street address

Birjand University of Medical Sciences, Shahid Qhafari
street

City

Qaen

Postal code

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