Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of foot reflexology on fatigue & quality of sleep in Birjand heamodialysis 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 18years 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 week 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 for16 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 heamodialysis 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
Useing 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