Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of two methods of reflexology massage and stretching exercises on the severity of restless leg syndrome among patients undergoing Hemodialysis in selected Hospitals in Isfahan

Protocol summary

Summary

The present study aimed to investigate the effect of two methods of reflexology and stretching exercises on the severity of restless leg syndrome among patients undergoing hemodialysis. This is a clinical trial. Among the patients undergoing hemodialysis in selected hospitals in Isfahan, 90 qualified patients (The hemodialysis clients that regularly came to these hospitals for treatment, Age between 18 – 65, 3 months past from starting hemodialysis for clients at least, Clients give positive answer to every four question of restlessness legs syndrome diagnostic questionnaire, Clients did not take any drugs that control of restless legs syndrome, Clients did not take any drugs that severity of restless legs syndrome and Absence of every infection, lesions or important complication in legs), diagnosed with restless leg syndrome through standard restless leg syndrome questionnaire, were randomly selected by random number table. They were assigned to reflexology, stretching exercises and control groups through random allocation. Reflexology and stretching exercises were conducted three times a week for 30-40 minutes for four straight weeks and the effect of these interventions on severity of restless legs syndrome have been studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040717159N1**
Registration date: **2014-05-23, 1393/03/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-23, 1393/03/02

Registrant information

Name
Sahrzad Khojandi Jazi
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 1668 5490
Email address
sh_khojandi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences Isfahan

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two methods of reflexology massage and stretching exercises on the severity of restless leg syndrome among patients undergoing Hemodialysis in selected Hospitals in Isfahan

Public title

Comparison the effect of reflexology and stretching exercises on the severity of restless leg syndrome

among patients undergoing Hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:The hemodialysis clients that regularly came to these hospitals for treatment;Age between 18 - 65;3 months past from starting hemodialysis for clients at least;Hemodialysis was performed 3 times a week with sodium bicarbonate solution;Restlessness legs syndrome was not idiopathic or familial;Clients did not take any drugs that control the signs of restless legs syndrome;Clients did not take any drugs that exacerbate the restless legs syndrome;Clients did not use relaxation techniques;Clients did not swimming, cycling, getting massage or stretching sports;Clients give positive answer to every four question of restlessness legs syndrome diagnostic questionnaire;Absence of any intellectual or physical disability;Clients should completely conscious and able to hear and answer the questions truly;Absence of any type of infection, lesions or important complication in legs;Absence of orthopedic complications to do stretching exercises;Absence of peripheral neuropathy or vascular complications in lower limbs;Exclusion criteria:Disinclination in every level of study;Changing in times of hemodialysis during the study;Start treatment with drugs which control the signs of restless legs syndrome during the study;start to take drugs that exacerbates the signs of restless legs syndrome;Engendering infection, lesions or important complications in legs;Engendering legs orthopedic complications inhibit stretching exercises during the study;Engendering neuropathy or vascular complications in lower limbs during the study;The patient died

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: **90**

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjirib Street, Azadi Street, Isfahan

City

Isfahan

Postal code

Approval date

2013-09-16, 1392/06/25

Ethics committee reference number

11/2707/د

Health conditions studied

1

Description of health condition studied

Restless legs syndrome

ICD-10 code

G25.8

ICD-10 code description

Other specified extrapyramidal and movement disorders

Primary outcomes

1

Description

Restless legs syndrome severity

Timepoint

Before the intervention, immediately after intervention

Method of measurement

International restless leg syndrome questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In this study reflexology was done 12 sessions, 3 times a week and every session 40 minutes in first 2 hours of hemodialysis that clients have not changing in blood pressure. In every session we have 15 minutes general stimulus and 5 minutes specific stimulus for every leg.

Category

N/A

2

Description

Stretching exercise was done in 12 sessions, 3 times a week and 30 minutes in first 2 hours of hemodialysis that patient has not changing blood pressure. Every session include 10 minutes warming up then 15 minutes

stretching exercise according to the protocol and after that 5 minutes cool down.

Category

N/A

3

Description

Control group got routine interventions. they got unspecific massage by their family or hospital accommodators.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Ali Shariati Hospital

Full name of responsible person

Fariba Taleghani

Street address

Shariati Street

City

Isfahan

2

Recruitment center

Name of recruitment center

Zahraye Marzieh Hospital

Full name of responsible person

Fariba Taleghani

Street address

Ghods square

City

Isfahan

3

Recruitment center

Name of recruitment center

Noor and Ali Asghar Hospital

Full name of responsible person

Fariba Taleghani

Street address

Hasht Behesht Street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Hezarjirib Street, Azadi Street, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice chancellor for research, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Shahrzad Khojandi Jazi

Position

MSc in Nursing Education

Other areas of specialty/work

Street address

College of Nursing and Midwifery, hezarjirib Street, Azadi Street

City

Isfahan

Postal code

Phone

+98 31 1335 7067

Fax

Email

shahrzad45@ymail.com; sh_khojandi@nm.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Nahid Shahgholian

Position

masters

Other areas of specialty/work

Street address

College of Nursing and Midwifery, Hezarjirib Street, Azadi Street

City

Isfahan
Postal code
Phone
+98 31 1792 2940
Fax
Email
shahgholian@nm.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Nahid Shahgholian
Position
masters
Other areas of specialty/work
Street address
College of Nursing and Midwifery, Hezarjirib Street, Azadi Street
City
Isfahan
Postal code
Phone
+98 31 1792 2940
Fax
Email
shahgholian@nm.mui.ac.ir
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