Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Progressive Muscle Relaxation on the Intensity of Restless Leg Syndrome in Hemodialysis Patients, Hasheminejad Hospital, Tehran

Protocol summary

Summary

This study aims to determine the effects of progressive muscle relaxation on the intensity of restless leg syndrome (RLS) in hemodialysis patients. A total of 74 patients who visit Hasheminejad Hospital for hemodialysis will be randomly allocated to two groups (intervention and control). The main inclusion criteria will be age range of 18-65 years, willingness to participate (declared by signing the informed consent form), and self-reports of RLS confirmed by the physician. The major exclusion criteria will be patient death or their family's disapproval of their participation. The intensity of RLS in the intervention and control groups will be compared before the application of the relaxation technique. The control group will receive routine care (provided in all similar therapeutic centers). In addition to receiving routine care, the intervention group will perform the progressive muscle relaxation twice daily (once during the day and once before going to bed) for a period of one month. Finally, the intensity of the RLS after the intervention will be compared to the values recorded before the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102824769N1**
Registration date: **2016-01-16, 1394/10/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-16, 1394/10/26

Registrant information

Name

Mahya Mousavi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2016-01-06, 1394/10/16

Expected recruitment end date

2016-02-06, 1394/11/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Progressive Muscle Relaxation on the Intensity of Restless Leg Syndrome in Hemodialysis Patients, Hasheminejad Hospital, Tehran

Public title

Effects of Progressive Muscle Relaxation on the Intensity of Restless Leg Syndrome in Hemodialysis Patients, Hasheminejad Hospital, Tehran

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age range of 18-65 years; willingness to participate (declared by signing the informed consent form); self-reports of restless leg syndrome confirmed by the physician. Exclusion criteria: patient death; patient

family’s disapproval of their participation.

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: **74**

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
Sabzevar University of Medical Sciences

Street address
Sabzevar, Mashhad, Khorasan Razavi

City
Sabzevar

Postal code

Approval date
2015-08-03, 1394/05/12

Ethics committee reference number
IR.MEDSAB.REC.1394.66

Health conditions studied

1

Description of health condition studied
Restless leg syndrome

ICD-10 code
R25-R29

ICD-10 code description
Symptoms and signs involving the nervous and musculoskeletal systems

Primary outcomes

1

Description
Intensity of restless leg syndrome

Timepoint
Before the intervention, after the intervention

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine care plus progressive muscle relaxation twice daily (once during the day and once before going to bed) for a period of one month.

Category
Other

2

Description
Control group: Routine care provided in all centers

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dialysis Unit, Hasheminejad Hospital

Full name of responsible person
Dr Shahrzad Osareh

Street address
Hasheminejad Hospital, Valinejad St., Vanak Sq.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Dr Mohammad Reza Najafi

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Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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

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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