

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Sabzevar University of Medical Sciences

Country

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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

Street address

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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****Contact****Name of organization / entity**

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Full name of responsible person

Mahya Mousavi

Position

MSc Student in Nursing

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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***Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Moosalreza Tadayonfar

Position

MSc in nursing, Faculty member

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