Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of stretching exercises on the sleep quality of type 2 diabetic patients suffering from restless leg syndrome

Protocol summary

Summary

Restless legs syndrome (RLS) is a sensorimotor disorder that is characterized by motor restlessness resulting in an uncontrolled urge to move the affected body parts. RLS symptoms often worsen in long sitting and rest, such as prolonged sleep . Generally the symptoms of restless leg syndrome in diabetic patients is more common and more severe and causing reduced sleep duration, sleep disruption and reduced quality of life. Since the symptoms of this syndrome occurs or gets worse during the period of immobilization, mild exercise such as stretching can relieve symptoms of restless leg syndrome.This study is a clinical trial to evaluate the impact of stretching on symptoms of restless leg syndromeand and sleep quality in type 2 diabetic patients in firozgar hospital in Tehran, Iran. 80 patients will be diagnosed with RLS symptoms as defined by the standard criteria and recruited for being part of the study. The recruited patients will be offered the option to exercise (Ex-group) or not to exercise (Con-group) for the period of 3 nights. Stretching exercises will be performed 3 nights, 30 minutes each time . Sleep quality and restless legs syndrome severity will be assessed using the Pittsburgh Sleep Quality questionnaires and International RLS (IRLS)study group rating scale for 3 nights after and before intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010725336N3**
Registration date: **2016-04-22, 1395/02/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-22, 1395/02/03

Registrant information

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Recruitment status

Recruitment complete

Funding source
Iran University of Medical Sciences

Expected recruitment start date

2015-11-21, 1394/08/30

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of stretching exercises on the sleep quality of type 2 diabetic patients suffering from restless leg syndrome

Public title

The effect of stretching exercises on the sleep quality of type 2 diabetic patients suffering from restless leg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: answering "yes" to the first four questions of the restless leg syndrome questionnaire; age over 30- no mental and physical disabilities; having full awareness; listening and speaking ability; no infection and ulcers in the legs-no orthopedic problems; no peripheral neuropathy or vascular problems in legs; restless leg syndrome confirmed by GP. Exclusion criteria: no exercise for three consecutive sessions and six sessions generally.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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 Nursing&Midwifery Iran University of Medical Sciences

Street address
Hemmat West highway between the intersection of Sheikh Fazlullah Nuri martyr and Chamran martyr

City
Tehran

Postal code

Approval date
2015-11-21, 1394/08/30

Ethics committee reference number
IR.IUMS.REC.1394.9221196201

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
Decrease severity of restless leg syndrome symptomes and increase sleep quality after exercise

Timepoint
3 night before and 3 night after intervention

Method of measurement
pittsburgh Questionnaire- International Restless Legs Syndrome Study Group (IRLSSG)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: stretching exercises will be performed for 3 nights and questionnaires will be completed 3 night before and 3 night after intervention

Category
Other

2

Description
Control group: questionnaires will be completed for 6 night. No intervention for the control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Firouzgar Hospital. Iran University of Medical Science.

Full name of responsible person
Fatemeh Mohaddes Ardebili

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Beh Afarin AVenue, Vali Asr Square, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Assistance of Iran University of Medical Sciences

Full name of responsible person
Dr. Nahid Akbari
Street address
Between the intersection of Sheikh Fazlullah Nuri and Shahid Chamran, Shahid Hemmat West Highway, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Assistance of Iran 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