

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

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

Protocol summary

2016-04-22, 1395/02/03

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 syndrome 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.

Registrant information

Name

Zahra Moeini

Name of organization / entity

Iran University of Medical Sciences

Country

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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

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

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 symptoms 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

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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

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Shahid Chamran, Shahid Hemmat West Highway,
Tehran**City**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceResearch 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****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Masters Student

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master

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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*