

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of Foot Reflexology Massage on Sleep Quality of Elderly Women with Restless Legs Syndrome

Protocol summary

Summary

This study is a non-randomized clinical trial. The aim of this study is to determine the effect of foot reflexology massage on sleep quality. The study population are women aged over 65 years who have Restless Legs Syndrome and sleep disorder. The sampling is done continuously available. Target sample size is 70 and trial recruitment centers are Shiraz nursing homes. Inclusion criterias are: sleep disorder for 1 year or more; restless leg syndrome for 1 year or more; No Experience of Foot Reflexology Massage; No Cognitive impairment; No alcohol and substance abuse; Lack of mental illness; Able to understand persian language; Having healthy feet. Exclusion criterias are: complex problems in foot during the intervention; Neuropathy or peripheral vascular disease of the lower extremities during the study period; Taking tricyclic antidepressants, selective serotonin reuptake inhibitors, antiemetic, anticonvulsants, antidepressants, dopamine antagonists; lack of willingness to continue cooperation; diseases that affect the quality of sleep during the intervention. Intervention group will receive reflexology massage in 8 sessions (each sessions: 20 Minute) in 4 weeks. The intervention will be done at evening (3 to 7 pm). Control group will receive routine cares. Before the first intervention, demographic check list, ATMs questioner and pretest for sleep quality will be completed for each person. In the fifth week, sleep quality will be evaluated by posttest.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032733154N1**

Registration date: **2017-06-18, 1396/03/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-18, 1396/03/28

Registrant information

Name

Amine Abbasi Fakhravari

Name of organization / entity

Nursing school, Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research- Iran University of Medical Science

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-18, 1396/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot Reflexology Massage on Sleep Quality of Elderly Women with Restless Legs Syndrome

Public title

The Effect of Foot Reflexology Massage on Sleep Quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: sleep disorder for 1 year or more; restless leg syndrome for 1 year or more; No Experience of Foot Reflexology Massage for treating RLS or sleep disorder; No Cognitive impairment; No alcohol and substance abuse; Lack of mental illness; Able to understand persian language; Having healthy feet. Exclusion criteria: Ulceration, infection or complex problems in foot during the intervention; Neuropathy or peripheral vascular disease of the lower extremities during the study period; Taking tricyclic antidepressants, selective serotonin reuptake inhibitors, antiemetic, anticonvulsants, antidepressants, dopamine antagonists; lack of willingness to continue cooperation; Complications, disorders and diseases that affect the quality of sleep during the intervention

Age

From **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not 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 the Iran University of Medical Science

Street address

Iran University of Medical Sciences, between the intersection of Chamran and Sheikh fazl o lah, Hemat highway

City

Tehran

Postal code**Approval date**

2016-07-26, 1395/05/05

Ethics committee reference number

IR.IUMS.REC.1395,9411580005

Health conditions studied**1****Description of health condition studied**

Sleep disorder

ICD-10 code

G47

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes**1****Description**

Improving in sleep quality

Timepoint

before the intervention and a week after intervention

Method of measurement

Pittsburgh sleep quality index

Secondary outcomes

empty

Intervention groups**1****Description**

Patients in the intervention group will receive reflexology massage in 8 sessions (each sessions: 20 Minute) in 4 weeks. the intervention will be done at evening (3 to 7 pm). in each session At first, General massage with an ineffective Lotion will be done by reasercher for 5 minutes for each foot. after that, Special reflexology for sleep will be done for 5 minutes

Category

Other

2**Description**

Patient in control group will receive routine cares.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Farzanegan nursing home

Full name of responsible person

Etemad

Street address

Number 5, Technology street, Mirzaye shirazi Boulevard, Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Yashaye Sepid Nursing Home

Full name of responsible person

Tajer

Street address

Number 3, 7th Alley, Kebar Martyr street, Maaliabad, Shiraz

City

Shiraz

3

Recruitment center

Name of recruitment center

Mehr Nursing Home

Full name of responsible person

Dehghan

Street address

Number 5, Alley 11, Southern Hemat, Shiraz

City

Shiraz

4

Recruitment center

Name of recruitment center

Fereshtegan Nursing Home

Full name of responsible person

Zarei

Street address

Number1, Alley 2, Soroush Avenue, Amir Kabir Boulevard, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Iran University of Medical Science

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Iran University of Medical Sciences, 5th Floor, between intersection of Chamran and Sheikh fazl o lah, Hemat Highway

City

Tehran

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

Yes

Title of funding source

Vice Chancellor of Research, Iran University of Medical Science

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**

Nursing school, Iran University of Medical Sciences

Full name of responsible person

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Position

Master student of Geriatric Nursing

Other areas of specialty/work**Street address**

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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