

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Foot Reflexology on Restless leg syndrome and Sleep Quality in Patients with Multiple Sclerosis

Protocol summary

Study aim

Determining the effect of foot reflexology on restless leg syndrome and sleep quality in patients with multiple sclerosis

Design

This study is a clinical trial with two groups, double blinded and randomized, with 32 patients in each group.

Settings and conduct

This double blinded study, will be done in the Kerman Center of the Special Diseases. Foot reflexology in the intervention group will be performed 3 times per week by a trained researcher in the morning shift for 4 weeks, and in the afternoon three other days of the week, will be performed by the patient at home. The variables will be measured before, immediately and one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of RRMS, Having all four international criteria to diagnose restless legs syndrome, RLS severity score based on the questionnaire of RLS should be 11 or above 11, a total score of 6 or more based on the PSQI. Exclusion criteria: sensory and vascular disorders, orthopedic problems in the lower limbs, Having neurological diseases other than MS, pregnancy and diseases that cause RLS such as anemia, chronic kidney disease and chronic diseases such as cancer, chronic respiratory failure, heart failure, Mental illness such as depression, Taking medications that worsen RLS, such as antidepressants and dopamine antagonists, History of foot reflexology, Alcohol and drug addiction

Intervention groups

Foot reflexology in the intervention group will be performed for 4 weeks and 3 times per week for 20 minutes by a trained researcher in the morning shift and in the afternoon three other days of the week, will be done by the patient at home; While the control group will receive non-specific foot massage without pressing the standard reflexology points with the same conditions and

duration.

Main outcome variables

Restless leg syndrome severity and Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N15**

Registration date: **2023-09-01, 1402/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-01, 1402/06/10**

Update count: **0**

Registration date

2023-09-01, 1402/06/10

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-31, 1402/05/09

Expected recruitment end date

2023-10-31, 1402/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot Reflexology on Restless leg syndrome and Sleep Quality in Patients with Multiple Sclerosis

Public title

The Effect of Foot Reflexology on Restless leg syndrome and Sleep Quality

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to communicate in Farsi Diagnosis of relapsing-remitting multiple sclerosis (RRMS), according to the patient's medical record Having all four international criteria to diagnose restless legs syndrome Restless leg syndrome severity score based on the questionnaire of the international study group of restless legs syndrome should be 11 or above 11. Having a sleep disorder (a total score of 6 or more based on the Pittsburgh Sleep Quality Index) Healthy and undamaged skin in the lower limbs

Exclusion criteria:

Paralysis, amputation, peripheral neuropathy, sensory disorders, vascular disorders, Coagulopathy, deformities or orthopedic problems in the lower limbs. Having neurological diseases other than MS, pregnancy and diseases that cause RLS such as anemia, chronic kidney disease and debilitating and chronic diseases such as cancer, chronic respiratory failure, heart failure, rheumatoid arthritis and lupus erythematosus, according to the patient's medical record Mental illness such as depression according to the patient's self-report Taking medications that worsen restless legs syndrome, such as antidepressants, selective serotonin reuptake inhibitors, antiemetics, anticonvulsants, and dopamine antagonists History of foot reflexology for the treatment of RLS or sleep disorder and use of other complementary and alternative therapies Alcohol and drug addiction

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into intervention and control groups by block randomization method. For this purpose, the block size of 4 is used; So that two participants will be placed in each of the intervention and control groups

within each block, and R software is used for this. Block randomization method. Block randomization works by randomizing participants within blocks such that an equal number are assigned to each treatment. The block size is determined by the researcher and should be a multiple of the number of groups (i.e., with two treatment groups, block size of either 4, 6, or 8) The method used in this study is as follows: BABA"ABBA "AAB"BABA"BBAA" "BAAB "AAB "ABAB"BABA "AABB"BBAA"AABB "ABBA "BAAB"AABB"

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants and the statistician who will be responsible for data analysis will be blinded to the participants in the intervention and control groups. The data analyst does not know which data are related to the intervention group and which data are related to the control group. The information related to the intervention and control groups will be entered into SPSS software under the title of group 1 and group 2. The analyst will not know which of the groups 1 and 2 is the intervention and control groups. To avoid contamination between the intervention and control groups, foot reflexology will be performed on even days for the intervention group and for the control group, simple foot massage will be performed on odd days.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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7616913555

Approval date

2023-08-06, 1402/05/15

Ethics committee reference number

IR.KMU.REC.1402.143

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

2

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

Restless leg syndrome severity

Timepoint

The severity of Restless leg syndrome will be measured before the intervention, immediately after the intervention (at the end of the fourth week) and one month after the intervention.

Method of measurement

International Restless Legs Syndrome Study Group
Rating Scale

2

Description

Sleep Quality

Timepoint

Sleep Quality will be measured before the intervention, immediately after the intervention (at the end of the fourth week) and one month after the intervention.

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Foot reflexology in the intervention group will be performed for 4 weeks and 3 times per week for 20 minutes (10 minutes for each foot) by a trained researcher in the morning shift and in the afternoon three other days of the week, except for the three days when the researcher performs the intervention in the morning shift, It is done at home by the patient herself.

Category

Other

2

Description

Control group: The control group will receive a non-specific foot massage without pressing the standard reflexology points with the same conditions and duration as the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical Center of the Special Diseases

Full name of responsible person

Batool Tirgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Vice-chancellor of research and technology, Kerman
University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

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

Kerman University of Medical Sciences

Full name of responsible person

Batool Tirgari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

