

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of foot massage with olive oil on the severity of restless legs syndrome in hemodialysis patients

Protocol summary

Study aim

To examine the effect of foot massage with olive oil on the severity of restless legs syndrome in hemodialysis patients

Design

Double blind randomised controlled clinical trial

Settings and conduct

The experimental group will receive foot massage with olive oil and oral paraffin oil will be used for the foot massage of the control group. A ten-minute massage (five minutes per foot) from below the knee to the soles of both feet will be performed six times in two weeks (three times a week). The massage starts from the plantar surface of the sole of the foot towards the heel and the dorsal surface of the foot towards the ankle, and then the posterior and anterior parts of the leg up to the knee are massaged. The same technique will be used immediately for the other leg. In the control group, each foot will be massaged using 10 cc of paraffin oil, as in the experimental group, in terms of method and duration. The effleurage technique will be used in the massage therapy protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Aged 18-65 years • Willingness to participate in the study • Being conscious • Continuous treatment with hemodialysis, three times a week for the last 6 months • Ability to walk on affected legs independently • Symptoms of RLS at least twice a week
Exclusion criteria: • Allergic to herbal plants • Any nervous system, vascular, skeletal and muscular disorders/abnormalities in the lower limbs • Simultaneous participation in other research studies investigating the relief of RLS • History of drug and alcohol abuse • Any mental illness, dementia, and intellectual impairment • History of deep vein thrombosis • Pregnancy and breastfeeding • Use of psychiatric and neurological medications • Use of other herbal products to relieve RLS

Intervention groups

Olive oil massage

Main outcome variables

Severity of Restless Legs Syndrome

General information

Reason for update

Foot massage will be performed by a well-trained nurse.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210523051370N1**

Registration date: **2021-07-06, 1400/04/15**

Registration timing: **prospective**

Last update: **2022-07-15, 1401/04/24**

Update count: **3**

Registration date

2021-07-06, 1400/04/15

Registrant information

Name

Seyed Afshin Shorofi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

ashorofi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-22, 1400/04/31

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot massage with olive oil on the severity of restless legs syndrome in hemodialysis patients

Public title

The effect of foot massage with olive oil on restless legs syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 18-65 years; Willingness to participate in the study; Being conscious (oriented to place, person and time); Continuous treatment with hemodialysis, three times a week for the last 6 months; Ability to walk on affected legs independently; Symptoms of restless legs syndrome (RLS) at least twice a week

Exclusion criteria:

Allergic to herbal plants (including essential oils and herbal extracts); Any nervous system, vascular, skeletal and muscular disorders/abnormalities in the lower limbs; Simultaneous participation in other research studies investigating the relief of restless legs syndrome; History of drug and alcohol abuse; Any mental illness, dementia, and intellectual impairment; History of deep vein thrombosis; Pregnancy and breastfeeding; Use of psychiatric and neurological medications; Use of other herbal products to relieve restless legs syndrome.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be recruited using convenience sampling method and then will be assigned to the experimental and control groups using permuted block randomisation (17 blocks - block size of 4). The blocks will be numbered and sealed in 17 sequentially numbered opaque envelopes in random order. The envelopes will be opened individually and the patients will be assigned to the relevant groups. The Random Allocation Software 2.0 will be used to generate randomisation sequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, assessor and masseur will be blinded to the

random allocation. A few drops of olive oil on the assessor's and masseur face mask can suppress the sharpness of the smell of olive oil. Patients will also be wearing a face mask during the intervention.

Placebo

Used

Assignment

Parallel

Other design features

The experimental group will receive foot massage with virgin olive oil (Loyeh, Iran) and oral paraffin oil (Fadak, Iran) will be used for the foot message of the control group. A ten-minute massage (five minutes per foot) from below the knee to the soles of both feet will be performed six times in two weeks (three times a week). The patients will receive massage one hour after the onset of dialysis. The massage starts from the plantar surface of the sole of the foot towards the heel and the dorsal surface of the foot towards the ankle, and then the posterior and anterior parts of the leg up to the knee are massaged. The same technique will be used immediately for the other leg. In the control group, each foot will be massaged using 10 cc of paraffin oil, as in the experimental group, in terms of method and duration. The effleurage technique will be used in the massage therapy protocol.

Secondary Ids

empty

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

Bioethics Committee of Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology, Moalem Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2021-06-08, 1400/03/18

Ethics committee reference number

IR.MAZUMS.REC.1400.9295

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

Restless legs syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Severity of Restless Legs Syndrome

Timepoint

Baseline (before intervention: T0); Follow-ups (after 6th session: T1; a week after the 6th session: T2)

Method of measurement

International Restless Legs Severity Scale

Secondary outcomes

empty

Intervention groups

1

Description

The experimental group will receive foot massage with virgin olive oil (Loyeh, Iran). A ten-minute massage (five minutes per foot) from below the knee to the soles of both feet will be performed six times in two weeks (three times a week). The patients will receive massage one hour after the onset of dialysis. The massage starts from the plantar surface of the sole of the foot towards the heel and the dorsal surface of the foot towards the ankle, and then the posterior and anterior parts of the leg up to the knee are massaged. The same technique will be used immediately for the other leg. The effleurage technique will be used in the massage therapy protocol.

Category

Other

2

Description

The control group will receive foot massage with oral paraffin oil. A ten-minute massage (five minutes per foot) from below the knee to the soles of both feet will be performed six times in two weeks (three times a week). The patients will receive massage one hour after the onset of dialysis. The massage starts from the plantar surface of the sole of the foot towards the heel and the dorsal surface of the foot towards the ankle, and then the posterior and anterior parts of the leg up to the knee are massaged. The same technique will be used immediately for the other leg. In the control group, each foot will be massaged using 10cc of paraffin oil, as in the experimental group, in terms of method and duration. The effleurage technique will be used in the massage therapy protocol.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Haj-Abbass Estarabadi Hemodialysis Center

Full name of responsible person

Dr Masoumeh Asgharpour

Street address

Haj-Abbass Estarabadi Hemodialysis Center, Sargord Ghasemi Street, Babol, Mazandaran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Prof. Majid Saeedi

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Vice Chancellor for Research and Technology, Moallem Square

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Seyed Afshin Shorofi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Complementary and Integrative Medicine

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Position

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable