

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of foot massage with lavender essential oil 1.5% in comparison to paraffin oil on the severity of restless legs syndrome and anxiety levels in hemodialysis patients

Protocol summary

Study aim

To examine the effect of foot massage with lavender essential oil in comparison to paraffin oil on the severity of RLS and anxiety levels in HD patients

Design

This is a double blind randomized controlled clinical trial. 68 patients will be recruited using convenience sampling method and then will be assigned to the experimental and control groups using permuted block randomisation. 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 groups. The Random Allocation Software 2.0 will be used to generate randomisation sequences.

Settings and conduct

Patients will be recruited from the Shahrvand Dialysis Center (Sari, Iran). The patients, assessor and masseur will be blinded to the random allocation. A few drops of lavender oil on the assessor's and masseur face mask can suppress the sharpness of the smell of aroma oil. Patients will be wearing a face mask during the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18-65 years; Willingness to participate in the study; Being conscious; Continuous treatment with HD, three times a week for the last 6 months; Ability to walk on affected legs independently; Having 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; participation in other studies investigating the relief of RLS; History of drug/alcohol abuse; Any mental illness, dementia, and intellectual impairment; History of DVT; Pregnancy and breastfeeding; Use of psychiatric, neurological medications and other herbal products

Intervention groups

The EG will receive foot massage with lavender oil. The CG will receive foot massage with paraffin oil.

Main outcome variables

Severity of RLS; anxiety levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210523051370N7**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-17, 1401/04/26**

Update count: **1**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Seyed Afshin Shorofi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-02, 1401/04/11

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of foot massage with lavender essential oil 1.5% in comparison to paraffin oil on the severity of restless legs syndrome and anxiety levels in hemodialysis patients

Public title

Effect of foot massage with lavender essential oil in comparison to paraffin oil on restless legs syndrome (RLS) and anxiety levels

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 (HD), three times a week for the last 6 months Ability to walk on affected legs independently Having symptoms of restless legs syndrome 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 Withdrawal criteria: Patient's death; Transfer to other hemodialysis centers; Emergency hemodialysis; Any side effects related to the intervention; Missing two hemodialysis sessions; Any interaction between the intervention and patients' medical and nursing care; Unwillingness to continue participation; Eligibility criteria violation.

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget 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

group (EG) and control group (CG) 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 lavender essential oil on the assessor's and masseur face mask can suppress the sharpness of the smell of aroma 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 lavender essential 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 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.

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, Sari, Mazandaran Province

City

Sari

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Mazandaran

Postal code

4815733971

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.MAZUMS.REC.1401.171

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

Restless legs syndrome; anxiety levels

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**1****Description**

Anxiety levels

Timepoint

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

Method of measurement

HADS-anxiety

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

The experimental group will receive foot massage with lavender 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. The effleurage technique will be used in the massage therapy protocol.

Category

Prevention

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

Prevention

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

Shahrvand Dialysis Center, Sari, Iran

Full name of responsible person

Dr Seyed Afshin Shorofi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To keep patient data confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable