

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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.

**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

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 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 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

**Province**

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**

Complementary and Integrative Medicine

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**Position**

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**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