Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 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 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
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Iran (Islamic Republic of)
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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
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Haj-Abbass Estarabadi Hemodialysis Center, Sargord Ghasemi Street, Babol, Mazandaran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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