Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the comparative effect of effleurage massage with and without black seed oil on the sleep quality of restless leg syndrome patients undergoing hemodialysis

Protocol summary

Study aim
Investigating the comparative effect of effleurage massage with and without black seed oil on the sleep quality of restless leg syndrome patients undergoing hemodialysis

Design
Randomised clinical trial with control group, with control group, parallel groups, randomized, on 56 patients

Settings and conduct
The research community will be dialysis patients suffering from restless leg syndrome referring to Hami and Salam Arak Center. Patients will be divided into two control and intervention groups based on the randomized method. Patients of both groups will complete the sleep quality questionnaire 4 weeks after the beginning of the study. The patients of the intervention group will perform effleurage massage with the help of black seed solution for 4 weeks, three times a week, each time 20 minutes and one hour before sleep, and the control group will only perform effleurage massage.

Participants/Inclusion and exclusion criteria
Having the age of 18 to 65 years, performing hemodialysis at least 3 times a week for 4 hours, not having diabetic foot ulcers and amputations, not having debilitating and chronic diseases such as cancer, rheumatoid arthritis and rheumatoid arthritis, not having psychological disorders such as depression and bipolar disorders, not having Cardiovascular and skin disease, lack of physical and mental sensitivity to massage, not taking sleeping pills (sedatives)

Intervention groups
The intervention group was trained on how to perform exfoliation massage during two training sessions, and for 4 weeks, 3 times a week, for a total of 12 sessions, and each time for 20 minutes, every two hours, one hour before bedtime, with the help of black seed oil solution. will give Also, during this period, the control group performs exfoliation massage like the test group without using black seed oil solution.

Main outcome variables
Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240618062169N1**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**
Update count: **0**

Registration date
2024-06-22, 1403/04/02

Registrant information

Name
Tayebeh Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3226 6958

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tybhqasmy654@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-05, 1403/04/15

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the comparative effect of effleurage massage with and without black seed oil on the sleep quality of restless leg syndrome patients undergoing hemodialysis

Public title

Effect of Efflorescence massage with and without black seed oil on hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having the age of 18 to 65 years Hemodialysis should be performed for patients at least 3 times a week and for 4 hours each time Not having physical and mental sensitivity to massage Not having cardiovascular and skin disease Not having psychological disorders such as depression and bipolar disorders Not having heart failure, lupus erythematosus Not having debilitating and chronic diseases such as various cancers and rheumatoid arthritis. No diabetic foot ulcers and orthopedic problems

Exclusion criteria:

Use Sedative drug

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use simple random sampling. The sampling method will be as follows: 56 sheets (A = test) and (B = control) will be provided in equal form and placed in envelopes of the same shape and sealed. Then the eligible patients are asked to take an envelope from the bag containing the envelopes and they are placed in one of the two control or test groups based on the luck of the patients.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Management of Research and Medical Information, Deputy of Research and Technology, University Complex of the Prophet (pbuh), Basij Square

City

Arak

Province

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Postal code

3819693345

Approval date

2024-06-02, 1403/03/13

Ethics committee reference number

IR.ARAKMU.REC.1403.102

Health conditions studied

1

Description of health condition studied

Restless leg syndrome in hemodialysis patients

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

Sleep quality score in the Pittsburgh Questionnaire

Timepoint

The beginning of the intervention (before the start of the intervention), 4 weeks after the start of the intervention.

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participating patients in the intervention group, along with their companions, will be taught how to perform effleurage massage in two face-

to-face training sessions. Also, the patients of the test group will be asked to perform effleurage massage using 10 cc of black seed oil with a concentration of 5% from Tubi company. The patients of the test group will be asked to massage both legs for 4 weeks, 3 times a week, and a total of 12 sessions, each time for 20 minutes, one hour before going to bed. In addition, a group will be formed on Rubik's and WhatsApp , and for patients in the intervention group, links to educational materials related to effleurage massage and videos containing proper instruction on effleurage foot massage with black seed oil will be provided. Patients are also allowed to raise their questions and doubts in the virtual group and receive proper training from the researcher.

Category

Treatment - Other

2

Description

Control group: Participating patients in the control group, along with their companions, will see face-to-face training on how to perform effleurage massage in two training sessions. The patients of the control group will be asked to massage 3 times a week for 4 weeks and a total of 12 sessions, each time for 20 minutes on both legs, one hour before going to bed. In addition, a group will be formed on Rubik's messengers, and for patients in the intervention group, links to educational materials related to effleurage massage and videos containing proper instruction on effleurage foot massage with black seed oil will be provided. Patients are also allowed to raise their questions and doubts in the virtual group and receive proper training from the researcher.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز دیالیز سلام

Full name of responsible person

طیبه قاسمی

Street address

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2

Recruitment center

Name of recruitment center

مرکز دیالیز حامی

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

مهدی صالحی

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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

Arak 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
Arak University of Medical Sciences

Full name of responsible person
Tayyaba Ghasemi

Position
Nursing master student

Latest degree
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Other areas of specialty/work
Nursery

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Person responsible for updating data

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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

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