

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of The Effects of Aromatherapy with Lavender Essence Oil and Lavender Tea on Pain, Fatigue and Sleep Quality in Hemodialysis Patients: A Controlled Clinical Trial

Protocol summary

Study aim

Comparison of determining the effect of inhalation of lavender essence oil and lavender tea on pain, fatigue and sleep quality of hemodialysis patients

Design

Single-blind randomized controlled clinical trial; with two intervention groups (aromatherapy and tea group) and a control group; random allocation will be performed using table of random numbers.

Settings and conduct

One-blind clinical trial will be performed on hemodialysis patients referring to Khalkhal Imam Khomeini hospital in three groups: lavender essence oil, lavender tea and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study ; Perform permanent hemodialysis; Have a history of hemodialysis for at least six months ; Age group 18 to 65 years; Ability to communicate; Lack of allergy to the smell of plant extracts; Absence of respiratory diseases such as asthma, having a healthy sense of smell (through patient statements and nasal examination for non-obstruction); Kidney transplant candidate; Non-pregnancy (for women); No addiction; Not receiving painkillers, hypnotics and sedatives in the last 3 hours. Exclusion criteria: Lack of interest in participating in the study.

Intervention groups

1. Lavender essential oil group 2. Lavender tea group 3. control group

Main outcome variables

Score of Pain; Score of Fatigue; Score of Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190531043778N2**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Khadijeh Nasiri

Name of organization / entity

Khalkhal University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3243 2003

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kh.nasiri@khalums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Effects of Aromatherapy with

Lavender Essence Oil and Lavender Tea on Pain, Fatigue and Sleep Quality in Hemodialysis Patients: A Controlled Clinical Trial	
Public title	Comparison of The Effects of Aromatherapy with Lavender Essence Oil and Lavender Tea on Pain, Sleep Quality and Fatigue
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Perform permanent hemodialysis Have a history of hemodialysis for at least six months Age group 18 to 65 years Ability to communicate Lack of allergy to the smell of plant extracts Absence of respiratory diseases such as asthma, having a healthy sense of smell (through patient statements and nasal examination for non-obstruction) Kidney transplant candidate Non-pregnancy (for women) No addiction Not receiving painkillers, hypnotics and sedatives in the last 3 hours Exclusion criteria: Lack of interest in participating in the study
Age	From 18 years old to 65 years old
Gender	Both
Phase	3
Groups that have been masked	Outcome assessor
Sample size	Target sample size: 90
Randomization (investigator's opinion)	Randomized
Randomization description	The placement of individuals will be random, simple and blocked in one of the three groups, intervention A (aromatherapy), intervention B (lavender tea) or control group C. First, various triple blocks will be written on different cards (ABC, CAB, CBA, BCA, BAC and ACB). One of these blocks will be randomly selected and patients will be allocated based on selected card. Then randomization will be performed for other patients.
Blinding (investigator's opinion)	Single blinded
Blinding description	Questionnaires will be completed by a person who is not aware of patients' allocation to groups.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees
<u>1</u>
Ethics committee
Name of ethics committee
Ethics Committee of Khalkhal University of Medical Sciences
Street address
Muzaffar St
City
Khalkhal
Province
Ardabil
Postal code
۵۶۸۱۷۶۱۳۵۱
Approval date
2021-03-01, 1399/12/11
Ethics committee reference number
IR.KHALUMS.REC.1399.021
Health conditions studied
<u>1</u>
Description of health condition studied
Hemodialysis
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis
Primary outcomes
<u>1</u>
Description
Score of Pain
Timepoint
At the beginning of the study (before the intervention) and 14 days after the start of intervention
Method of measurement
Visual Analogue Scale questionnaire
<u>2</u>
Description
Score of Fatigue
Timepoint
At the beginning of the study (before the intervention) and 14 days after the start of intervention
Method of measurement
Scale Severity Fatigue questionnaire
<u>3</u>
Description
Score of Sleep Quality
Timepoint
At the beginning of the study (before the intervention) and 14 days after the start of intervention
Method of measurement

Secondary outcomes

empty

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

Intervention group: First: Inhalation of lavender with a concentration of 10% for six times in two weeks, each time 5 drops of lavender extract prepared from Barich Essential Oil Company of Iran

Category

Rehabilitation

2**Description**

Intervention group 2: participants will be asked to put lavender tea prepared in the form of a tea bag with 2 grams of dried lavender flowers in 300 ml of boiled water for 10 to 15 minutes for two weeks at night, 1 hour before bedtime

Category

Rehabilitation

3**Description**

Control group: During the first session, after explaining the objectives of the study and obtaining informed consent, the questionnaire will be completed by the research colleague and no extract will be provided to them. After 14 days, the questionnaire will be completed for them again.

Category

N/A

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

Imam Khomeini Hospital Khalkhal

Full name of responsible person

Khadijeh Nasiri

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5681761351

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

Khalkhal 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?**

No

Title of funding source

Khalkhal 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**

Khalkhal University of Medical Sciences

Full name of responsible person

Khadijeh Nasiri

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data from the study will be published after the individuals are not identified

When the data will become available and for how long

Access time from 2023

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Dissemination of data is possible only to verify its accuracy and no statistical analysis and activity is acceptable.

From where data/document is obtainable

Khalkhal University of Medical Sciences

What processes are involved for a request to access data/document

Send a letter to Khalkhal Medical Sciences Research Vice-Chancellor

Comments