Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Email address
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

1

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

1

Description of health condition studied
Hemodialysis
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

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

2

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

3

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

Pittsburgh sleep quality index questionnaire

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
Street address
Muzaffar St
City
Khalkhal
Province
Ardabil
Postal code
5681761351
Phone
+98 45 3243 2002
Fax
+98 45 3242 1979
Email
khadije.nasiri@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khalkhal University of Medical Sciences
Full name of responsible person
Khadijeh Nasiri
Street address
Muzaffar St
City
Khalkhal
Province
Ardabil
Postal code
5681761351
Phone
+98 45 3243 2002
Email
khadije.nasiri@yahoo.com
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
Street address
Muzaffar St
City
Khalkhal
Province
Ardabil

Postal code
5681761351
Phone
+98 45 3243 2002
Email
khadije.nasiri@yahoo.com

Person responsible for scientific 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
Street address
Muzaffar St
City
Khalkhal
Province
Ardabil
Postal code
5681761351
Phone
+98 45 3243 2002
Email
khadije.nasiri@yahoo.com

Person responsible for updating data

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
Street address
Muzaffar St
City
Khalkhal
Province
Ardabil
Postal code
5681761351
Phone
+98 45 3243 2002
Email
khadije.nasiri@yahoo.co

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