Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

The effect of different doses of lavender on the psychological states and physical fatigue in dialysis patients

Protocol summary

Study aim
To examine the effect of aromatherapy with lavender essential oil on well-being, severity of anxiety, depression and fatigue in patients undergoing hemodialysis

Design
This study is a single-blind randomized clinical trial with 120 hemodialysis patients allocated to three groups: control 1 (selected on even days), experimental (selected on even days) and control 2 (selective on odd days).

Settings and conduct
Shahrvand Dialysis Center

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 years and older Willingness to participate in the study Dialysis treatment for at least 6 months Performing dialysis three times a week Ability to communicate Absence of mental disorders No experience of any stressful event in the last 6 months Not using sedatives No history of hospitalization due to psychological problems No history of drug and alcohol addiction Exclusion criteria: Kidney transplant candidate Pregnancy or decision to become pregnant Breastfeeding History of allergies to essential oils and perfumes Acute respiratory disease

Intervention groups
In the experimental group, during the first hour of hemodialysis, a cotton ball impregnated with two drops of lavender essential oil at concentrations of 10% in the first week (3 sessions), 20% in the second week (3 sessions), 30% in the third week (3 sessions), 40% in the fourth week (3 sessions) and 50% in the fifth week (3 sessions) will be attached to the collar at a distance of 10 cm from the nose, and they are asked to breathe normally for 20 minutes. In the control group, a cotton ball soaked in two drops of sweet almond oil is attached to the patient's collar at a distance of 10 cm from the nose. In this study, two control groups are considered.

Main outcome variables
Anxiety Depression Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210523051370N5**
Registration date: **2021-12-20, 1400/09/29**
Registration timing: **prospective**

Last update: **2021-12-20, 1400/09/29**
Update count: **0**

Registration date
2021-12-20, 1400/09/29

Registrant information

Name
Seyed Afshin Shorofi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of different doses of lavender on the psychological states and physical fatigue in dialysis patients

Public title
The effect of lavender on dialysis patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years and older Willingness to participate in the study Undergoing dialysis three times a week Ability to communicate Absence of mental disorders No experience of any stressful event in the last 6 months (such as the death of a close relative) Not using sedatives No history of hospitalization due to psychological problems No history of drug and alcohol addiction Dialysis treatment for a minimum of 6 months

Exclusion criteria:
Kidney transplant candidates Pregnancy or decision to become pregnant Breastfeeding History of allergies to essential oils and perfumes Acute respiratory disease

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be selected based on systematic random sampling. Since about 140 patients are at the dialysis center every day, and the number of participants in each group is 40, the fixed periodic interval becomes 3 (140/40~3). Therefore, every third of the patients admitted to this center on Saturdays, Mondays, and Wednesdays are recruited into the experimental group, and the next one enters the control group-1. If any of these patients do not meet the inclusion criteria, the next one will be selected. If they do not meet the inclusion criteria, the previous one will be selected. Finally, 80 patients will be allocated to the experimental group and control group-1. Likewise, the number of patients referring to the center is 140 on Sundays, Tuesdays, and Thursdays. Since the number of required participants in the control group-2 is 40, every third patient will be selected.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the assessor will be blinded to treatment allocation. To eliminate the effect of lavender fragrance on the assessor, a few drops of lavender essential oil will be splashed on the internal layer of their face mask.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bioethics Committee of Mazandaran University of Medical Sciences

Street address
Vice Chancellor (Research), Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2020-03-25, 1399/01/06

Ethics committee reference number
IR.MAZUMS.REC.1399.035

Health conditions studied

1

Description of health condition studied
hemodialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
anxiety and depression

Timepoint
Before the intervention and the end of the first, second, third, fourth and fifth weeks

Method of measurement
The Hospital Anxiety and Depression Scale

2

Description
Fatigue

Timepoint
Before the intervention and the end of the first, second, third, fourth and fifth weeks

Method of measurement

Fatigue Severity Scale

Secondary outcomes

1

Description
wellbeing
Timepoint
Before the intervention and the end of the first, second, third, fourth and fifth weeks
Method of measurement
Visual Analog Scale

Intervention groups

1

Description
Experimental group undergo inhalation of Lavender Angustifolia essential oil with herbarium number 1-133 procured from the Barij Essence Pharmaceutical Company (Kashan, Iran) and stored in semi-opaque UV-resistant glass bottles at room temperature. Lavender essential oil is inhaled on dialysis days for 5 weeks. A cotton ball soaked in two drops of lavender essential oil with concentrations of 10% in the first week (3 sessions), 20% in the second week (3 sessions), 30% in the third week (3 sessions), 40% in the fourth week (3 sessions) and 50% in the fifth week (3 sessions) will be attached to the collar at a distance of 10 cm from the patient's nose. Patient will be asked to breathe normally for 20 minutes. All patients will be in a semi-sitting position when inhaling lavender essential oil.
Category
Prevention

2

Description
Control group 1: a cotton ball soaked in two drops of sweet almond oil is attached to the patients' collars at a distance of 10 cm from the nose.
Category
Prevention

3

Description
Control group 2: a cotton ball soaked in two drops of sweet almond oil is attached to the patients' collars at a distance of 10 cm from the nose. The difference between the two control groups is the hemodialysis days. If these two control groups have outcomes that differ significantly, then this cannot reflect an effect of the treatment. The power of two control groups exceeds the probability of falsely detecting a treatment effect.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrvand Dialysis Center, Sari, Iran
Full name of responsible person
Dr. Fatemeh Espahbodi
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Shahrvand Dialysis Center, Keshavarz Boulevard, Sari, 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

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
All data will be kept 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