

# 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)

##### Phone

+98 11 3336 7342

##### Email address

ashorofi@yahoo.com

##### 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

## 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

##### Street address

Shahrvand Dialysis Center, Keshavarz Boulevard, Sari, Iran

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Sari

##### Province

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##### Postal code

4815733971

##### Phone

+98 11 3329 1897

##### Email

ftespahbodi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Professor Majid Saeedi

##### Street address

Vice Chancellor for Research, Moallem Square, Sari, Iran

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##### Phone

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pajhooheshi@mazums.ac.ir

#### 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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**

Ph.D.

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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