

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### The effect of lavender aromatherapy on sleep quality in hemodialysis patients

#### Protocol summary

##### Summary

(1)Objectives: The aim of this study is determine the effect of inhalation of lavender essential oil on sleep quality in patients undergoing hemodialysis. (2)Design: The study population included patients undergoing hemodialysis. The study will be done in a group of 53 patients without controls group, without blinding and randomization and in a single dialysis center in Valiasr hospital in Arak city for 4 weeks. (3)Setting and conduct: This quasi-experimental study will be conducted before and after a group. Patients will be selected based on purposive sampling and written consent of the samples will be collected for the study. Researcher will check sleep quality of patients by using of Pittsburgh Sleep Quality Index and a weekly sleep diary. (4) Inclusion criteria: having sleep quality score over of 5 based on Pittsburgh index; no history of asthma and allergies to flowers and plants; no history of olfactory dysfunction. Exclusion criteria: If occur a crisis or an unforeseen event for patients during the intervention period. (5)Intervention: Patients are taught how to use of inhalation of lavender essential oil by cotton ball soaked in 2 drops of pure essential oil at a distance of 20-15 cm of pillow will be placed and then will be asked of them to do this work for 3 times in a week for a night in between before bedtime for 4 weeks. (5)Main outcome measures: After 4 weeks, sleep quality of samples will be tested again and sleep quality survey results will be compared before and after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015061622774N1**

Registration date: **2015-09-20, 1394/06/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-09-20, 1394/06/29

##### Registrant information

###### Name

Maryam Sadeghi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 863313605558

###### Email address

m.sadeghi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2012-04-03, 1391/01/15

##### Expected recruitment end date

2012-10-06, 1391/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of lavender aromatherapy on sleep quality in hemodialysis patients

##### Public title

The effect of lavender aromatherapy on sleep quality in hemodialysis patients

##### Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: Having the age of minimum 18 and maximum 65 years; no history of asthma and allergies to flowers and plants; Agreement for attending in the study; experience of at least 6 months of hemodialysis; no history of olfactory dysfunction; having sleep quality score over of 5 based on Pittsburgh index; Complementary medicine treatment methods (Herbal methods and other Methods) are not used in the last week; Do not use sleeping medications, sedatives; No drug addiction; No dialysis in the night shift; Not suffering from known mental illness; Being consciousness and acceptable ability of listening and speaking to answer questions and learn using of lavender essential oil. Exclusion criteria: no agreement for attending in the study; If occur a crisis or an unforeseen event for patients during the intervention period; If the patient didn't complete weekly sheet of sleep records. (Patients should record at least 21 days of sleeps them in sheet notes, otherwise they will exclude of study).

### 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: **53**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services

##### Street address

Shahid Chamran Highway-Yemen Street-Shahid Arabi street- Next Ayatollah Taleghani hospital- Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Postal code

## Approval date

2012-09-30, 1391/07/09

## Ethics committee reference number

9018685681

## Health conditions studied

### 1

#### Description of health condition studied

sleep disorders in hemodialysis patients

#### ICD-10 code

N18.9

#### ICD-10 code description

Chronic renal failure, unspecified

## Primary outcomes

### 1

#### Description

sleep quality

#### Timepoint

After 4 weeks of intervention

#### Method of measurement

Pittsburgh Sleep Quality Index and weekly sheet of sleep record

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention including inhalation of lavender essential oil by cotton ball soaked in 2 drops of pure essential oil ( made by Barij Essence Pharmaceutical Company of Kashan) at a distance of 20-15 cm of pillow will be placed and then do this work for 3 times in a week for a night in between before bedtime for 4 weeks.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hemodialysis ward of Vali-e-Asr hospital affiliated with Arak University of Medical Sciences

##### Full name of responsible person

Maryam Sadeghi

##### Street address

Vali-e-Asr Sq,Vali-e-Asr Hospital

##### City

Arak

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Investigator

**Full name of responsible person**

Maryam Sadeghi

**Street address**

Vali-e-Asr sq,Vali-e-Asr Hospital

**City**

Arak

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Investigator

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Nursing and Midwifery school of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Aazam Dabirian

**Position**

Ms Degree in Nursing Education

**Other areas of specialty/work**

**Street address**

Vali-e-Asr Street,Crossing Niayesh ,Against Shahid Rajaei Hospital, Nursing and Midwifery school of Shahid Beheshti University of Medical Sciences

**City**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Fax**

+98 21 8820 2521

**Email**

AazamDabirian@yahoo.comAazamDabirian@sbmu.ac.ir ,

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

School of Pharmacy of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Faraz Mojab

**Position**

Pharmacy PHD, Assistant Professor

**Other areas of specialty/work**

**Street address**

Vali-e-Asr Street,Near the Crossing Niayesh ,School of Pharmacy of Shahid Beheshti University of Medical Sciences

**City**

Tehran

**Postal code**

1991953381

**Phone**

+98 86 8820 0118

**Fax**

**Email**

sfmojab@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Maryam Sadeghi

**Position**

Ms Degree in Nursing Education

**Other areas of specialty/work**

**Street address**

Shahid Shirudi Street,Alam-Al-Hoda Street, Arak University of Medical Sciences

**City**

Arak

**Postal code**

**Phone**

+98 86 3313 6055

**Fax**

+98 33133147

**Email**

m.sadeghi@arakmu.ac.irmaryamsadeghi1360@yahoo.commsadeghi1672@yahoo.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*