

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Effect of aromatherapy on Sleep Quality of Patients Undergoing Hemodialysis in zarrin shahr Dialysis Center and Akhavan hospital kashan in 2013.

#### Protocol summary

##### Summary

This study is a quasi - experimental research which is a kind of randomized clinical trial. The population is the patients who hospitalized in dialysis centers of Akhavan hospital in Kashan and Shohadaye Lenjan hospital in Zarrin Shahr. After obtaining written consent from patients, sampling should be done continuously and purposefully, and eligible individuals, after inclusion, randomly divided into intervention group or control group. Intervention group is the group who exposed of two drops of pure lavender oil which dripped on a cotton ball, and pinned to patients' collar every night for seven nights. There is no intervention for control group. In this study, data collection is demographic questionnaire and Pittsburgh sleep quality index questionnaire (PSQI). Before intervention, demographic form and Pittsburgh sleep quality index will be completed for both groups control and intervention. In intervention group, before and after intervention (end of the first week), Pittsburgh sleep quality questionnaire will be completed. In control group, Pittsburgh sleep quality will also be completed matched with the intervention group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013042111572N2**

Registration date: **2013-05-23, 1392/03/02**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-05-23, 1392/03/02

##### Registrant information

##### Name

Zahra Najafi

##### Name of organization / entity

Kashan University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1555 0021

##### Email address

najafi-za@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2013-06-05, 1392/03/15

##### Expected recruitment end date

2013-07-06, 1392/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of aromatherapy on Sleep Quality of Patients Undergoing Hemodialysis in zarrin shahr Dialysis Center and Akhavan hospital kashan in 2013.

##### Public title

The Effect of aromatherapy on Sleep Quality of Patients Undergoing Hemodialysis

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Having the age of minimum 18 and maximum 70; Agreement for attending in the study;

Hemodialysis history for at least 6 months; Performing hemodialysis at least 2 times in a week and every time at least 3 hours; Being consciousness and no hearing and speech impaired (known); No history of allergic rhinitis, eczema or known respiratory problems such as asthma and lack of olfactory dysfunction; Not suffering from known mental illness; No drug addiction Exclusion criteria: Suffering from severe physical crisis, acute illness, hospitalization and surgery; Suffering from mental crisis, bereavement and divorce; Traveling; Lack of cooperation during the study; Patient decease; Allergic to the smell of lavender; Non-performing aromatherapy less than 3 times a week for any reason.

#### **Age**

From **18 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Kashan University of Medical Sciences

###### **Street address**

Kashan, Ravandi Ghotb Boulevard

###### **City**

Kashan

###### **Postal code**

##### **Approval date**

2013-04-23, 1392/02/03

##### **Ethics committee reference number**

577/1/5/29/پ

### **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**

Quality of sleep

##### **Timepoint**

A week

##### **Method of measurement**

Pittsburgh sleep quality index questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention1: Interventiongroup is the group who exposed of two drops of pure lavender oil. which dripped on a cotton ball, and pinned to patients' collar every night for seven nights.

##### **Category**

Other

#### **2**

##### **Description**

Intervention: There is no intervention for control group.

##### **Category**

Other

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

dialysis centers of Shohadaye Lenjan hospital

###### **Full name of responsible person**

Zahra Najafi

###### **Street address**

Kashan University of Medical Sciences

###### **City**

Zarrin Shahr

#### **2**

##### **Recruitment center**

###### **Name of recruitment center**

Akhavan hospital

###### **Full name of responsible person**

Zahra Najafi

###### **Street address**

Kashan University of Medical Sciences  
**City**  
Kashan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Gholamali Hamidi  
**Street address**  
Vice chancellor for research, Kashan University of  
Medical Sciences  
**City**  
Kashan  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Kashan University of Medical Sciences  
**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**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Zahra Najafi  
**Position**  
Graduate student critical care nursing  
**Other areas of specialty/work**  
**Street address**  
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87155/111  
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zahranajafi90@yahoo.comzahranajafi90@ymail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

### Contact

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## 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*