Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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