Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison the effects of inhalation aromatherapy with essential oil of Lavender and Orange on fatigue, anxiety and depression in hemodialysis patients

Protocol summary

Summary

Objective: Comparing the effects of inhalation aromatherapy with Lavender and Orange essential oils on the level of fatigue, anxiety and depression in hemodialysis patients. Design: randomized controlled clinical trial. Setting and conduct: sample size is 90 patients. Eligible patients randomly will be assign to intervention and control groups. Inclusion and exclusion criteria: inclusion criteria include Consent to participate in the study, age 18-65 years, Lack of allergies, having healthy sense of smell. Exclusion criteria is the patient's unwillingness to continue cooperation, become critically ill during the study, and receiving narcotic and oxygen during aromatherapy. Interventions: The study will perform for two consecutive weeks. Initially the DASS-21 and FSS questionnaire will be completed by patients. In groups one and two, inhalation of five drops of Lavender and Orange essential oils will be used for 30 minutes, respectively. Control group will be received inhalation of five drops of sterile water for 30 minutes. These essences will be spilled on a piece of cotton and will be attached to the patient`s cloth on the chest for 30 minutes. At the end of two weeks the questionnaires will be complete again by the patients. The main outcome variables: fatigue, anxiety and depression

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610244736N17**
Registration date: **2016-12-10, 1395/09/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-12-10, 1395/09/20

Registrant information

Name
Alireza Khatony
Name of organization / entity
Kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 3827 9394
Email address
akhatony@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of inhalation aromatherapy with essential oil of Lavender and Orange on fatigue, anxiety and depression in hemodialysis patients

Public title

Effect of aromatherapy on fatigue, anxiety and depression in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: willingness for participating in the research; doing hemodialysis three times a week; doing hemodialysis for at least 6 month; age between 18-65 year; being conscious; having verbal contact; having no allergy to essential oils of Lavender and Orange; having healthy sense of smell. Exclusion criteria: the patient's unwillingness to continue cooperation; become critically ill during the study; and receiving narcotic and oxygen during aromatherapy.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshty Boulevard, Kermanshah, Iran

City

Kermanshah

Postal code

Approval date

2016-11-23, 1395/09/03

Ethics committee reference number

KUMS.RES.1395.510

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Fatigue

Timepoint

at the beginnig of the study and fourteenth day

Method of measurement

fatigue severity scale

2

Description

depression

Timepoint

at the beginnig of the study and fourteenth day

Method of measurement

DASS-21 questionaire

3

Description

anxiety

Timepoint

at the beginnig of the study and fourteenth day

Method of measurement

DASS-21 questionaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Before intervention the fatigue, depression and anxiety questionnaires will be completed by the samples. Intervention will be conducted for two consecutive. For this purpose, in group one 5 drops of Lavender essential oil will be dropped on a piece of cotton and then it will be attached to the patient`s clothing on chest area and will be inhaled for 30 minutes by the patient. One hundred percent concentration of essential oils are used. The time of using the fragrances is half an hour after initiation of dialysis. At the end of two weeks, the questionnaires will be completed again by the patients.

Category

Other

2

Description

Intervention2: In group 2 before intervention the fatigue, depression and anxiety questionnaires will be completed

by the samples. Intervention will be conducted for two consecutive weeks. In group one 5 drops of Orange essential oil will be dropped on a piece of cotton and then it will be attached to the patient`s clothing on chest area and will be inhaled for 30 minutes. One hundred percent concentration of essential oils are used. The time of using the fragrances is half an hour after initiation of dialysis. At the end of two weeks, the questionnaires will be completed again by the patients.

Category
Other

3

Description
In the control group for two consecutive weeks, 5 drops of distilled, will be dropped on a piece of cotton by dropper and it will be attached to the patient's clothing and will be inhaled by the patient for 30 minutes. Before and after the intervention the fatigue, depression and anxiety questionnaires will be completed by the samples.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Alireza Khatony

Street address
Kermanshah University of Medical Science, Shahid Beheshti Boulevard, Kermanshah, Iran

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Cancellor for Research, Kermanshah University of Medical Science

Full name of responsible person
Behrooz Hamzeh

Street address
kermanshah, Shahid Beheshty Boulevard, kermanshah university of medical science

City
Kermanshah

Grant name

Grant code / Reference number

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

Title of funding source
Vice Cancellor for Research, Kermanshah University of Medical Science

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
Kermanshah School of Nursing and Midwifery

Full name of responsible person
Alireza Khatony

Position
PhD, Faculty Member

Other areas of specialty/work

Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Boulevard, Kermanshah,Iran

City
kermanshah

Postal code

Phone
+98 83 3827 9394

Fax

Email
akhatony@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah School of Nursing and Midwifery

Full name of responsible person
Alireza Khatony

Position
PhD in Nursing Education-faculty member

Other areas of specialty/work

Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Boulevard, Kermanshah, Iran

City
Kermanshah

Postal code

Phone
+98 83 3827 9394

Fax

Email
akhatony@kums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah School of Nursing and Midwifery
Full name of responsible person
Alireza Khatony
Position
PhD in Nursing Education , Faculty Member
Other areas of specialty/work
Street address
Nursing Department, Kermanshah School of Nursing and Miwifery, Dolat Abaad, Kermanshah, Iran
City
Kermanshah
Postal code
Phone
+98 83 3827 9394
Fax
Email
akhatony@kums.ac.ir
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