Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The assessment of the jasmine oil aroma effectiveness on sleep quality in patients undergoing hemodialysis.

Protocol summary

Study aim
Determining the effect of jasmine oil on sleep quality of patients undergoing hemodialysis in Sabzevar dialysis centers in 2021

Design
Randomized Clinical trial with control group, with parallel, single -blind, and outcome assessment

Settings and conduct
The location of the project performong will be Vasei Hospital and Kashefi Dialysis Center in Sabzevar. Hemodialysis patients who meet the inclusion criteria are divided into two groups using random allocation: intervention (receiving jasmine aroma) and control (not receiving jasmine aroma) for one month. before and after intervention sleep quality of patients measured and compared by Pittsburgh questionnaire. In this clinical trial, the statistician will be blinded with lack of information about data in two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Get a Pittsburgh questionnaire score greater than 5 • At least 18 years old and at most 70 years old • History of at least 6 months of hemodialysis • Perform hemodialysis at least twice a week for at least 3 hours each time • Having full consciousness exclusion criteria: • Significant hearing and speech disorders • Known respiratory problems such as asthma • Existence of olfactory disorder • Known mental illness and drug addiction

Intervention groups
The intervention group is exposed to 5 drops of jasmine oil every night before going to bed for a month with a cotton swab dipped in oil.This oil, which is prepared from the jasmine flower by Ben Marie method with a concentration of 50% by the Gold Company of Nature, contains the active ingredients of linalyl acetate and benzyl acetate.The control group will receive only standard therapeutic interventions during the study.

Main outcome variables
A sleep quality score based on the Pittsburgh Sleep Quality Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210217050396N1**
Registration date: **2021-03-27, 1400/01/07**
Registration timing: **prospective**

Last update: **2021-03-27, 1400/01/07**
Update count: **0**

Registration date
2021-03-27, 1400/01/07

Registrant information

Name
Alemeh Sultani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 4465 6867

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-09, 1400/01/20

Expected recruitment end date
2021-06-10, 1400/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The assessment of the jasmine oil aroma effectiveness on sleep quality in patients undergoing hemodialysis.

Public title
The assessment of the jasmine oil aroma effectiveness on sleep quality in patients undergoing hemodialysis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Get a Pittsburgh questionnaire score greater than 5 Having a minimum age of 18 and a maximum of 70 years Have a history of at least 6 months of hemodialysis Perform hemodialysis at least twice a week for at least 3 hours each time Having full consciousness

Exclusion criteria:
Significant hearing and speech disorders Known respiratory problems such as asthma Existence of olfactory disorder Known mental illness and drug addiction

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

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be selected by available sampling and will be randomly assigned to intervention and control groups using random allocation blocks.R Software will be used to get the blocks. The blocks are made up of 6 English letters (A,B,C,D,E,F). A ,B,C will be considered for the intervention group, and other three letters (D,E,F) will be considered for the control group. The blocks will be randomly selected in blindfolded manner. Each block will determine the order of entry in the intervention and control groups. Assuming choosing the DCAFBE block means from left hand, first, fourth and sixth, respectively, will be located in the control group, and the second, third, and fifth of participants will be located in the intervention group, respectively. Thus, ten blocks will be selected to complete the sampling.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the lack of a placebo and researcher assistant, blinding the participant and the researcher will not be possible. Only the data analyzer is blinded due to lack of knowing the patients and giving data as A and B group to her.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar university of medical sciences

Street address
Vice Chancellor for Research and Technology , University of Medical Sciences , Campus University , above the Memorial of the Unknown Martyrs, Nuclear Martyrs Boulevard

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Sabzevar

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Razavi Khorasan

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9617913112

Approval date
2021-03-15, 1399/12/25

Ethics committee reference number
IR.MEDSAB.REC.1399.196

Health conditions studied

1

Description of health condition studied
Patients undergoing hemodialysis

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Sleep quality score on the Pittsburgh questionnaire is less than 5

Timepoint
اندازه گیری کیفیت خواب در ابتدای مطالعه و یکماه پس از شروع استفاده از رایحه روغن یاسمین

Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Every night for a month, before going to bed, they are exposed to 5 drops of jasmine oil. This oil, which is prepared from jasmine flowers by the Ben Marie method with a concentration of 50% by the Golden Nature Company, contains the active ingredients linalyl acetate and benzyl acetate. The method of using this oil in the present study is that we ask the patient or his companion to put 5 drops of Yasmin oil in a dropper containing 10 ccs of oil on a cotton ball each night before going to bed. Drop the prepared material and attach it to the collar of the research unit with a pin, and after waking up, remove it and throw it away. The method of use will be explained to the patient or his companion by the researcher in a practical way.

Category

Treatment - Other

2

Description

Control group: Since the aroma of any type of oil to be used as a placebo may affect the sleep quality of the control group units, we prefer not to use a placebo for these people. Therefore, the control group will receive only standard therapeutic interventions during the study. After one month, the sleep scores of the control and intervention groups are determined using the Pittsburgh questionnaire.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sabzevar Vasei Dialysis Center

Full name of responsible person
Alemeh Soltani

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A large educational and medical hospital , Nuclear Martyrs Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences

Full name of responsible person
Alemeh Sultani

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
There is no more information

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
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available