Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of eucalyptus oil aromatherapy on anxiety and sleep disorders of hemodialysis patients

Protocol summary

Study aim
Determining the effect of eucalyptus oil aromatherapy on anxiety and sleep disorders in hemodialysis patients

Design
This study is a randomized controlled clinical trial with parallel groups on 90 patients undergoing hemodialysis. After meeting the inclusion criteria, participants were randomly assigned to two intervention and control groups. Randomization was performed using SPSS software. This study is conducted without blinding.

Settings and conduct
This randomized clinical trial will be conducted on hemodialysis patients in Gonabad. In the intervention group, eucalyptus aromatherapy will be administered during each dialysis session for 6 weeks (18–24 sessions), using a gauze or tissue with 10 drops of eucalyptus essential oil attached to the patient's collar for continuous inhalation. The control group will receive routine hemodialysis care only.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Willingness to participate Score ≥20 on the Spielberger Anxiety Inventory and ≥5 on the PSQI No history of psychiatric disorders No olfactory dysfunction No use of medications for anxiety or sleep disorders On hemodialysis ≥6 months, three times weekly (3–5 hours/session) Exclusion Criteria:Withdrawal from the study Non-adherence to study instructions Allergy to eucalyptus or development of olfactory problems

Intervention groups
This study evaluates the effectiveness of eucalyptus aromatherapy on anxiety and sleep disorders in hemodialysis patients. The control group receives routine hemodialysis care according to the center's protocol, including standard monitoring and nursing care. No aromatherapy intervention is provided to this group.

Main outcome variables
Anxiety, Sleep disorders

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260422069132N1**
Registration date: **2026-05-10, 1405/02/20**
Registration timing: **prospective**

Last update: **2026-05-10, 1405/02/20**
Update count: **0**

Registration date
2026-05-10, 1405/02/20

Registrant information

Name
Neda Pishbin nooghabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5723 1122

Email address
nedapishbin@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-05, 1405/03/15

Expected recruitment end date
2026-08-06, 1405/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of eucalyptus oil aromatherapy on anxiety and sleep disorders of hemodialysis patients

Public title
The effect of eucalyptus extract aroma on anxiety and sleep disorders in hemodialysis patients.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the project Having anxiety disorders The person does not have any mental or underlying disorders Obtaining a score of 20 as the cut-off point of the Spielberger Anxiety Questionnaire and also obtaining a score of 5 or higher as the cut-off point of the Pittsburgh Sleep Quality Questionnaire They had no smell problems They were not taking any medication for anxiety or sleep disorders The patients were undergoing hemodialysis (HD) treatment for at least 6 months, the patients underwent hemodialysis treatment (at least) three times a week, each time for three to five hours
Exclusion criteria:
Failure to comply with and complete training Withdrawing from further participation in the study The patient is allergic to medication or has a sense of smell disorder.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Main method: Simple random probability; in case of limitations, available sampling Randomization method: Simple randomization, in this study, the allocation of patients to two intervention groups (inhalation/eucalyptus aromatherapy) and the control group is done by simple randomization method. For this purpose, the allocation group is determined for each patient entered into the study, based on a pre-prepared random sequence. Randomization unit: Individual Strategic randomization is not used in this study and randomization is performed without stratification. The randomization tool is statistical software (SPSS) How to create a random sequence: First, an allocation number is considered for each sample unit (patient). Then, using the random number generation function in SPSS software, a random number is assigned to each number. The list of patients is sorted from small to large based on these random numbers, and patients are placed alternately or in a predetermined sequence in the two groups "intervention" and "control" until the sample size in each group is completed. Concealment: In order to prevent bias in assigning patients to groups, the method of opaque, non-transparent, numbered, and sealed envelopes is used sequentially.
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 Gonabad University of Medical Sciences
Street address
No. 13, 6th 22 Bahman Street, Nooghab, Gonabad, Iran
City
Gonabad
Province
Razavi Khorasan
Postal code
9691896389
Approval date
2023-09-20, 1402/06/29
Ethics committee reference number
IR.GMU.REC.1402.148

Health conditions studied

1

Description of health condition studied
Anxiety and Sleep Disorders in Hemodialysis Patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Outcome Variable 1:The level of anxiety in patients undergoing hemodialysis, measured using the Spielberger State–Trait Anxiety Inventory (STAI). This variable will be assessed at two time points: before the start of the intervention and at the end of the sixth week after the implementation of aromatherapy with eucalyptus essential oil. Outcome Variable 2:Sleep quality in patients undergoing hemodialysis, measured using the Pittsburgh Sleep Quality Index (PSQI). This variable will also be assessed at two time points: before the start of the intervention and at the end of the sixth

week after the implementation of aromatherapy with eucalyptus essential oil.

Timepoint

After 6 weeks of hemodialysis

Method of measurement

Spielberger Anxiety Questionnaire and Pittsburgh Sleep Disorders Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The intervention group will receive aromatherapy during each dialysis session for 6 weeks (18-24 sessions, depending on the number of dialysis sessions per week (twice or three times a week)) using gauze or a tissue with 10 drops of pure eucalyptus oil, fixed to the collar of the patient's clothing, and inhaled during hemodialysis.

Category

Lifestyle

2

Description

Control group: In the control group, routine measures are performed during and after hemodialysis.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlool Gonabadi Hospital

Full name of responsible person

Neda PishbinNooghabi

Street address

No. 13, 6th 22 Bahman Street, Nooghab, Gonabad, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691896389

Phone

+98 915 533 0757

Email

nedapishbin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr Ali Firouzi Chahak

Street address

Research and Technology Committee, Gonabad University of Medical Sciences, Asian Highway, Gonabad, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691896389

Phone

+98 915 533 0757

Email

ali_firoozi66@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Neda Pishbin nooghabi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

No. 13, 6th 22 Bahman Street, Nooghab, Gonabad, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691896389

Phone

+98 51 5723 1122

Fax

Email

nedapishbin@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Neda Pishbin nooghabi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

No. 13, 6th 22 Bahman Street, Nooghab, Gonabad, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691896389

Phone

+98 51 5723 1122

Fax

Email

nedapishbin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Neda Pishbin nooghabi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

No. 13, 6th 22 Bahman Street, Nooghab, Gonabad, Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691896389

Phone

+98 51 5723 1122

Fax

Email

nedapishbin@gmail.com

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

No further information is available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable