Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Inhalation of Melissa officinalis essence on symptom burden and Anxiety of Patients under Hemodialysis

Protocol summary

Study aim
Determining the effect of inhalation of Melissa officinalis essence on the of symptom burden and anxiety in hemodialysis patients

Design
Clinical trial with control group, with parallel groups, one-way blind, randomized

Settings and conduct
The study will be performed at the hemodialysis center of Hazrat Zahra Marzieh Hospital in Isfahan. Depending on the couple or individual referral, patients will be randomly divided into control and intervention groups using coin toss. Then a simple random method will be used to determine people to enter the groups. Patients in both control and intervention groups will receive routine care of the hemodialysis ward. In the intervention group, aromatherapy with lemon balm essential oil will be performed three times a week for a month. One-way blindness: outcome assessor and data analyzer

Participants/Inclusion and exclusion criteria
Inclusion criteria : - Age 18 years old and older - Perform 6 months of hemodialysis - Perform hemodialysis 3 times a week - Able to understand and speak Persian language Exclusion criteria - Respiratory and allergic problems such as asthma, history of allergies to plants, chronic mental illness - Chronic mental illness - Intolerance to essential oils during the intervention - Any allergies to aromatic oils used during the intervention Acute pain during the intervention Absence of more than two consecutive sessions - The patient's unwillingness to continue

Intervention groups
In the intervention group, 200 microliters of Melissa officinalis essence is poured on a cotton ball and for 20 minutes, at the beginning of hemodialysis, it is attached to the patient's clothes with a pin at a distance of 20 cm from the patient's nose. Breathe normally during hemodialysis. In the control group, 200 microliters of bitter almond oil will be used.

Main outcome variables
symptom burden , anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191021045178N3**
Registration date: **2021-04-27, 1400/02/07**
Registration timing: **retrospective**

Last update: **2021-04-27, 1400/02/07**
Update count: **0**

Registration date
2021-04-27, 1400/02/07

Registrant information

Name
Nilofar Pasyar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3623 6293

Email address
pasyarn@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-01-19, 1399/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Inhalation of Melissa officinalis essence on symptom burden and Anxiety of Patients under Hemodialysis

Public title
Evaluation of the effect of lemon balm on anxiety and symptom burden of patients undergoing hemodialysis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 years and older At least 6 months have passed since the start of hemodialysis hemodialysis three times a week to do Able to understand and speak Persian

Exclusion criteria:
Patients who do not have the desire or ability to collaborate with researchers Patients with acute respiratory problems History of allergies to plants Chronic mental illness Intolerance to essential oils during the intervention Acute pain during the intervention

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization: First, the researcher selects the samples randomly based on the list in the section based on a table of random numbers. Then, patients are selected according to the inclusion criteria and based on the purpose, and due to the fact that patients are referred to the hemodialysis center as couples and individuals, the days of individuals and couples will be determined as days of intervention or control by tossing a coin. Then, by simple random sampling in each group, patients will be placed in the experimental and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
To blind the study, participants are given full explanations on how to perform the intervention before the intervention, but participants are unaware of the allocation of study groups. Also, in collecting data and completing questionnaires, the help of a researcher who is not aware of the division of groups will be used. Also, the statistician who analyzes the data will not know about the assignment of groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand St., in front of Phelestine St., the central building of Shiraz University of Medical Sciences

City
shiraz

Province
Fars

Postal code
۷۱۳۴۸۱۴۳۳۶

Approval date
2020-12-10, 1399/09/20

Ethics committee reference number
IR.SUMS.REC.1400.065

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F40

ICD-10 code description
Phobic anxiety disorders

2

Description of health condition studied
Chronic renal failure. Patients undergoing hemodialysis

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Anxiety

Timepoint
Before the intervention and 30 days after the intervention

Method of measurement

Spielberger state- trait anxiety inventory

2

Description
symptom burden
Timepoint
Before the intervention and 30 days after the intervention
Method of measurement
Dialysis Symptoms Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In the intervention group, 200 microliters of pure Melissa officinalis essence is poured on a cotton ball and for 20 minutes, at the beginning of hemodialysis, at a distance of 20 cm from the patient's nose by pin to The patient's clothes are attached and we ask the patient to breathe normally during hemodialysis.
Category
Treatment - Other

2

Description
Control group: In the control group, 200 microliters of bitter almond oil is poured on a cotton ball and inhaled by patients. The intervention will be performed 3 times a week during hemodialysis (initial 20 minutes of dialysis) for one month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zahra Marzieh Hospital
Full name of responsible person
mansuoreh aghababaei
Street address
Ghods Square, Sahib Ibn Ebad Alley, Allameh Majlisi St., Zahra Marzieh Hospital
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8155816171
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Shiraz, Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences
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Email
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Nilofar Pasyar
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address

Shiraz, Namazi Square, Hazrat Fatemeh School of Nursing

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Person responsible for scientific inquiries

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Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Nursing Graduate Student

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Other areas of specialty/work
Nursery

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Esfahan

Province
Isfehan

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Obtaining an official letter of introduction from Hazrat Fatemeh School of Midwifery and Nursing in Shiraz and obtaining permission from the officials of Shiraz University of Medical Sciences Obtaining written consent from the samples to participate in the study - Assuring the research units about the confidentiality of the information received - Participate freely and completely voluntarily in the research samples and considering the right to withdraw from the research - Creating a private environment for interviewing the patient and completing a questionnaire Provide the results of the research if desired by the training center where the researcher has sampled.

When the data will become available and for how long
After studying and printing the results

To whom data/document is available
The results of the research will be provided to the participants and relevant organizations upon request.

Under which criteria data/document could be used
Obtain permission from the relevant authorities in the faculty, university and hospital. Keeping participants' information confidential

From where data/document is obtainable
Shiraz. Zand St., Library of Shiraz School of Nursing and Midwifery. Mr. Ghasemi's library manager. Phone: 00987136474254

What processes are involved for a request to access data/document
The request for the results will be sent to the library of Shiraz School of Nursing and Midwifery. It will be provided to them with the coordination done.

Comments