

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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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Email

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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

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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

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nilofar Pasyar

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Mansuoreh Aghababaei

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

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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