

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8155816171

##### Phone

+98 31 3445 6061

#### Fax

+98 31 3445 4300

#### Email

info@zmhospital.ir

## 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

##### City

shiraz

##### Province

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##### Postal code

71348-14336

##### Phone

+98 71 3212 2713

##### Fax

+98 71 3230 8200

##### Email

info@sums.ac.ir

#### 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

**City**

shiraz

**Province**

Fars

**Postal code**

71345-1978

**Phone**

+98 71 3647 4254

**Email**

Npasyar@sums.ac.ir

## Person responsible for scientific 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**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mansuoreh Aghababaei

**Position**

Nursing Graduate Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Jey St. Shariati St. Azadi Alley

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8159863811

**Phone**

+98 31 3523 3271

**Email**

m\_babaei@sums.ac.ir

## 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**