

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Aug 2022

### Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' sleep quality

#### Protocol summary

##### Study aim

To determine the effect of aromatherapy with essential oils of lavender and peppermint on the sleep quality of cardiac patients

##### Design

Clinical trials, with parallel groups, randomized

##### Settings and conduct

In this study, heart patients hospitalized in Imam Ali Hospital and eligible individuals were randomly divided into three groups (two intervention groups and one control group). For 7 nights at 22 o'clock, in group one, three drops of peppermint essential oil, in group two, three drops of lavender essential oil, and in group three (control group), three drops of distilled water, on a napkin, and held for 20 minutes by the gauze, Will be attached in the chest area.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include Consent to participate in the study, positive reaction to smell, earn points equal to or more than five from the Pittsburgh sleep quality Index. Exclusion criteria include Unwillingness to continue to cooperate, and administering oxygen for patients.

##### Intervention groups

In group1, for seven nights at 22 o'clock, the three drops of Peppermint essential oil will be used. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes. In group2: for seven nights at 22 o'clock, the three drops of lavender essential oil will be used. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes. In control group: for seven nights at 22 o'clock, the three drops of distilled water and is connected to the patient's clothing at the chest and inhaled for 20 minutes

##### Main outcome variables

sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201601244736N10**

Registration date: **2016-11-04, 1395/08/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-24, 1397/10/03**

Update count: **1**

##### Registration date

2016-11-04, 1395/08/14

##### Registrant information

##### Name

Alireza Khatony

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3827 9394

##### Email address

akhatony@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' sleep quality

## Public title

Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' sleep quality

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Consent to participate in the study  
Positive reaction to smell  
Stability of vital signs (blood pressure, pulse, respiration and temperature) having aged 18 to 65 years  
Earn points equal to or more than five from the Pittsburgh sleep quality Index  
Lack of sinusitis and Pneumonia  
No addiction to drugs and alcohol  
Being alert  
Passed 48 hours of admission not having mental disease and no history of hospitalization in psychiatric wards  
Do not take caffeine one hour before bedtime

### Exclusion criteria:

Unwillingness to continue to cooperate  
Transition to other wards or death  
Receiving narcotic and oxygen during aromatherapy  
Critically ill patient during the study

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **105**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Qualified samples were entered into the study by accessible method and randomly divided into intervention groups (peppermint and lavender) and control. Blocks were done as follows: To aromatic groups with peppermint essential oil and Lavender was assigned A and B codes respectively, and the control group received C code. The study blocks were ABC, ACB, BAC, BCA, CAB, CBA, BCC, CAB, CAB, and the ABC block was selected as the first block. Patients were assigned to peppermint, lavender, and control groups, respectively, and this method continued until the samples were completed.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

##### Street address

Kermanshah University of Medical Sciences, Shahid Beheshti Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

##### City

kermanshah

##### Province

Kermanshah

##### Postal code

62663455667

#### Approval date

2016-09-28, 1395/07/07

#### Ethics committee reference number

kums.rec.1395.380

## Health conditions studied

### 1

#### Description of health condition studied

Coronary Artery Disease

#### ICD-10 code

I25.1

#### ICD-10 code description

Coronary Artery Disease

### 2

#### Description of health condition studied

Myocardial infarction

#### ICD-10 code

I22

#### ICD-10 code description

Myocardial infarction

### 3

#### Description of health condition studied

Congestive heart failure

#### ICD-10 code

I50.0

#### ICD-10 code description

Congestive heart failure

## Primary outcomes

### 1

#### Description

sleep quality

**Timepoint**

at the beginning of study and Eighth day

**Method of measurement**

Pittsburgh sleep quality questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In group 1, for seven nights before going to sleep at 22 o'clock, the three drops of lavender essential oil will be used. Trade name of this essence is lavender essential oil and its scientific name is *Lavandula stoechas* which is produced by Tehran Zarband Company. This essential oil will be used in pure form with a concentration of 100 percent. Major chemical compounds included are linalyl acetate and linalool. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes.

**Category**

Other

**2****Description**

In group 2, for seven nights before going to sleep at 22 o'clock, the three drops of Peppermint essential oil will be used. Colpermin' is a pharmaceutical brand name for peppermint oil and its scientific name is *Mentha piperita* which is produced by Tehran Zarband Company. This essential oil will be used in pure form with a concentration of 100 percent. Major chemical compounds included Menthol, Mentol and methyl acetate. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes.

**Category**

Other

**3****Description**

In control group, for seven nights before going to sleep at 22 o'clock, the three drops of distilled water will be used which is produced by Tehran Samen Company. Distilled water will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes.

**Category**

Placebo

**Recruitment centers****1****Recruitment center**

Name of recruitment center

Imam Ali Hospital of Kermanshah

**Full name of responsible person**

Alireza Khatony

**Street address**

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Street, Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714634698

**Phone**

+98 83 3827 9394

**Email**

akhatony@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

**Full name of responsible person**

Behrooz Hamzeh

**Street address**

Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran

**City**

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**Province**

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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**

Vice chancellor for research, Kermanshah 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**

Kermanshah School of Nursing and Midwifery

**Full name of responsible person**

alireza khatony

**Position**

PhD, Faculty Member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah School of Nursing and Midwifery

**Full name of responsible person**

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**Position**

PhD in Nursing Education

**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**

Kermanshah School of Nursing and Midwifery

**Full name of responsible person**

Alireza Khatony

**Position**

PhD in Nursing Education, Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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**Fax****Email**

akhatony@kums.ac.ir

**Web page address**

## 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**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The main consequence is the possibility of sharing information.

**When the data will become available and for how long**

Six months after the publication of the article

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

There is no right to extract the article from the documentation.

**From where data/document is obtainable**

Dr. Alireza Khatony

**What processes are involved for a request to access data/document**

Within a week of receiving the email, it will be answered.

**Comments**