

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Dec 2023

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

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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

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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

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv., Kermanshah, Iran

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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

Alireza Khatony

Position

PhD in Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Alireza Khatony

Position

PhD in Nursing Education, Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Fax**Email**

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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