

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' level of fatigue, anxiety and depression

Protocol summary

Study aim

Comparative of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' level of fatigue, anxiety and depression

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 to the clothes of the patient in the chest area.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the study, positive reaction to smell, The absence of any physical pain, the stability of vital signs. having aged 18 to 65 years, Lack of sinusitis and nasal septum deviation, no addiction to drugs and alcohol. Exclusion criteria: Unwillingness to continue to cooperate, Transition to other wards, and Receiving narcotic and oxygen during aromatherapy

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

Anxiety : Depression and Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181105041563N2**

Registration date: **2018-12-16, 1397/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-16, 1397/09/25**

Update count: **0**

Registration date

2018-12-16, 1397/09/25

Registrant information

Name

Somayeh Mahdavian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 9394

Email address

somayeh.mahdavian@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-21, 1397/06/30

Expected recruitment end date

2019-08-21, 1398/05/30

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' level of fatigue, anxiety and depression

Public title

Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' level of fatigue, anxiety and depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Consent to participate in the study, positive reaction to smell, The absence of any physical pain, the stability of vital signs (blood pressure, pulse, respiration and temperature), having aged 18 to 65 years, earn points equal to or more than seven for Depression and earn points equal to or more than six for Anxiety from the Depression Anxiety Stress Scales (DASS), earn points more than 40 for Fatigue from the Fatigue Severity Scale (FSS). Lack of sinusitis and nasal septum deviation, no addiction to drugs and alcohol.

Exclusion criteria:

Exclusion criteria: Unwillingness to continue to cooperate, Transition to other wards, and Receiving narcotic and oxygen during aromatherapy

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

2

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 Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Approval date

2018-05-08, 1397/02/18

Ethics committee reference number

IR.KUMS.REC.1397.195

Health conditions studied**1****Description of health condition studied**

Cardiac disease

ICD-10 code

Ischaemic

ICD-10 code description

I20-I25

2**Description of health condition studied**

Heart failure

ICD-10 code

Heart fail

ICD-10 code description

I50.9

3**Description of health condition studied**

Acute myocardial infarction

ICD-10 code

Acute myoc

ICD-10 code description

I21

Primary outcomes

1

Description

depression

Timepoint

at the beginning of study and eighth day

Method of measurement

Depression Anxiety Stress Scales DASS21

2

Description

Anxiety

Timepoint

at the beginning of study and eighth day

Method of measurement

Depression Anxiety Stress Scales DASS21

3

Description

Fatigue

Timepoint

at the beginning of study and eighth day

Method of measurement

Fatigue Severity Scale FSS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group 1, for seven nights 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

2

Description

Intervention group: In group I, for seven nights 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

3

Description

Control group: In control group, for seven nights 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

Somayeh Mahdavian

Street address

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

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Phone

+98 83 3816 2560

Fax

Email

Somayeh.Mahdavian@kums.ac.ir

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

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

City

Kermanshah

Province

Kermanshah

Postal code

676715987479

Phone

+98 83 3816 2560

Email

Somayeh.Mahdavian@kkums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Somayeh Mahdavian

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Phone

+98 83 3816 2560

Email

Somayeh.Mahdavian@kums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah School of Nursing and Midwifery

Full name of responsible person

Somayeh Mahdavian

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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Phone

+98 83 3816 2560

Email

Somayeh.Mahdavian@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah School of Nursing and Midwifery

Full name of responsible person

Somayeh Mahdavian

Position

Faculty member

Latest degree

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable