Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 for20minutes. 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 for20 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 Mahdavikian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3827 9394

Email address
somayeh.mahdavikian@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
Age
From **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
121

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 Mahdavikian
Street address
Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Street, Kermanshah
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Email
Somayeh.Mahdavikian@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 Beheshty Blv., Kermanshah, Iran
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Email

Somayeh.Mahdavikian@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 Mahdavikian

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

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Somayeh.Mahdavikian@kums.ac.ir

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

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

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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

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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