Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of three methods of inhalation aromatherapy, massage and aromatherapy massage on sleep quality of cardiac patients

Protocol summary

Summary

Objective: Comparing the effect of three methods of inhalation aromatherapy, massage and aromatherapy in combination with massage on sleep quality of cardiac patients hospitalized in Imam Ali and Imam Reza hospitals. Design: randomized controlled clinical trial. Setting and conduct: required sample size is 200 patients. Eligible patients will be allocated to one of the four groups of inhalation aromatherapy, massage, aromatherapy in combination with massage and control group by block randomization. Inclusion criteria include Consent to participate in the study; not having skin disorders and eczema; Stable vital signs; Lack of allergies; not having coagulation and bleeding disorders; not having mental disease and no history of hospitalization in psychiatric wards; not being sensitive to hand and foot massage and aromatherapy; score equal to or more than five from the Pittsburgh quality of sleep questionnaire and positive smell test. Exclusion criteria include death or discharge; critically ill patient during the study; the patient's unwillingness to continue cooperation and oxygen administration for patients. Interventions: Initially the quality of sleep questionnaire will be completed by patients. The study will be conducted for seven consecutive nights; at bedtime. In group one; inhalation of lavender essential oil will be done for 20 minutes. In group two; massage with sweet almond Oil will be performed for 20 minutes. In group three, massage is performed for 20 minutes, using a combination of lavender and sweet almond oil. Control group will receive routine cares. In the morning of the eighth day, the Pittsburgh Sleep Quality questionnaire will be completed again by the patients. The main outcome variables: quality of sleep.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603094736N12**
Registration date: **2017-01-05, 1395/10/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-05, 1395/10/16

Registrant information

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Alireza Khatony
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of three methods of inhalation aromatherapy, massage and aromatherapy massage on

sleep quality of cardiac patients

Public title
The effect of three methods of inhalation aromatherapy، massage and aromatherapy massage on cardiac patients' sleep quality
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Consent to participate in the study; not having skin disorders and eczema; Stable vital signs; Lack of allergies; not having coagulation and bleeding disorders; not having mental disease and no history of hospitalization in psychiatric wards; not being sensitive to hand and foot massage and aromatherapy; score equal to or more than five from the Pittsburgh quality of sleep questionnaire and positive reaction to smell. Exclusion criteria: death or discharge; critically ill patient during the study; the patient's unwillingness to continue cooperation and oxygen administration for patients.
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: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not 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 Blvd
City
Kermanshah
Postal code
6714634698
Approval date
2016-11-23, 1395/09/03
Ethics committee reference number
KUMS.RES.1395.511

Health conditions studied

1

Description of health condition studied
Cardiac disease
ICD-10 code
I20-I25
ICD-10 code description
Ischaemic heart diseases

2

Description of health condition studied
Acute myocardial infarction
ICD-10 code
I21
ICD-10 code description
Acute myocardial infarction

3

Description of health condition studied
Heart failure
ICD-10 code
I50.9
ICD-10 code description
Heart failure

4

Description of health condition studied
Acute pulmonary edema
ICD-10 code
I50.1
ICD-10 code description
Acute pulmonary edema

Primary outcomes

1

Description
sleep quality
Timepoint
At the beginning of the study and eighth day
Method of measurement
Pittsburgh sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: In group I, before going to sleep at 10 P.M. two drops of lavender essential oil with the trade name of lavender essential oil and scientific name of Lavandula stoechas, manufactured by Barij Essence Company, will be dropped on a napkin and will be attached to the patient's cloth by the clamp in the chest area for 20 minutes and this process will be repeated for seven nights. This essence will be inhaled by the patient. This essential oil will be used in the pure form with 100 percent concentration. linalyl acetate and linalool are the major chemical compounds of this essence.

Category

Other

2

Description

Intervention 2: In group 2, using sweet almond oil manufactured by Barij essence company, hands and feet (from the planter surface of the foot up to the knee and the palm of the hand up to elbow) are given massage by the trained nurse with the same sex for 20 minutes. The oil used in this kind of massage is sweet almond oil with the scientific name of Prunus amygdalus var dulcis and the trade name of sweet almond oil. This oil is manufactured by Kashan Barij Essence Company. The main component of this oil is glyceryl oleate.

Category

Other

3

Description

Intervention 3: in group 3, using a combination of sweet almond oil and lavender (10-15 ml sweet almond oil mixed with lavender, dilution of 1/5 percent) hands and feet (from the planter surface of the foot up to the knee and the palm of the hand up to elbow) are given massage by the trained nurse with the same sex for 20 minutes. The oil used in this kind of massage is sweet almond oil with the scientific name of Prunus amygdalus var dulcis and the trade name of sweet almond oil. This oil is manufactured by Kashan Barij Essence Company. The main component of this oil is glyceryl oleate.

Category

Other

4

Description

Control group: The control group will receive usual care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali and Imam Reza Hospitals of Kermanshah

Full name of responsible person

Alireza khatony

Street address

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

City

Kermanshah

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 street, Kermanshah, Iran

City

Kermanshah

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

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 in Nursing Education-Faculty member

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty