

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 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

###### 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

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 1, 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

##### Street address

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

##### City

Kermanshah

##### Postal code

##### Phone

+98 83 3827 9394

##### Fax

##### Email

akhatony@kums.ac.ir

**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

**Other areas of specialty/work**

**Street address**

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

**City**

Kermanshah

**Postal code**

**Phone**

+98 83 3827 9394

**Fax**

**Email**

akhatony@kums.ac.ir

**Web page address**

## 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

**Other areas of specialty/work**

**Street address**

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

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Kermanshah

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**Fax**

**Email**

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**Web page address**

## 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*