

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of aromatherapy with essence of “Citrus Aurantium” and “chamomile” flowers on anxiety, quality of sleep and vital sings in hospitalized patients of the cardiac care units

Protocol summary

Study aim

Identifying The effect of aromatherapy with essence of “Citrus Aurantium” and “chamomile” flowers on anxiety, quality of sleep and vital sings in hospitalized patients of the cardiac care units in hospitals of Sirjan in 2018-2019

Design

A clinical trial; the research community is cardiac patients referring to cardiac care. The sample of the study is 120 cardiac patients selected by available method and divided into two groups of intervention and control through a randomization table with return blocks.

Settings and conduct

The researcher refers to the cardiac care units of Sirjan Hospitals in order to reach the samples. Available samples are selected according to the criteria of entry and exit and are randomly assigned to the two groups, then the questionnaire Before and after intervention, both groups are completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient's willingness to participate in the study and the passage of time at least 24 hours after the patient's admission; Aged over 18; Achieve score of 31 and above of the Spillberger anxiety questionnaire; The absence of sleep disorder before admission; Having proper alertness; No history of any allergies and allergies to herbs and essential oils; Not having olfactory defects and respiratory illnesses, such as asthma; Not having a history of migraine disease and completing and signing a informed consent form. Exit criteria: A history of known mental illness or taking mental drugs; The history of a new crisis, such as the death of first-degree relatives; Clearance before the fourth day and deterioration of the clinical condition.

Intervention groups

Patients receive nursing care in all four groups.1- The intervention group with aromatherapy 2- Control group without aromatherapy

Main outcome variables

Anxiety, Quality of sleep, Vital sings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160914029817N9**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

Esmat Nuhi

Name of organization / entity

Kerman University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5220

Email address

e_nuhi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-04, 1397/09/13

Expected recruitment end date

2019-06-03, 1398/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with essence of "Citrus Aurantium" and "chamomile" flowers on anxiety, quality of sleep and vital signs in hospitalized patients of the cardiac care units

Public title

The effect of aroma therapy in heart patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient's willingness to participate in the study and the passage of time is at least 24 hours after the patient's admission Being over 18 years of age Earn Points 31 and above Spillberg's Anxiety questionnaire The absence of sleep disorder before admission (Self-reported by the patient) Having proper alertness (ability to understand and speak Persian in the language) No history of any allergies and allergies to herbs and essential oils Not having olfactory defects and respiratory illnesses, such as asthma No history of migraine disease Complete and sign a Consent Form

Exclusion criteria:

A history of known mental illness or taking mental drugs The history of a new crisis, such as the death of a first-degree relative Clearance before the fourth day and deterioration of the clinical condition

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

En Block Randomize, The subjects are randomly assigned into two groups using software

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**

Ethical committee of kerman University of Medical Sciences

Street address

University of Medical Sciences, Seven Alavi Gardens, Kerman

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-11-12, 1397/08/21

Ethics committee reference number

IR.KMU.REC.1397.267

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

cardiovascular patients

ICD-10 code

I51

ICD-10 code description

Complications and ill-defined descriptions of heart disease

Primary outcomes**1****Description**

Anxiety

Timepoint

Before and after the intervention

Method of measurement

Spilberger State-Trait Anxiety Inventory

2**Description**

Sleep Quality

Timepoint

Before and after the intervention

Method of measurement

St. Mary's Hospital Sleep Quality Questionnaire

3**Description**

Vital Signs

Timepoint

Half an hour before the intervention and every 6 hours once during the intervention, except for the patient's bedtime

Method of measurement

Routine registration of vital signs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention will be such that during the three consecutive nights, the patients in the intervention group will be exposed to the pad after dipping the mixture of essential oil and chamomile at 21 o'clock, so that two drops of a mixture of essential oils of orange and chamomile To a ratio of 2-5 /. The patient will be asked to place the pad in the palm of his hand at a distance of 5 cm from the nose and take 10 breaths deep. Then, the same pad will be placed next to the patient's pillow until the next morning, and each morning after waking up, the patient will be relieved from the corresponding sleep pad.

Category

Behavior

2

Description

Control group: In this group, patients receive only nursing care in the heart and no action will be taken.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Fatemeh Mahmoodabadi poor

Street address

Imam Reza Specialty Hospital, Hijrat Blvd, Sirjan

City

Sirjan

Province

Kerman

Postal code

7816817964

Phone

+98 34 4234 0301

Fax

+98 34 4234 0300

Email

emamrezahp@sirums.ac.ir

Web page address

2

Recruitment center

Name of recruitment center

Dr. Gorazi Hospital

Full name of responsible person

Fatemeh Mahmoodabadi poor

Street address

Dr. Gorazi Hospital, Shafa Street, Sirjan

City

Sirjan

Province

Kerman

Postal code

7817835816

Phone

+98 34 4142 2204

Email

Gharazi_Sirjan.Hos@Tamin.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.Abbas Pardakhty

Street address

Compus University of Medical Sciences rdens Alavi, Research Management, St.Ibn Sina, Tahmasebabad Crossroads.

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3855

Fax

+98 34 3226 3857

Email

abpardakhty@kmu.ac.ir

Web page address

http://vcrt.kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Email

e_nuhi@kmu.ac.ir

Web page address<http://kmu.ac.ir>**Person responsible for general inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Mahmoodabadi poor

Position

Master of Internal Surgery Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Medicine, Razi Nursing and Midwifery

Faculty Primary Highway of Al-Awat Garden

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 32119021

Email

Mahmoodabadi.fatemeh72@gmail.com

Web page address<http://kmu.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Mahmoodabadi poor

Position

Master of Medical Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Campus University of Medical Sciences beginning

around seven gardens Alavi;Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5219

Fax

+98 34 3132 5218

Email

Mahmoodabadi.fatemeh72@gmail.com

Web page address<http://kmu.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Smat nohi

Position

Ph.D. in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Campus University of Medical Sciences beginning

around Seven Gardens Alavi;Kerman

City

Kerman

Province

Kerman

Postal code

7616931555

Phone

+98 34 3132 5220

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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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