Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 sings 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 pill 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

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 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
Email
e_nuhi@kmu.ac.ir
Web page address
htpp://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
htt://kmu.ac.ir

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