Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

study of the effects of Aromatherapy with Rose and Lavender on the Quality of Sleep in patients after CABG in Dr. Heshmat Hospital in Rasht, 2017-2018

Protocol summary

Study aim

study of the effects of Aromatherapy with Rose and Lavender on the Quality of Sleep and Depression in patients after Coronary Artery Bypass Grafting

Design

Clinical trial study, Phase 2, randomized, triplicate and control group, each group of 34 patients was designed in the period of 2017-2018.

Settings and conduct

The statistical population is the patients after open heart surgery in the surgical wards of Heshmat Hospital in Rasht, Iran

Participants/Inclusion and exclusion criteria

The eligibility criteria included the following: age 65 years or less (based on the WHO age of 65 and older as an aging age, so as to ensure that the sense of aging is caused by aging), the patient's willingness to participate in the study, the lack of use Patients with anti-depressant drugs and narcotics, speeches of patients in Persian, having clear verbal ability, not having a history of known psychological disorders, having no history of allergic rhinitis and other respiratory and sinusitis problems, not having a history of effective systemic or chronic disease On the sense of smell or hearing and not having a history of sleep disorders and relying on non-use Eating drugs and hypnotics.

Intervention groups

The patients are randomly divided into 3 groups: the first group inhaled 2% lavender essence , the second group inhaled 2% rose essence, and the third group without any intervention.

Main outcome variables

Demographic information and sleep quality and Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038626N1**
Registration date: **2018-03-12, 1396/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-29, 1397/11/09**
Update count: **1**

Registration date

2018-03-12, 1396/12/21

Registrant information

Name

Zahra Ahmadnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

zahmadnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-24, 1396/12/05

Expected recruitment end date

2018-05-26, 1397/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
study of the effects of Aromatherapy with Rose and Lavender on the Quality of Sleep in patients after CABG in Dr. Heshmat Hospital in Rasht, 2017-2018

Public title
study of the effects of Aromatherapy with Rose and Lavender on the Quality of Sleep in patients after CABG in Dr. Heshmat Hospital in Rasht, 2017-2018

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 65 years or less (according to the WHO, the age of 65 and older is considered to be aged, so to ensure that the sense of aging is caused by aging), the patient's willingness to participate in the study, the inability of patients to use anti-depressant drugs and narcotics , Speaking of patients' language in Persian, having clear verbal ability, having no history of known psychological disorders, having no history of allergic rhinitis and other respiratory and sinusitis problems, having no history of certain systemic or chronic diseases, affecting the sense of smell or hearing and having no history Sleep disorders and reliance on non-use of medications and sleep apnea.

Exclusion criteria:

Age
To **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Since the nature of the interventions restricts the ability to run in a common room environment, it was decided that the rooms would randomly be randomized based on 6 random blocks and would be changed in three randomized rooms in order to eliminate potential confusion. In the eligible patients entered in each room, the intervention will be applied.

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 Guilan University of Medical Sciences

Street address
Dr. Heshmat Hospital - Valiasr Square, Bayani St.

City
rasht

Province
Guilan

Postal code
4193955588

Approval date
2018-02-10, 1396/11/21

Ethics committee reference number
IR.GUMS.REC.1396.450

Health conditions studied

1

Description of health condition studied
Patients post cardiac artery bypass surgery

ICD-10 code
I97.1

ICD-10 code description
Other functional disturbances following cardiac surgery

Primary outcomes

1

Description
sleep quality

Timepoint
6 days after aromatherapy with Rose and Lavender

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description
Depression

Timepoint
6 days after aromatherapy with Rose and Lavender

Method of measurement
Beck Depression Inventory

Intervention groups

1

Description
Intervention group: The first group, a group of lavender essential oil, the second group is a group of medicinal herbs with a basil leaf essential oil.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Heshmat Rasht Hospital
Full name of responsible person
zahra ahmadnia
Street address
Dr. Heshmat Rasht Hospital - Valiasr Square, Baniyan St.
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zahmadnia@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
shadman nemati
Street address
Rasht, Namjoo Ave., Shahid Siadati St., Faced to the 17th Shahrivar Hospital, Old Building, School of Health, University of Technology Research and Technology
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Guilan
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41446-66949
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
zahra ahmadnia
Position
Nurse
Latest degree
Master
Other areas of specialty/work
Nursery
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Dr. Heshmat Rasht Hospital - Valiasr Square, Baniyan St.
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
zahra ahmadnia

Position
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Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Patients in the two groups of patients undergoing lavender and flower mourning therapy are asked to inhale the lavender and flower of Mohammadi, which is as much as three drops, for 5 nights each night during the period from 21 to 23 Put on a piece of cloth attached to the patient pillow. It should be noted that during the intervention period, people who develop symptoms such as dyspnea or allergic symptoms will be excluded from the study. Monitor the patient in the department by the partner of the patient and the nurse. Then the sixth day of the questionnaire of sleep quality assessment is completed by the researcher. The researcher in the control group completes the sleep quality questionnaire without any intervention the morning of the day after entering the surgical department and the sixth day of the sleep quality questionnaire.

When the data will become available and for how long
Between 21:00 and 23:00

To whom data/document is available
For scholars working in academia and academia

Under which criteria data/document could be used
After collecting data, SPSS-V.21 software is used to describe the data. Descriptive statistics (percentage) and mean (standard deviation) will be used. The normal distribution of quantitative amounts based on the Kolmogrov-Smironov test will be investigated. In order to compare the groups in terms of demographic characteristics, one-way analysis of variance (with Tukey's post hoc test) and Kruskal-Wallis test will be used if no normal distribution is made. In order to compare the groups in terms of qualitative demographic characteristics, the Chi-square test was used and for the qualitative variables of Kruskal-Wallis test (using the Man-Whitney post-mortem test along with the correction of Ben Freonny). To compare the mean sleep quality score in the three groups at the end of the intervention, the covariance analysis will be used by adjusting to the base sleep quality score and eliminating the effect of other adjuncts. In the absence of a condition for covariance analysis, stratified analysis will be used.

From where data/document is obtainable
Dr. Heshmat Rasht Hospital - Valiasr Square, Baniyan St.

What processes are involved for a request to access data/document
Through automation correspondence or email

Comments