Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Rose Damascene aromatherapy on sleep quality of patients hospitalized in the Cardiac Care Units

Protocol summary

Study aim
The purpose of this study is to investigate the effect of Rose Damascene aromatherapy on sleep quality of patients hospitalize in the cardiac care units.

Design
This study is a control clinical trial. Sixty patients admit to the CCU who are qualify for study are randomly divide into intervention and control groups.

Settings and conduct
Several studies have been carried out on the effectiveness of aromatherapy in improving sleep quality. Which have reported different results. In this study, 60 cardiac care units patients of those hospitals which are affiliate to Qom University of Medical Sciences are randomly divide into intervention and control groups. Patients of the intervention group will smell the Rose Damascene aroma for three nights and the control group patients receive routine care. The data collector is blind to which participant is in the group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients has ability to communicate, patient has normal orientation (time, place and person), patient has hemodynamic stability, Exclusion criteria: Patients have history of allergy or allergy to plants.

Intervention groups
This is a clinical trial with two intervention and control groups. Patients in the intervention group smell the Rose Damascene aroma and patients in the control group receive routine care.

Main outcome variables
The main consequence of this study is the sleep quality of patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033998N3**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date
2018-03-10, 1396/12/19

Registrant information

Name
Kurosh Jodaki

Name of organization / entity
Qom University of Medical Sciences

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Iran (Islamic Republic of)

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kjodaki@muq.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-06-22, 1397/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Rose Damascene aromatherapy on sleep quality of patients hospitalized in the Cardiac Care Units

Public title
The effect of Rose Damascene aromatherapy on sleep

quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have ability to communicate Patient know to time, place and person Patient has hemodynamic stability Sleep, Antidepressant, and Diuretics have not been received within the last 12 hours Do not drink stimulants such as coffee in the last 12 hours No pain due to illness No history of allergy to plants

Exclusion criteria:

Patients have history of allergy to plants Patients have pain due to illness

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Random allocation is done by randomize blocking method. In this method, in order to be able to compare individuals and maintain equilibrium of the samples in groups, by randomize blocking method, participants in the study are divide into two equal groups. Block sizes are also randomly select (block 2, 4, 8), which In each block there are equal numbers of participants in each group. For example, in a 4-d piece block, 2 blocks belong to the intervention group and 2 blocks belong to the control group. Or in a 8-d piece block, 4 blocks belong to the intervention group and 4 blocks belong to the control group. Blocks are also randomly select to prevent disclosure of the last allocation in each block. For example, the select block is a 4-d piece, Which for each person to study is take a tab from inside the 4-d piece block and accidentally assign to one of the intervention or control groups and this process continues until the tabs in the block are complete. Again, the 4-d piece block is return to the drawer desk and to select the group of other participants, a block is randomly select from among the remaining blocks, which may be 8-d piece block, 4-d piece block, and this process continues until the sample size is complete.

Blinding (investigator's opinion)

Single blinded

Blinding description

This single blind study and the person who collects the data is blind to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

No. 83, Street No. 4, Safashahr Street, Qom

City

Qom

Province

Ghoum

Postal code

3713649373

Approval date

2017-12-05, 1396/09/14

Ethics committee reference number

IR.MUQ.REC.1396.119

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality

Timepoint

At the beginning of the study and 72 hours after the intervention

Method of measurement

St. Mary's Hospital Sleep Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The researcher will use the Rose Damascene aromatherapy to affect the quality of sleep among patients. For three nights, the researcher tied three drops of Rose Damascene aroma on a paper towel and connected it to the patient's cloth, close to his head, with a pin. It remains on counterpane for 8 hours (from 10 pm to 6:00 am). After three nights of aroma therapy,

the fourth morning of the study, the sleep quality of the intervention group is measured. The Rose Damascene aroma is from Barij Essence Co., Iran.

Category

N/A

2

Description

Control group: The control group receives routine care such as noise and light reduction. The fourth morning of the study, the sleep quality of the control group is measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Kurosh Jodaki

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Shahid Chamran Street, Shahid Beheshti hospital, Qom

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr Saghafi

Street address

No. 83, Street No. 4, Safashahr Street, Qom

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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

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Kurosh Jodaki

Position

mentor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Shared data including demographic and disease information, type and method of intervention, information about sleep quality of participants before and after intervention.

When the data will become available and for how long

Start the access period 6 months after the results are published

To whom data/document is available

Researchers and people working in nursing education as well as nursing clinical staff

Under which criteria data/document could be used

The data can be used for education, research and clinical nursing. The applicant must be in the nursing field The data applicant only uses data for teaching, research and clinical nursing.

From where data/document is obtainable

Qom University of Medical Sciences, School of Allied, Qom. Email: kuroshjodaki@gmail.com Tel: 00989905514601

What processes are involved for a request to access data/document

After ensuring that the data applicant is in the nursing field, we will be immediately responded to the request form by email.

Comments