

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating the effect of rose extract aromatherapy on anxiety and physiological indices of conscious patients admitted at intensive care units of Rafsanjan Ali Ibn Abitaleb hospital, 2018-2019

Protocol summary

Study aim

Determination the effect of rose extract aromatherapy on anxiety and physiological indices of conscious patients admitted at intensive care units of Rafsanjan Ali Ibn Abitaleb hospital, 2018

Design

Clinical trial with parallel control group, single blind, randomized

Settings and conduct

This study, which is a blind clinical trial, is carried out in the caregiver of Ali ibn Abi Talib Hospital in Rafsanjan. The sample size is 60 people who are selected by available method and then assigned to two intervention and control groups by the method of random sampling by minimization method. For the intervention group, three drops of 10% of the essential oil are poured into the grass, and 20 cm away from the nose, the patients are placed on their shirt and the patients inhale it for 20 minutes. In the control group, three drops of distilled water are deposited on the same gaseous gas and, as in the intervention group, are placed on their shirt at the same time. The intervention is performed three times a day for one day every 20 minutes. Before and after each intervention, physiological indicators are recorded. The anxiety questionnaire is completed before the study begins and then completed at the end of the intervention.

Participants/Inclusion and exclusion criteria

No history of allergy to spring floral aroma; age 60-20 years old; pass at least 24 hours after admission to the intensive care unit; being alert to the patient; no olfactory problems.

Intervention groups

Three drops of 10% of the essential oil are poured into the grass, and 20 cm away from the nose, the patients are placed on their shirt and patients are inhaled for 20 minutes. In the control group three drops of distilled

water. Intervention three times a day.

Main outcome variables

Anxiety; physiological indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170122032111N3**

Registration date: **2018-12-30, 1397/10/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-30, 1397/10/09**

Update count: **0**

Registration date

2018-12-30, 1397/10/09

Registrant information

Name

Maryame Shahabi nejad

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

m_shahabi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-30, 1397/10/09

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of rose extract aromatherapy on anxiety and physiological indices of conscious patients admitted at intensive care units of Rafsanjan Ali Ibn Abitaleb hospital, 2018-2019

Public title
Investigating the effect of rose extract aromatherapy on anxiety and physiological indices of conscious patients admitted

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Inclination to participate in research No history of allergy to spring floral aroma Age of 60-20 years Pass at least 24 hours after admission to the intensive care unit Not having a previous history of admission to the intensive care unit Patient's chewiness (four Score Above 12 Not having a ban on a physician for aesthetic remedy No history of psychiatric illness No History of the use of psychoneurology Lack of olfactory problems Lack of any underlying illness, such as epilepsy and skin disease
Exclusion criteria:
 Allergy Find out the odor problem after coffee smell testing Use of other stress-reducing methods Use Neurology and Neuron in the section

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are selected according to the criteria of entry in the method and then assigned to the intervention and control groups by random sampling method by the method of minimization

Blinding (investigator's opinion)
Single blinded

Blinding description
Analyzer

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd, Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717932777

Approval date

2018-06-27, 1397/04/06

Ethics committee reference number

IR.RUMS.REC.1397.069

Health conditions studied

1

Description of health condition studied

anxiety and physiological indices of conscious patients admitted at intensive care units

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

Before the beginning of the study and at the end of the third turn

Method of measurement

Spielberger's apparent anxiety questionnaire

2

Description

physiological indices

Timepoint

Before and after each intervention

Method of measurement

Monitoring and observation device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three drops of 10% Rose Essential Oil, three times a day, 20 minutes each, inhalation, Golab Darin Kashan Company

Category

Other

2

Description

Control group: routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb hospital

Full name of responsible person

Shahabi Nejad Maryam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Shamsizadeh Ali

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Shahabi Nejad Maryam

Position

MSN

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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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

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Research use

From where data/document is obtainable

M_Shahabi@rums.ac.ir

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

Start the access period 6 months after printing the results

Comments