

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of the effect of lavender and Rosa-damascena on sleep quality of pre-hospital emergency staff

Protocol summary

Study aim

Determining the effect of lavender and rosemary aroma on sleep quality of pre-hospital emergency personnel

Design

This randomized controlled clinical trial study with parallel and third phase groups will be performed on 150 patients and a random number table will be used for randomization.

Settings and conduct

Initially, based on the inclusion and exclusion criteria of sampling, after identifying the eligible samples, the samples will be randomly divided into three groups. In one group, the scent of lavender and in the other group, the scent of rose will be used. In the control group, distilled water will be given. The Pittsburgh Sleep Quality Questionnaire and demographic information checklist will be used to assess patients' sleep quality. Eligible patients will be included in the inclusion criteria.

Participants/Inclusion and exclusion criteria

Have at least one year of work experience Have the health of the sense of smell No underlying sleep-related illnesses (such as rheumatoid arthritis and migraines), No known sleep disorders as reported by the patient (hospitalization, sleep-related medications) No history of allergic asthma or rhinitis No history of flower allergies, and Herbs and the smell of sweat and their essential oils Not taking neuroleptic drugs Not having vision problems and Not having a care or treatment plan during sleep hours lack of respiratory problems

Intervention groups

Intervention group 1 (aromatherapy with Lavender) and intervention group 2 (aromatherapy with Rosa-damascena)

Main outcome variables

Sleep quality score changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210809052128N1**

Registration date: **2022-06-21, 1401/03/31**

Registration timing: **prospective**

Last update: **2022-06-21, 1401/03/31**

Update count: **0**

Registration date

2022-06-21, 1401/03/31

Registrant information

Name

Abas Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3522 2649

Email address

abas1123.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-27, 1401/04/06

Expected recruitment end date

2022-07-28, 1401/05/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of lavender and Rosa-damascena on sleep quality of pre-hospital emergency staff

Public title

The effect of lavender and Rosa-damascena on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Have at least one year of work experience Have the health of the sense of smell No underlying sleep-related illnesses (such as rheumatoid arthritis and migraines), No known sleep disorders as reported by the patient (hospitalization, sleep-related medications) No history of allergic asthma or rhinitis No history of flower allergies, and Herbs and the smell of sweat and their essential oils Not taking neuroleptic drugs Not having vision problems and Not having a care or treatment plan during sleep hours lack of respiratory problems

Exclusion criteria:

Arbitrary use of sedatives Severe sensitivity to the scent of Rosa-damascena or lavender and

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using a table of random numbers. The numbers 0 to 49 will be considered for the first intervention group, 50 to 99 for the second intervention group, and 100 to 149 for the control group. The researcher will randomly put a hand on one of the numbers and move in one of the predetermined paths, then record the numbers and assign the individuals to the groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Kermanshah University of Medical Science

Street address

Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.Kermashah,iran

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-12-27, 1400/10/06

Ethics committee reference number

IR.KUMS.REC.1400.636

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

Sleep disorders

ICD-10 code

G47

ICD-10 code description

Sleep disorders

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

Sleep quality

Timepoint

Before intervention and four weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In intervention group 1 (aromatherapy with Lavender), the method of intervention will be that the person pours two drops of the solution into the vial using a dropper on a cotton ball or paper towel and puts it at a distance of 15 to 20 cm from his nose. He takes a deep breath for two minutes and does this every other night for four weeks in the absence of shifts and at home. Due to the fact that this intervention is performed by the individual, the experimental group will give a vial of Lavender with a concentration of 2% (produced by Kashan Barij Essential Oil Company) to each of the samples.

Category

Other

2

Description

Intervention group: Intervention group: In intervention group 2 (aromatherapy with Rosa-damascena), the method of intervention will be that the person pours two drops of the solution into the vial using a dropper on a cotton ball or paper towel and puts it at a distance of 15 to 20 cm from his nose. He takes a deep breath for two minutes and does this every other night for four weeks in the absence of shifts and at home. Due to the fact that this intervention is performed by the individual, the experimental group will give a vial of Rosa-damascena with a concentration of 2% (produced by Kashan Barij Essential Oil Company) to each of the samples.

Category

Other

3

Description

Control group: In Control group (water), the method of intervention will be that the person pours two drops of the solution into the vial using a dropper on a cotton ball or paper towel and puts it at a distance of 15 to 20 cm from his nose. He takes a deep breath for two minutes and does this every other night for four weeks in the absence of shifts and at home. Due to the fact that this intervention is performed by the individual, the experimental group will give a vial of water to each of the samples.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Road and non-road emergency medical bases of Kermanshah province

Full name of responsible person

Abbas Jalali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Tayebeh Mahvar

Position

PhD in Nursing

Latest degree

Ph.D.

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

Data on demographic information and patient pain are distributed as anonymous codes

When the data will become available and for how long

Starting data access is from 2022

To whom data/document is available

Access to data will be free for anyone interested in research

Under which criteria data/document could be used

Granting data for scientific use without fringe is allowed

From where data/document is obtainable

Can contact with a.noyani@shmu.ac.ir email

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

About a month from the time of the first call through the email

Comments