Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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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Person responsible for updating data

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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