

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The effect of lavender aroma on occupational stress and sleep quality of pre-hospital emergency personnel

#### Protocol summary

Occupational stress, sleep quality

##### Study aim

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

##### Design

This study is a clinical trial with control group, with parallel groups, single blind, Randomized by coin toss, sample size is 70, 2-3 phase

##### Settings and conduct

Participants in this study will be Kerman pre-hospital emergency personnel. Intervention group will receive glass pendant neck containing 25% lavender essence and control group will receive glass pendant containing sweet almond oil. Intervention will be one month. Before, immediately and one month after the intervention, sleep quality and job stress questionnaires will be completed.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 20 to 45 years, no anxiolytic and other relaxing herbal remedies, no drug addiction, no working in other health care facilities, normal olfactory test, no history of nasal surgery, no liver or kidney problems, work experience more than one year. Exclusion Criteria: Respiratory and allergic problems

##### Intervention groups

intervention group: 25% lavender essence will be provided by Tabib Darou Co., Kashan. Intervention group will inhale lavender essence. Intervention group will be presented with 5 cc glass neck pendants containing lavender essential oil. The pendants will be installed within 30 cm of the subjects nose. The pendants will be used for one month, 3 times a week and daily for two hours at the end of each shift. The researcher will remind the subjects during the intervention by telephone and text message. Finally, the questionnaires will be completed again immediately and 30 days after the intervention. control group: It will look exactly like the intervention group. In this group, the pendants contain refined and odorless sweet almond oil

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190515043601N3**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### Registration date

2020-02-01, 1398/11/12

##### Registrant information

##### Name

Hossein Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3238 1427

##### Email address

hosseinrahimi92@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

2019-01-21, 1397/11/01

##### Actual recruitment end date

2019-09-23, 1398/07/01

##### Trial completion date

2019-09-23, 1398/07/01

### Scientific title

The effect of lavender aroma on occupational stress and sleep quality of pre-hospital emergency personnel

### Public title

The effect of lavender aroma on occupational stress and sleep quality of pre-hospital emergency personnel

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Ages between 20 to 45 years  
Not use anxiolytic and other Relaxing herbal remedies  
non-drug addiction  
no Working in other health care facilities  
passing an olfactory test  
Having no history of nasal surgery  
not having liver or kidney problems  
work experience more than one year

#### Exclusion criteria:

Respiratory and allergic problems

### Age

From **20 years** old to **45 years** old

### Gender

Male

### Phase

2-3

### Groups that have been masked

- Data analyser

### Sample size

Target sample size: **70**

Actual sample size reached: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

12 pre-hospital emergency bases will be randomly divided into intervention and control groups using the coin toss (only bases will be randomized when personnel will not be randomized).

### Blinding (investigator's opinion)

Single blinded

### Blinding description

The data analyst will be unaware of the type of intervention for each group

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Birjand University of Medical

Sciences

### Street address

Ayatollah Ghafari Blv

### City

Birjand

### Province

South Khorasan

### Postal code

9717853577

### Approval date

2019-02-05, 1397/11/16

### Ethics committee reference number

IR.BUMS.REC.1397.352

## Health conditions studied

### 1

#### Description of health condition studied

Sleep quality,Occupational stress

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

sleep quality

#### Timepoint

Before, immediately, one month after the end of the intervention

#### Method of measurement

Pittsburgh Sleep Quality Questionnaire

### 2

#### Description

Occupational stress

#### Timepoint

Before, immediately, one month after the end of the intervention

#### Method of measurement

Nursing stress scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: There will be 35 participants in the lavender group.Participants will receive a 5cc glass necklace containing 25% lavender essence. pendants will be used at the end of each shift for 2 hours, three times a week for one month.Questionnaires will be completed before, immediately and one month after the intervention.

#### Category

Treatment - Drugs

## 2

### Description

Control group: There will be 35 participants in this group. Participants will receive a 5cc glass necklace containing refined Sweet almond oil without odor .pendants will be used at the end of each shift for 2 hours, three times a week for one month. Questionnaires will be completed before, immediately and one month after the intervention.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kerman University of Medical Sciences, Pre-hospital emergency bases

##### Full name of responsible person

Seyyed Mohamad Saberi

##### Street address

Emergency Management Center, Campus of Medical Sciences University, Haft Bagh Alavi Blv

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3132 9000

##### Email

Ems@kmu.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Tooba Kazemi

##### Street address

Birjand University of Medical Sciences, Ayatollah Ghaffari Blv

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717803077

##### Phone

+98 56 3238 1200

##### Email

drtooba.kazemi@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Birjand 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

Birjand University of Medical Sciences

##### Full name of responsible person

Hossein Rahimi

##### Position

Instructor

##### Latest degree

Master

##### Other areas of specialty/work

CAM

##### Street address

Ayatollah Ghafari Blv

##### City

Birjand

##### Province

South Khorasan

##### Postal code

971780307

##### Phone

+98 56 3238 1424

##### Email

hosseinrahimi92@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Hossein Rahimi

##### Position

Instructor

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Ayatollah Ghafari Blv

##### City

Birjand  
**Province**  
South Khorasan  
**Postal code**  
971785357  
**Phone**  
+98 56 3238 1400  
**Email**  
hosseinrahimi92@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Hossein Rahimi  
**Position**  
Instructor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Ayattolah Ghafari Blv  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
971785357  
**Phone**  
+98 56 3238 1400  
**Email**  
hosseinrahimi92@yahoo.com

## 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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

All potential data can be shared after unidentifiable participants

### When the data will become available and for how long

Start of access period 12 months after printing results

### To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

### Under which criteria data/document could be used

In order to access the data, researchers can request access to the information 12 months after the results are published. Within two weeks, the information will be sent to them. It should be noted that applicants must be faculty members of the Ministry of Health.

### From where data/document is obtainable

Applicants can apply to the Birjand University of Medical Sciences School of Nursing and Midwifery for information.

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

After verifying the identity of the applicant, the data will be submitted to the researcher within 2 weeks.

### Comments