

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of aromatherapy with Geranium essential oil on fatigue and sleep quality of nurses working in the intensive care unit

Protocol summary

Study aim

Determining the effect of aromatherapy with Geranium essential oil on fatigue and sleep quality of nurses working in the intensive care unit

Design

Clinical trial with control group, 84 intensive care unit nurses, double-blind, stratified random block

Settings and conduct

A double-blind clinical trial with a control group on 84 male and female nurses in the intensive care unit of Lorestan Medical Sciences-affiliated teaching hospitals. By easy and consecutive sampling method, participants will be randomly assigned in equal numbers to the intervention and control groups. The intervention group of pure geranium essential oil and control of pure sunflower essential oil will be inhaled in 3 consecutive shifts (morning / evening) for 20 minutes with normal breathing.

Participants/Inclusion and exclusion criteria

Entry requirements : Volunteering to participate in the study, having at least 2 years of work experience and 6 months of work experience in the special unit, rotating shifts with night shifts, at least 3 night shifts in the monthly program, olfactory health, earning a score of 3 or more on the Visual Fatigue Scale; Score 150 or more on the Osipow Job Stress Scale No entry conditions: Pregnancy, use of herbal products, allergy to herbal and aromatic products, history of allergic rhinitis and migraine and respiratory problems, use of sedatives and effective drugs on sleep, liver and kidney problems, inflammatory and immune diseases

Intervention groups

The nurses of the intervention group poured a drop of pure geranium essential oil on an absorbable patch in a personal protective mask and the fragrance will be inhaled for 20 minutes in 3 consecutive work shifts (morning / evening) with normal breathing and twice in each shift. The control group will also receive a drop of pure sunflower essential oil in a completely similar way

to the intervention group.

Main outcome variables

Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100609004129N5**

Registration date: **2021-01-29, 1399/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-29, 1399/11/10**

Update count: **0**

Registration date

2021-01-29, 1399/11/10

Registrant information

Name

Shirin Hasanvand

Name of organization / entity

Lorestan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with Geranium essential oil on fatigue and sleep quality of nurses working in the intensive care unit

Public title

The effect of aromatherapy on fatigue and sleep quality of nurses working in the intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Volunteer to participate in the study Have at least 2 years of work experience and 6 months of work experience in the intensive care unit Rotating shift with night shift Have at least 3 night shifts in the monthly schedule Olfactory health score 3 or higher on the Visual Analogue Scale Fatigue Score 150 or more on the Osipow Job Stress Scale

Exclusion criteria:

Pregnancy Use of herbal products, herbal teas Sensitivity to herbal and aromatic products History of allergic rhinitis, respiratory allergies, respiratory problems and migraines Use of sedatives and analgesics (steroids, non-steroids), benzodiazepines and sleeping pills History of liver and kidney problems Inflammatory and autoimmune diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

Considering the two classes of sex (male and female) and body mass index (lean-normal [$<25.5-18$) and overweight-obesity (25-30), a total of 4 classes are formed. The method of 4 random blocks is used to assign nurses to two groups A (geranium fragrance intervention) and group B (placebo). To do this, first a list of blocks is written and numbers are assigned to them (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) Then select the numbers between one to 6 (for example 1 4 5 and ...) using a random number table. Finally, the allocation list will be based on a sequence of letters A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

All bottles containing essential oils will be identical in appearance and the pharmacist will assign a specific and random number on each bottle and the pharmacist will be unaware of the allocation of each essential oil to the experimental or control group. Also, the type of aroma and assignment of participants to the intervention and control group for the researcher and data analyst will not be known.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, 4 km of Khorramabad-Borujerd road, Kamalvand, Khorramabad, Lorestan, Iran

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.LUMS.REC.1399.194

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

Intensive care unit nurses

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fatigue

Timepoint

Immediately and 60 minutes after the intervention

Method of measurement

Visual Analogue Scale fatigue

Secondary outcomes

1

Description

sleep quality

Timepoint

The beginning of the first, second, third work shifts

Method of measurement

Verran and Snyder- Halpern sleep scale

Intervention groups

1

Description

Intervention group: Intervention group: In the intervention group, a drop of pure geranium essential oil was poured by the research colleague on an absorbable patch attached to the nurses' personal protective mask and they were asked to inhale the fragrance for 20 minutes by normal breathing. Aromatherapy in 3 consecutive work shifts (morning / evening) and each work shift twice and at certain times (9-10 and 11-12 in the morning shift and 15-16 and 17-17 in the evening shift) will be done.

Category

Other

2

Description

Control group: In the control group, a drop of pure sunflower essential oil was poured on an absorbable patch attached to the nurses' personal protective mask by the research colleague and they were asked to inhale the fragrance for 20 minutes by normal breathing. Aromatherapy in 3 consecutive work shifts (morning / evening) and each work shift twice and at certain times (9-10 and 11-12 in the morning shift and 15-16 and 17-17 in the evening shift) will be done.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Teaching hospitals affiliated to Lorestan University of Medical Sciences

Full name of responsible person

Dr. Shirin Hasanvand

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Lorestan University of Medical Sciences, 4 km of Khorramabad-Borujerd road, Kamalvand, Khorramabad, Lorestan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Falahi

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Shirin Hasanvand

Position

Doctor of Nursing, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available