

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the effect of aromatherapy with Rosa damascena mill L. oil on severity of fatigue and physical discomfort of operating room nurses at Qom university of Medical Sciences hospitals

Protocol summary

Study aim

Determining the effect of aromatherapy with Rosa damascena mill L. oil on severity of fatigue and physical discomfort of operating room nurses at Qom university of Medical Sciences hospitals

Design

Clinical trial with control group, with parallel groups, randomized, on 60 individuals. Blocking method is used for randomization.

Settings and conduct

Individuals are randomly allocated into intervention and control groups by random block method. In Intervention group, two drops of 40% Rosa damascena mill L. oil will be applied to cotton and individuals will be asked to attach it to their clothes or scarf at a distance of ten centimeters below the chin and inhale for 10 minutes. People in the control group will inhale two drops of placebo (normal saline) for 10 minutes. Completion of tools will be done before and immediately after aromatherapy. The study is conducted in the Kamkar-Arabnia, Nekoochi and Shahid Beheshti hospitals of Qom.

Participants/Inclusion and exclusion criteria

Inclusion conditions: tendency to participate in the study; Exclusion conditions: history of allergies and respiratory diseases, suffering from pulmonary diseases (asthma and obstructive lung diseases), sensitivity to herbal medicines, olfactory disorders, colds and nasal congestion, history of allergies and respiratory diseases, history of diseases such as rheumatism and multiple sclerosis.

Intervention groups

Individuals in the intervention group will inhale two drops of 40% rose essence for 10 minutes. People in the control group will inhale two drops of placebo (normal saline) for 10 minutes.

Main outcome variables

Severity of fatigue, Physical discomfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140428017468N7**

Registration date: **2023-07-22, 1402/04/31**

Registration timing: **prospective**

Last update: **2023-07-22, 1402/04/31**

Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

Name

Meysam Hoseini Amiri

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of aromatherapy with Rosa damascena mill L. oil on severity of fatigue and physical discomfort of operating room nurses at Qom university of Medical Sciences hospitals

Public title

The effect of aromatherapy with Rosa damascena mill L. oil on severity of fatigue and physical discomfort

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Tendency to participate in the study No history of allergies and respiratory diseases No suffering from pulmonary diseases (asthma and obstructive lung diseases) Insensitivity to herbal medicines, Olfactory disorders, colds and nasal congestion No history of allergies and respiratory diseases No history of diseases such as rheumatism and multiple sclerosis

Exclusion criteria:

Using sleeping pills and painkillers

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects will allocate to two equal groups of intervention (A) and control (B) using blocking randomization method. In this method, 6 blocks of 4 are used (ABAB=1, BABA=2, ABBA=3, BAAB=4, AABB=5, BBAA=6). First, blocks of 4 are written on pieces of paper, and then the pieces of paper are placed in envelopes and numbered on the envelope to conceal random assignment. Then the choice of each envelope is randomly determined by throwing a dice based on the number of the dice.

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

Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical sciences, Basij Bolverd, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2023-06-26, 1402/04/05

Ethics committee reference number

IR.SEMUMS.REC.1402.075

Health conditions studied

1

Description of health condition studied

Fatigue

ICD-10 code

R53

ICD-10 code description

Malaise and fatigue

Primary outcomes

1

Description

Severity of fatigue

Timepoint

Before and immediately after intervention

Method of measurement

Brief Fatigue Inventory

2

Description

Physical discomfort

Timepoint

Before and immediately after intervention

Method of measurement

Patient Health Questionnaire-15

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, two drops of 40% Rosa damascena mill L. oil will be applied to cotton and individuals will be asked to attach it to their clothes or scarf at a distance of ten centimeters below the chin and inhale for 10 minutes.

Category

Treatment - Other

2

Description

Control group: In this group, two drops of normal saline will be applied to cotton and individuals will be asked to attach it to their clothes or scarf at a distance of ten centimeters below the chin and inhale for 10 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamkar-Arabnia Hospital

Full name of responsible person

Seyed Alireza Chavooshi Zade

Street address

Kamkar-Arabnia Hospital, Bajak road

City

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2

Recruitment center

Name of recruitment center

Nekoohi Hospital

Full name of responsible person

Javad Hakim Elahi

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Ayatollah Taleghani St., Nekouei Hospital

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3

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Majid Moghadam

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Shahid Beheshti Hospital, Shahid Behashti road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

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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

Semnan University of Medical Sciences

Proportion provided by this source

10

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

Hoseini_amiri@yahoo.com

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Meysam Hosseini Amiri

Position

Ph.D Candidate

Latest degree

Master

Other areas of specialty/work

Nursery

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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