Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, Nekoohi 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

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Iran (Islamic Republic of)

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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
Ghom
Province
Ghoum
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1497537138
Phone
+98 25 3771 3511
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Hosseini_amiri@yahoo.com

2

Recruitment center

Name of recruitment center
Nekoohi Hospital
Full name of responsible person
Javad Hakim Elahi
Street address
Ayatollah Taleghani St., Nekouei Hospital
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7335537158
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3

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Majid Moghadam
Street address
Shahid Beheshti Hospital, Shahid Behashti road
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Ghom
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Ghoum
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6479737199
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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
Street address
Semnan university of medical sciences, Basij road, Semnan
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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

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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Person responsible for scientific inquiries

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Person responsible for updating data

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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