

# 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

Iran (Islamic Republic of)

##### Phone

+98 35 1824 0936

##### Email address

hoseiniam911@mums.ac.ir

##### 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

**Postal code**

1497537138

**Phone**

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**2**

**Recruitment center**

**Name of recruitment center**

Nekoohi Hospital

**Full name of responsible person**

Javad Hakim Elahi

**Street address**

Ayatollah Taleghani St., Nekouei Hospital

**City**

Ghom

**Province**

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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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**Province**

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6479737199

**Phone**

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Hosseini\_amiri@yahoo.com

**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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+98 23 3345 1336

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Hosseini\_amiri@yahoo.com

**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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Full name of responsible person**

Meysam Hosseini Amiri

**Position**

Ph.D Candidate

**Latest degree**

Master

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**Email**

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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