

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigating the effect of lavender scent on emotion regulation and sleep quality of second grade elementary school students

#### Protocol summary

##### Study aim

Investigate the effect of lavender scent on emotion regulation and sleep quality of second grade of elementary school students

##### Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 120 children. The rand function of Excel software is used for randomization.

##### Settings and conduct

This study is conducted in Semnan second grade elementary schools. Children who score above 41 on the sleep questionnaire are included in the study. They are given unlabeled containers of lavender essential oil or water, so they will not know the contents of the solution

##### Participants/Inclusion and exclusion criteria

Elementary school children of the second grade, getting a score higher than 41 from the sleep quality questionnaire, not getting sick during the study period, healthy sense of smell of the child (tested with lemon juice), not allergic to herbal medicines.

##### Intervention groups

Test group: 20 minutes before going to bed, a cotton pad soaked in 3 drops of lavender is placed on the child's collar. Placebo group: 20 minutes before going to bed, a cotton pad soaked in 3 drops of water is placed on the child's collar.

##### Main outcome variables

Sleep quality, emotion regulation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110430006342N16**

Registration date: **2023-10-25, 1402/08/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-25, 1402/08/03**

Update count: **0**

##### Registration date

2023-10-25, 1402/08/03

##### Registrant information

###### Name

Ali Asghar Ghods

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 1335 4192

###### Email address

aaghods@sem-ums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-22, 1402/07/30

##### Expected recruitment end date

2023-12-21, 1402/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of lavender scent on emotion regulation and sleep quality of second grade elementary school students

##### Public title

effect of lavender scent on emotion regulation and sleep quality of students

##### Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The second grade of elementary school children

### Exclusion criteria:

getting a score higher than 41 from the sleep quality questionnaire healthy sense of smell of the child (tested with lemon juice) not allergic to herbal medicines

## Age

From **9 years** old to **12 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each person is placed once in the test group and once in the placebo group

## Randomization (investigator's opinion)

Randomized

## Randomization description

This study is cross-over. Allocation of samples to test and placebo groups in the first stage is done randomly using RAND of Excel. In this method, the odd number represents group A, who will receive lavender scent first, and the even number represents group B, who will receive placebo first. In this way, group A or B is determined for each person. After finishing the first stage and passing the rest period (washout), the child is placed in the remaining group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Lavender essential oil and water are given to the samples in similar containers without labels

## Placebo

Used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Biomedical Research, Semnan University of Medical Sciences

##### Street address

Deputy of research and technology, Central Headquarters of Semnan University of Medical Sciences, Basij Boulevard

## City

Semnan

## Province

Semnan

## Postal code

3519899951

## Approval date

2023-10-01, 1402/07/09

## Ethics committee reference number

IR.SEMUMS.REC.1402.143

## Health conditions studied

### 1

#### Description of health condition studied

Insomnia

#### ICD-10 code

F51.0

#### ICD-10 code description

Insomnia not due to a substance or known physiological condition

## Primary outcomes

### 1

#### Description

Quality of sleep

#### Timepoint

Before and after intervention

#### Method of measurement

Child Sleep Habit Questionnaire

### 2

#### Description

Emotion regulation

#### Timepoint

Before and after intervention

#### Method of measurement

Emotion regulation questionnaire for children and adolescents

## Secondary outcomes

### 1

#### Description

#### Timepoint

#### Method of measurement

## Intervention groups

### 1

#### Description

Intervention group: Every night for two weeks, 20 minutes before going to sleep, a cotton swab dipped in 3 drops of 100% lavender essential oil, which has no label, is attached to the child's neck.

**Category**

Treatment - Other

**2****Description**

Control group: For two weeks, every night 20 minutes before going to bed, cotton soaked in 3 drops of water in a container similar to lavender is attached to the child's neck.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Schools of Semnan province

**Full name of responsible person**

Tahere Gholami

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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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**

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**

Semnan University of Medical Sciences

**Full name of responsible person**

Tahere Gholami

**Position**

MS. Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Asghar Ghods

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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## 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

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

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

Only part of the data, such as information related to the main outcome, can be shared

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

The access period will start 6 months after the results are published

### To whom data/document is available

University students and faculty members

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

Published data is available upon request

### From where data/document is obtainable

Ali Asghar Ghods aaghods@yahoo.com

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

After the request, the data will be sent one month later

### Comments