

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

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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

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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

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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

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Other areas of specialty/work

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

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Person responsible for updating data

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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