Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the Effect of Aromatherapy on Anxiety Among Dental Students During Orthodontic Exam at TehranUniversity of Medical Sciences

Protocol summary

Study aim

The objective of this trial is to determine the effect of aromatherapy with lemon essential oil and lavender essential oil, compared with odorless water vapor, on state anxiety of dental students during the Practical Orthodontics One examination. Changes in heart rate, peripheral blood oxygen saturation, momentary anxiety, and examination score will also be assessed.

Design

This is a randomized controlled clinical trial with a parallel design and three study groups. The unit of randomization is the individual participant. Eligible participants will be allocated equally to the three groups. The statistical analyst will be blinded to group allocation.

Settings and conduct

The study will be conducted in classrooms at the Faculty of Dentistry. After random allocation, participants will enter the classroom assigned to their study group and will be exposed to aroma or odorless water vapor before and during the examination. Data will be collected using questionnaires and a digital pulse oximeter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: undergraduate dental student at Tehran University of Medical Sciences, taking the Practical Orthodontics One course, and providing written informed consent. Non inclusion criteria: common cold, asthma or other respiratory diseases, known allergy to lemon or lavender essential oils, use of medications affecting anxiety or heart rate, and diseases affecting anxiety or heart rate.

Intervention groups

Participants will be divided into three groups. The first group will receive aromatherapy with lemon essential oil. The second group will receive aromatherapy with lavender essential oil. The control group will receive odorless water vapor. Exposure to aroma or water vapor will be delivered by a diffuser.

Main outcome variables

State anxiety score based on the state anxiety subscale of the Spielberger State Trait Anxiety Inventory.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260502069240N1**
Registration date: **2026-05-10, 1405/02/20**
Registration timing: **prospective**

Last update: **2026-05-10, 1405/02/20**
Update count: **0**

Registration date

2026-05-10, 1405/02/20

Registrant information

Name

Amirhossein Lohrasebi poor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2223 6974

Email address

amirlohi80@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-06, 1405/05/15

Expected recruitment end date

2026-08-06, 1405/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the Effect of Aromatherapy on Anxiety Among Dental Students During Orthodontic Exam at TehranUniversity of Medical Sciences

Public title
The effect of lemon and lavender aromatherapy on exam anxiety in dental students

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The participant should be an undergraduate dental student. The participant should be taking or have taken the Practical Orthodontics 1 course. The participant should be a student at Tehran University of Medical Sciences. The participant should provide written informed consent to participate in the study.

Exclusion criteria:
The participant has a common cold at the time of enrollment. The participant has asthma or other respiratory diseases. The participant has a known allergy to lemon or lavender essential oils. The participant uses medications that may affect anxiety or heart rate, such as beta-blockers, sedatives, or anxiolytic drugs. The participant has diseases that may affect anxiety or heart rate, such as anxiety disorders or cardiovascular diseases.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed at the individual level, and each eligible dental student will be considered as the unit of randomization. After assessment of eligibility criteria and obtaining written informed consent, participants will be allocated in a 1:1:1 ratio to three groups: lemon aromatherapy, lavender aromatherapy, and control group. Randomization will be performed using permuted blocks with variable block sizes of 3 and 6.Within each stratum, an independent randomization list will be generated by the statistical consultant using a random number table or statistical software.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the aromatherapy intervention, complete blinding of participants and intervention providers is not feasible, because lemon and lavender aromas are recognizable and the control group receives odorless water vapor. However, the statistician/data analyst will be blinded to group allocation. For this purpose, study groups will be coded in the dataset using non-identifiable labels such as A, B, and C, and statistical analysis will be performed without knowledge of the actual intervention assigned to each code.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of the School of Dentistry, Tehran University of Medical Sciences, Tehran,

Street address
End of North Kargar Street, next to the Atomic Energy Organization, before reaching the Hakim Shargh Highway exit, Faculty of Dentistry, Tehran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
۱۴۳۹۹۵۵۹۹۱

Approval date
2026-02-16, 1404/11/27

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1404.110

Health conditions studied

1

Description of health condition studied
Test-related situational anxiety in dental students

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
State anxiety score of students measured by the state anxiety subscale of the STAI questionnaire. The score ranges from 20 to 80, and a higher score indicates higher state anxiety.

Timepoint
At baseline, before students enter the classrooms.Fifteen

minutes after entering the classroom and before the start of the exam, after exposure to lemon aroma, lavender aroma, or water vapor in the control group.Immediately after the end of the exam

Method of measurement

Spielberger State-Trait Anxiety Inventory, State Anxiety Subscale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Participants in this group will be exposed to odorless water vapor in the examination classroom. Fifteen minutes before students enter the classroom, an electric diffuser containing distilled water will be turned on, and vapor without essential oil will be dispersed in the classroom environment. After entering the classroom, students will remain exposed to the water vapor for 15 minutes. The diffuser will remain on until completion of outcome measurements.

Category

Rehabilitation

2

Description

Intervention group 1: Participants in this group will receive aromatherapy with lemon essential oil. Fifteen minutes before students enter the classroom, an electric diffuser containing water and 10 drops of pure lemon essential oil will be turned on, and the aroma will be dispersed in the classroom environment. After entering the classroom, students will remain exposed to the lemon aroma for 15 minutes. The diffuser will remain on until completion of outcome measurements.

Category

Rehabilitation

3

Description

Intervention group 2: Participants in this group will receive aromatherapy with lavender essential oil. Fifteen minutes before students enter the classroom, an electric diffuser containing water and 10 drops of pure lavender essential oil will be turned on, and the aroma will be dispersed in the classroom environment. After entering the classroom, students will remain exposed to the lavender aroma for 15 minutes. The diffuser will remain on until completion of outcome measurements.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, University of Tehran

Full name of responsible person

Dr Elahe Gholamrezayi

Street address

End of North Kargar Street, next to the Atomic Energy Organization, before reaching the Hakim Shargh Highway exit, Faculty of Dentistry, Tehran University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Sedighe Sadat Hashemi Kamangar

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Amirhossein Lohrasebi Poor

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Unit 4, Block B, Yas Complex, No. 34, Next to Chaman Alley, Opposite Rahbar, Dr. Ali Mohammadi St., Mirzapour St., Shariati St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amirhossein Lohrasebi poor

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying the individuals participating in the study.

When the data will become available and for how long

Access period starts 6 years after results are published.

To whom data/document is available

The data is available for use in all professions.

Under which criteria data/document could be used

The data can be used to conduct research and improve the general health of the community. Data and documentation will be provided to them if needed.

From where data/document is obtainable

Contact Amir Hossein Lohrasbipour for data and documentation. Contact number: 0098 912 4427629 Email: amirlohi80@gmail.com

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

By calling the contact information provided, the applicant can specify their request and the type of data and documents required, and then the documents will be provided to them within one to several weeks.

Comments