

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluating the effect of Lemongrass aromatherapy on reducing the anxiety of patients undergoing scaling and root planing

Protocol summary

Study aim

Determining the effect of aromatherapy with Lemongrass in reducing the anxiety of patients undergoing scaling and root planing (SRP)

Design

randomized, unblinded, controlled clinical trial with parallel group design of 40 patients, PASS 2021 software was used for randomization.

Settings and conduct

40 eligible patients from Yazd Dental Faculty will be divided into two groups using stratified randomization. During SRP, the intervention group will receive aromatherapy with lemongrass essential oil, while the control group will receive distilled water. Before and after aromatherapy, the patients' subjective and objective anxiety will be measured using the state scale of Spielberger's State-Trait Anxiety Inventory and physiological indicators (blood pressure, heart rate, blood oxygen), respectively. The level of perceived pain during treatment and treatment satisfaction will also be assessed after aromatherapy.

Participants/Inclusion and exclusion criteria

Entry criteria: Age between 25 and 50 years; having periodontitis stage II to IV and grade A or B Non-entry criteria: History of SRP; systemic conditions such as high blood pressure, diabetes and lung problems; smoking; history of allergy to certain medicinal plants; having problems such as nasal congestion; loss of sense of smell due to Covid-19, etc; being diagnosed with sinusitis; being diagnosed with anxiety disorders; pregnancy; breastfeeding; receiving chemotherapy; taking pain relievers; taking anti-anxiety medications; taking medications that affect heart rate and blood pressure; taking antiseizure medications; taking immunosuppressive medications

Intervention groups

Intervention group: This group will receive aromatherapy with lemongrass essential oil during SRP treatment
Control group: For this group, during SRP treatment,

distilled water will be used instead of lemongrass essential oil

Main outcome variables

The level of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230615058492N2**

Registration date: **2024-02-21, 1402/12/02**

Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**

Update count: **0**

Registration date

2024-02-21, 1402/12/02

Registrant information

Name

Fahimeh Rashidimeibodi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3625 5881

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Lemongrass aromatherapy on reducing the anxiety of patients undergoing scaling and root planing

Public title

Effect of Lemongrass aromatherapy on reducing anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 25 and 50 years Having periodontitis stage II to IV and grade A or B

Exclusion criteria:

History of scaling and root planing Having systemic conditions such as high blood pressure, diabetes or lung problems Smoking History of allergy to certain medicinal plants Having allergies or problems such as nasal congestion Loss of sense of smell due to Covid-19, etc Being diagnosed with sinusitis Being diagnosed with anxiety disorders The patient is pregnant The patient is breastfeeding The patient is receiving chemotherapy Taking pain relievers Taking anti-anxiety medications Taking medications that affect heart rate and blood pressure, such as diuretics and beta blockers Taking antiseizure medications Taking immunosuppressive medications

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in the form of simple stratified randomization. The strata include age variable in two groups (aged 25-37 and aged 38-50) and gender in two groups, and in total, random allocation is done in 4 separate layers, 10 samples considered in each layer. First, the age and gender are determined and the eligible individual is entered into the study in one of the 4 layers based on the random allocation table. Using PASS 2021 software, we will generate a random sequence using a simple random allocation method. The output of the software in the form of an Excel file includes the sequence from 1 to 40, the strata and unique codes for the research units. After determining the stratum based on age and gender for the eligible individuals, a number from 1 to 10 is considered for each person; and the person is assigned to an intervention group (A or B). The first eligible patient is assigned number 1, the second is

assigned number 2, and so on, up to 10 patients in each stratum, and this is repeated for all the 4 strata.

Allocation concealment: In order to blindly assign the patients randomly, we will ask for the help of a third person who is unaware of the interventions and this table is given to them. When a patient eligible for the study visits, based on the patient's code, the intervention group will be asked from the third person over the phone and the patient will be assigned to one of the groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Blinding in this study will not be possible due to the presence of smellable aroma in the intervention group and its absence in the control group; Because the clinical caregivers and participants will distinguish the scent distinctly from distilled water anyway. However, the data analyst is blinded and has no knowledge of the case and control groups.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Faculty of Dentistry_ Shahid Sadoughi University of Medical Sciences, Yazd

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Faculty of Dentistry, the beginning of Imam Reza Blvd, Imam Reza Square

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Province

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Postal code

8914881167

Approval date

2023-12-11, 1402/09/20

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1402.044

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2

Description of health condition studied

Perceived pain during treatment

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Anxiety score

Timepoint

Before the beginning of scaling and after scaling for two thirds of the teeth

Method of measurement

Spielberger's State-Trait Anxiety Inventory-State Scale (containing 20 questions and scoring from 20 to 80)

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

Before the beginning of scaling and after scaling for two thirds of the teeth

Method of measurement

Digital sphygmomanometer model Ri-champion N from Riester® (measurement unit: millimeters Hg)

2

Description

Diastolic blood pressure

Timepoint

Before the beginning of scaling and after scaling for two thirds of the teeth

Method of measurement

Digital sphygmomanometer model Ri-champion N from Riester® (measurement unit: millimeters Hg)

3

Description

Pulse rate

Timepoint

Before the beginning of scaling and after scaling for two thirds of the teeth

Method of measurement

P-01 pulse oximeter device

4

Description

Arterial blood oxygen saturation percentage

Timepoint

Before the beginning of scaling and after scaling for two thirds of the teeth

Method of measurement

P-01 pulse oximeter device

5

Description

Pain grade on Visual Analogue Scale

Timepoint

After scaling for two thirds of the teeth

Method of measurement

Visual Analogue scale

6

Description

Patient satisfaction

Timepoint

After scaling for two thirds of the teeth

Method of measurement

Graded scale from 1 to 5 (1=dissatisfied/ 5=completely satisfied)

Intervention groups

1

Description

Intervention group: For this group, 3 drops (0.15 ml) of lemongrass essential oil (100% pure, non-edible) from Naringol brand (Tehran, Iran), which is originally a product of Moksha company (New Delhi, India) diluted in 100 ml of distilled water (according to the manufacturer's instructions), is poured onto sterile cotton/gauze and then rubbed around the patient's nostrils. Aromatherapy will continue from the beginning to the end of scaling and root planing treatment (for 25 to 35 minutes).

Category

Treatment - Drugs

2

Description

Control group: For this group, distilled water will be used for moistening the cotton/gas and rubbing around nostrils

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Faculty of Dentistry, Yazd

Full name of responsible person

Fahimeh Rashidi Maybodi

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Sponsors / Funding sources

1

Sponsor

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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
Yazd 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
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Mahta Sadat Vaezpour
Position
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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