

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of inhaling the essence of orange and lavender on client's dentistry anxiety in Shiraz Dentistry Clinic, 2017

Protocol summary

Study aim

Determination of the effect of inhalation of orange extract and lavender on dental anxiety in dental clinic of Shiraz in 2017.

Design

Randomized clinical trial, Three arm parallel group, two side blinded

Settings and conduct

This randomized clinical trial will do in Shiraz milad dentistry clinic. In order to blind the investigator, the medications (extracts) were named A, B, and C.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- People between the ages of 18 and 60 years. 2- At least, have Lower secondary education certification 3- Any history of allergy to aromatic agents 4- No history of discomfort in the sense of smell. 5- Having informed consent to participate in the study 6- coming to the dentistry clinic just For examination, root canal treatment or tooth repairmen Exclusion criteria: 1- Pregnancy 2- Using sedative medications before going to the clinic 3- known cases of psychiatric disorders 4- Positive history of the sensitivity response to the administered drugs in the study 5- known cases of mental and neurological disorders

Intervention groups

Group 1: Using the essential oil of the drug A for 20 minutes Group 2: Using the essential oil of the drug B for 20 minutes Group 3: Using the essential oil of the drug C for 20 minutes

Main outcome variables

Anxiety score in patients who referred to Shiraz Milad dentistry clinic

General information

Reason for update

Acronym

TPM

IRCT registration information

IRCT registration number: **IRCT20150825023753N4**

Registration date: **2018-01-24, 1396/11/04**

Registration timing: **retrospective**

Last update: **2018-01-24, 1396/11/04**

Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

Name

Mohammad Mahdi Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3212 5592

Email address

parvizim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

2017-07-23, 1396/05/01

Actual recruitment end date

2017-11-21, 1396/08/30

Trial completion date

empty

Scientific title

Comparison of the effect of inhaling the essence of orange and lavender on client's dentistry anxiety in Shiraz Dentistry Clinic, 2017

Public title

Effect of aromatherapy by essence of lavender and orange on dentistry anxiety .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People between the ages of 18 and 60 years. At least, have Lower secondary education certification any history of allergy to aromatic agents No history of discomfort in the sense of smell. Having informed consent to participate in the study For examination, root canal treatment or tooth filling only

Exclusion criteria:

Pregnancy Using sedative medications before going to the clinic known cases of psychiatric disorders Positive History of the Sensitivity Response to the Drugs Involved in the Study Known cases of mental and neurological disorders

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software Ink was used to create a randomization table by a block size of six.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the investigator, the medications (extracts) were named A, B, and C. The researcher asked the researcher for the impregnated cotton with the essential oils (2 drops of lavender essential oil, orange, sesame, with the help of the researcher on a piece of cotton) in boxes labeled C, A , B, and placed them at the disposal of patients. (Scholar blinding). Subsequently, they were asked to take the cotton at a distance of 3 cm from the eye. The codes listed for statistical analysis were employed. Then the statistical analyzer of the essence of the essential oils was unknowing for the patients (statistical analyzer blinding).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Bushehr University of Medical sciences

Street address

Faculty of Nursing and Midwifery, University of Medical Science, Behnani Street, Buser City,

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Province

Boushehr

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7518759577

Approval date

2017-07-21, 1396/04/30

Ethics committee reference number

IR .BPUMS.REC.1396.86

Health conditions studied

1

Description of health condition studied

Dental Anxiety

ICD-10 code

F40.2

ICD-10 code description

Specific (isolated) phobias

Primary outcomes

1

Description

Anxiety Score

Timepoint

Before and after

Method of measurement

Using Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Aromatic odor of 0.1 cc (two drops) impregnated cotton with orange extract made by Barij Essence Company for 20 minutes with a distance of 3 cm from the patient nose before dentistry intervention

Category

Treatment - Drugs

2

Description

Aromatic odor of 0.1 cc (two drops) impregnated cotton with lavender extract made by Zarband Company for 20 minutes with a distance of 3 cm from the patient nose before dentistry intervention

Category

Treatment - Drugs

3

Description

Aromatic odor of 0.1 cc (two drops) impregnated cotton with sesame oil (for placebo) made by Nosahd Company for 20 minutes with a distance of 3 cm from the patient nose before dentistry intervention

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Milad Shiraz

Full name of responsible person

Dr. Ali Mohammad Salehi

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Milad Dentistry Clinic. Alam Square Aveiroud
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Dr. Masoud Bahreini

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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

Boushehr 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mahdi Parvizi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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

Not applicable

Title and more details about the data/document

Demographic data and the result of the clinical trial

When the data will become available and for how long

6 month later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After publication of the extracted article of the clinical trial

From where data/document is obtainable

sending Email to the researchers

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

Sending the request via the email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Boushehr University of Medical Sciences

Full name of responsible person

Samane Hasanshahi

Position

Student ,Master of Psychiatric Nursing

Latest degree

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