Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Jasmine aroma on patient’s anxiety, pain and cooperation in dental Procedures in 7-12 years old children

Protocol summary

Study aim
The effect of jasmine aromatherapy on patient cooperation and pain and anxiety during dental practice in pediatric dentistry

Design
A randomized clinical trial with 4 patients using random allocation software

Settings and conduct
Aromatherapy is accomplished by a container of water and a candle so that the candle is placed under the container and the jasmine extract is dispersed at room temperature. After aromatherapy, the anxiety level of all patients in both groups after completion of dental work was assessed

Participants/Inclusion and exclusion criteria
1. Age 6 to 12 years 2. Candidate for dental practice with previous record 3. Child with Frankel + or ++ 4. A history of dentistry for a child to perform simple tasks such as fluoride therapy and fissure sealant. 5. Children in need of Class 1 restorative treatment of primary or permanent tooth with infiltration anesthesia, 1. Patients with the first visit to dentistry 2. The systemic and mental illness of the child in such a way as to prevent the necessary co-operation at work 3. Odor disorder or any respiratory illness that may affect the sense of smell 4. A history of allergy sensitivity 5. Affected by allergies and colds 6. Sensitivity to jasmine odor 7. Patients with spontaneous pain

Intervention groups
The demographic information of patients, including age and sex, will be reviewed and recorded first. In the first and second week, the control group received aromatherapy with distilled water, and in the third and fourth weeks, the intervention group received aromatherapy. All patients in both groups receive aromatherapy in a 10-square-meter waiting room. Then all patients in the intervention group received aromatherapy with 2 ml of jasmine extract and control group received aromatherapy with distilled water for 15 minutes.

Main outcome variables
Pain and anxiety control during dental procedures

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200218046545N1**
Registration date: **2020-05-10, 1399/02/21**
Registration timing: **retrospective**

Last update: **2020-05-10, 1399/02/21**
Update count: **0**

Registration date
2020-05-10, 1399/02/21

Registrant information

Name
Mehdi Jaafarzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3662 0028

Email address
mejsamani@yahoo.co.uk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-19, 1398/11/30

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Jasmine aroma on patient’s anxiety, pain and cooperation in dental Procedures in 7-12 years old children

Public title

The effect of Jasmine aroma on patient’s anxiety

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Age 7 to 12 years Candidate for dental practice with previous record Child with Frankel + or ++ A history of dentistry for a child to perform simple tasks such as fluoride therapy and fissure sealant Children in need of Class 1 restorative treatment of primary or permanent tooth with infiltration anesthesia

Exclusion criteria:

Patients with the first referral to dentistry Systemic and mental illness of the child in such a way as to prevent the necessary cooperation during the work Odor disorder or any respiratory illness that may affect the sense of smell A history of anesthesia Affected by allergies and colds Sensitivity to jasmine odor Patients with spontaneous pain

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

a simple accident Individual accident Randomization software with statistical software

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Medical Sciences Ethics Committee

Street address

hezarjrib aveneu Isfahan University of Medical Sciences

City

isfahan

Province

Isfehan

Postal code

8157895561

Approval date

2020-02-19, 1398/11/30

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.657

Health conditions studied

1

Description of health condition studied

Pain during dental procedures

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Patient anxiety during dental procedures

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

1.modified child dental anxiety scale : This questionnaire has 8 questions, each of which measures the anxiety level on each index with a range of five Elikert options from extreme fear, high fear, moderate fear, low fear, and complete relaxation, which scores from 1 to 5 The order of the minimum and maximum points for each person is 8 and 40 respectively. 2.Visual Analogue Scale: Visual pain rating scales are used to assess the severity of pain during dental procedures, including smileys, and the child identifies the severity of pain with a finger from zero to 10.

Timepoint

30 days

Method of measurement

1.modified child dental anxiety scale2.Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 28 children aged 7 to 12 years are in this group and are treated with jasmine flower aromatherapy. For each child in a waiting room of 3 square meters, they underwent aromatherapy once. Then, all patients in the intervention group undergo aromatherapy with 2 ml of jasmine flower extract.

Category
Placebo

2

Description
Control group: 28 children aged 7 to 12 years are in this group. They are controlled by aromatherapy with jasmine flowers. For each child, 1 bar of distilled water in a waiting room of 3 square meters replaces aromatherapy with jasmine flowers.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Dental School

Full name of responsible person
Mehdi Jafarzade

Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezar Jarib Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mehdi Jafarzade

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Faculty of Dentistry, Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mehdi Jafarzade

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

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Mehdi Jafarzade

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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

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

Only part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any scientific analysis to expand the field under investigation

From where data/document is obtainable

Dr Mehdi Jafarzadeh email mejsamani@yahoo.co.uk

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

The applicant must be a professional doctoral student or one of the professors or researchers of scientific centers, and after reading the e-mail, it will be delivered to the applicant.

Comments