Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Vanilla aromatherapy and Orange aromatherapy on Pain and Anxiety in Children under Dental Procedures

Protocol summary

Study aim
2-عنوان به لاتین Effectiveness of Vanilla aromatherapy and Orange aromatherapy on Pain and Anxiety in Children under Dental Procedures

Design
A clinical trial with two intervention groups and a control group with parallel, double-blind, randomized groups was designed to determine the effect of vanilla aroma therapy and orange reed aroma on dental pain and anxiety.

Settings and conduct
This study will be conducted in a dental clinic affiliated to the Kurdistan University of Medical Sciences in a double-blind manner, the participants and also the person who will analyze the data will be blinded.

Participants/Inclusion and exclusion criteria
Consent of children and their parents to participate in the study Children aged 8 to 12 who need treatment for at least one decayed tooth No vision or hearing impairment. Not having fever, illness and mental disorders. Children should not undergo dental surgery. Children should not be under psychiatric or psychological treatment. The first visit of the child

Intervention groups
intervention groups including orange and vanilla aromatherapy

Main outcome variables
Dental pain and anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190703044082N6**
Registration date: **2023-03-10, 1401/12/19**
Registration timing: **registered_while_recruiting**
Last update: **2023-03-10, 1401/12/19**
Update count: **0**

Registration date
2023-03-10, 1401/12/19

Registrant information
Name
Fateme Mohammadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 4567 8904
Email address
f-mohammadi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-01, 1401/12/10

Expected recruitment end date
2024-02-29, 1402/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Vanilla aromatherapy and Orange aromatherapy on Pain and Anxiety in Children under Dental Procedures

Public title
The effect of parsnip and vanilla scent on dental pain and anxiety

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Children and their parents should be satisfied to participate in the study 8-12 year old children who need at least one decayed tooth treatment based on doctor's diagnosis. Not having vision or hearing defects Not having fever or illness Not having physical or mental disorders. Children should not undergo dental surgery Children should not be under psychiatric or psychological treatment The child's first visit to the dentist

Exclusion criteria:
1) Reluctance of parents and children to continue studying. 2) Being unpleasant or sensitive to the smell of orange or vanilla for the child.

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly assign the participants to aromatherapy groups with orange essential oil, aromatherapy with vanilla essence and control, the names of the three groups will be written on paper and taken randomly, and the order of sampling of the groups will be determined. 20 blocks of 6 will be used for random allocation of samples in three groups. In this way, the letter A will be considered for the orange group, the letter B for the vanilla group, and the letter C for the control group. on pieces of paper, and we will pick them randomly. Then, according to the possible order of sampling, it will start.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are blinded to the allocation of which group they will be placed in. That is, children and their families are unaware of whether they have been placed in the orange or vanilla aromatherapy group or the control group. In addition, the person who analyzes the data is blinded to the assignment of individuals to groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University of Medical Sciences (Research Ethics Committee)

Street address
Hamedan, Shariati Crossroads, Ayatollah Kashani Boulevard, Hamedan University of Medical Sciences

City
Hamadan

Province
Hamadan

Postal code
6517838698

Approval date
2023-01-21, 1401/11/01

Ethics committee reference number
IR.UMSHA.REC.1401.909

Health conditions studied

1

Description of health condition studied
Tooth Decay

ICD-10 code
K02.9

ICD-10 code description
Dental caries, unspecified

Primary outcomes

1

Description
anxiety

Timepoint
Before and immediately after the procedure

Method of measurement
Modified Child Dental Anxiety Scale by Wang et al

2

Description
pain

Timepoint
Before and immediately after the procedure

Method of measurement
Wong and Baker pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In group A (orange aroma therapy), 10 minutes before any

intervention by the dentist, the researcher pours 80 cc of distilled water and 8 drops of orange essential oil into the nebulizer. After 10 minutes, the children are subjected to dental procedures, and during the dental procedures, which averaged 30 minutes, orange aroma therapy (8 drops every two minutes) continues.

Category

Treatment - Other

2

Description

Intervention group: Intervention method: In group B (vanilla aroma therapy), 10 minutes before any intervention by the dentist, the researcher pours 80 cc of distilled water and 8 drops of vanilla essential oil into the nebulizer and adds 8 drops of vanilla essential oil every two minutes to intensify Do not reduce the scent. After 10 minutes, children are subjected to dental procedures. During the dental procedures, which averaged 30 minutes, vanilla aroma therapy (8 drops every two minutes) continues.

Category

Treatment - Other

3

Description

Control group: In group C, the researcher pours 80 cc of distilled water and 8 drops of placebo (distilled water) into the nebulizer and adds 8 drops of placebo to it every two minutes so that the severity of the pain does not decrease. After 10 minutes, children are subjected to dental procedures. Aromatherapy with placebo (8 drops every two minutes) continues during dental procedures, which averaged 30 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental clinic affiliated with Kurdistan University of Medical Sciences

Full name of responsible person

Marzieh Hemmatzadeh

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Service

City

Hamadan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3334 5634

Email

F-mohammadi@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services

City

Hamadan

Province

Hamadan

Postal code

6517838698

Phone

+98 81 3334 5634

Email

F-mohammadi@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Hamedan University of Medical Sciences

Full name of responsible person

Fateme Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services

City

Hamadan

Province

Hamadan

Postal code

6517838698

Phone
+98 81 3334 5634

Email
F-mohammadi@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Fateme Mohammadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services

City
Hamadan

Province
Hamadan

Postal code
6517838698

Phone
+98 81 3334 5634

Email
F-mohammadi@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Fateme Mohammadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Beginning of Ayatollah Kashani Boulevard, Hamadan University of Medical Sciences and Health Services

City
Hamadan

Province
Hamadan

Postal code
6517838698

Phone
+98 81 3334 5634

Email
F-mohammadi@umsha.ac.ir

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