Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of watching cartoons and Aromatherapy with orange on pain and anxiety in children under dental procedures in the dental clinic affiliated kurdistan univercity of medical science 2022

Protocol summary

Study aim
Determining the effect of playing cartoons and orange aroma therapy on pain and anxiety of children undergoing dental procedures in the dental clinic affiliated to Kurdistan University of Medical Sciences.1401

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, on 126 children with dental caries, block randomization

Settings and conduct
This study will be conducted in the dental clinic affiliated to the Kurdistan University of Medical Sciences. This clinic has 3 separate rooms, in one room there is a television, in the other room there is a nebulizer, and in the other room there is the main dental equipment. In the cartoon group, a cartoon is selected and placed on the unit. The researcher will play the cartoon on TV 10 minutes before the procedure, and the cartoon will continue to be played during the procedure. In the aroma group, 10 minutes before the intervention by the research dentist, a drop of orange essential oil was poured into the nebulizer. After 10 minutes, the children will undergo the procedure. During the procedure, the orange aroma therapy will continue. In the control group, they receive routine care

Participants/Inclusion and exclusion criteria
Entry: Children aged 8 to 12 years who need treatment for a decayed tooth Not having vision or hearing defects or fever and illness. Children should not undergo dental surgery. Failure to enter: lack of desire to continue studying by parents and children. The child's lack of attention to the cartoon for more than five minutes.

Intervention groups
In the intervention groups, during 1 session of playing a cartoon or orange aroma therapy, each of which lasts 10 minutes before the start of work and 30 to 40 minutes during the procedure. and the control group for whom routine dental procedures are performed

Main outcome variables
Pain and dental anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190703044082N8**
Registration date: **2023-03-26, 1402/01/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-26, 1402/01/06**
Update count: **0**

Registration date
2023-03-26, 1402/01/06

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
2023-03-05, 1401/12/14

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date

2023-02-20, 1401/12/01

Actual recruitment end date

2023-08-23, 1402/06/01

Trial completion date

2023-09-23, 1402/07/01

Scientific title

The effect of watching cartoons and Aromatherapy with orange on pain and anxiety in children under dental procedures in the dental clinic affiliated kurdistan univercity of medical science 2022

Public title

The effect of watching cartoons and Aromatherapy with orange on pain and anxiety in children under dental procedures

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children and their parents should be satisfied with their participation in the study Children 8-12 years old who need at least one decayed tooth to be treated based on the doctor's diagnosis No vision or hearing impairment No fever or illness Not having physical or mental disorders Children should not undergo dental surgery The child's first visit to the dentist

Exclusion criteria:

Parents' and children's unwillingness to continue studying. Smell of orange is unpleasant for the child Child not paying attention to the cartoon for more than five minutes.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were divided into two intervention groups and one control group by random block sampling method (20 blocks of 6).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Hamadan University of Medical Sciences

Street address

Hamedan University of Medical sciences, Hamadan Town, Khajeh Rashid Blvd

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.UMSHA.REC.1401.939

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: In group A (cartoon therapy), children chose a cartoon and 10 minutes before the procedure and during the procedure, the cartoon continues to play.

Category

Treatment - Other

2

Description

Intervention group: 10 minutes before the intervention, the researcher pours 80 cc of distilled water and 8 drops of orange essential oil into the nebulizer and adds 8 drops of orange essential oil to it every two minutes and continues throughout the procedure, which is 30 to 40 minutes.

Category

Treatment - Other

3

Description

Control group: The control group of children received routine care

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

Erice Gross Building، Taleghani Street, Kurdistan

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh mohammadi

Street address

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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

Hamedan 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

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Fateme Mohammadi

Position
Assistant Professor

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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