

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A comparative study of the effect of educational animation and lavender scent on anxiety, anger and pain in children referred to dentistry

Protocol summary

Study aim

A comparative study of the effect of educational animation and lavender scent on the level of anxiety, anger and pain in children who go to the dentist

Design

A clinical trial with a control group with randomized parallel groups on 132 patients. To randomize, the rand function of Excel software for boys and girls was used separately for random blocks.

Settings and conduct

Children with dental problems in the age range of 4 to 6 years who refer to Tadayon Health Center and the School of Dentistry, if they wish to participate in the study, enter the study with the informed consent of their parents. After measuring anxiety, anger and pain, randomization is performed and the relevant intervention is performed and then the dependent variables are measured before entering the office and after anesthesia injection.

Participants/Inclusion and exclusion criteria

The desire of the patient (parents) to participate in the study Children in the age range of 4 to 6 First visit to dentistry No disturbance in the five senses Do not take sedatives the day before Not having a known case of mental illness Absence of asthma, bronchitis, chronic respiratory diseases

Intervention groups

In the animation group, before the child goes to the dentist room, an animation is shown to the child for 3 minutes by a tablet. In the lavender group, 2 drops of 100% lavender essential oil prepared by Barij Essential Oil Company are poured on a piece of gauze 10 minutes before going to the dentist's room and attached to the patient's collar and removed before going to the room. No action is taken in the control group

Main outcome variables

Child Anxiety Measured using the Anxiety Scale Video Scale Anger, which is measured using the Anger Image Scale Pain, which is measured by the scale of behavioral reactions caused by pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110430006342N13**

Registration date: **2022-01-07, 1400/10/17**

Registration timing: **prospective**

Last update: **2022-01-07, 1400/10/17**

Update count: **0**

Registration date

2022-01-07, 1400/10/17

Registrant information

Name

Ali Asghar Ghods

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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aaghods@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of educational animation and lavender scent on anxiety, anger and pain in children referred to dentistry

Public title

The effect of animation and lavender on anxiety, anger and pain in children in dentistry

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All children 4 to 6 years old referring to dentistry

Exclusion criteria:

Second or more visits to the dentist - having a disorder of the five senses - taking sedatives the day before the visit - a known case of mental illness - the presence of asthma, bronchitis and chronic respiratory diseases

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks by gender using a table of random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research

Street address

Deputy of research and technology, Central Headquarters of Semnan University of Medical Sciences, Basij Boulevard

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2021-12-28, 1400/10/07

Ethics committee reference number

IR.SEMUMS.REC.1400.261

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Anxiety score

Timepoint

Before the intervention, immediately after the intervention and after the anesthetic injection

Method of measurement

Wenham Anxiety Scale

2

Description

Anger score

Timepoint

Before the intervention, immediately after the intervention and after the anesthetic injection

Method of measurement

Visual Anger Scale

3

Description

Pain score

Timepoint

Before the intervention, immediately after the intervention and after the anesthetic injection

Method of measurement

behavioral pain assessment scale

Secondary outcomes

1

Description

Pulse rate

Timepoint

Before the intervention, immediately after the intervention and after the anesthetic injection

Method of measurement

Count the pulse number

2

Description

Respiration rate

Timepoint

Before the intervention, immediately after the intervention and after the anesthetic injection

Method of measurement

Count the respiration number

Intervention groups

1

Description

Intervention group:

Category

Prevention

2

Description

Intervention group:

Category

Prevention

3

Description

Control group:

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry faculty

Full name of responsible person

Elham Mirahmadi

Street address

School of Dentistry, 17 Shahrivar Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Ali Asghar Ghods

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

After collecting the data, the report will be submitted to the Deputy Minister of Research and Technology

When the data will become available and for how long

one year after data collection

To whom data/document is available

researchers

Under which criteria data/document could be used

Citing the source

From where data/document is obtainable

Responsible researcher

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

Delivered one month after request

Comments