

# 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)

##### Phone

+98 23 1335 4192

##### Email address

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.

##### **City**

Semnan

##### **Province**

Semnan

##### **Postal code**

3518794431

##### **Phone**

+98 23 3332 4700

##### **Email**

dent@semums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Semnan University of Medical Sciences

#### **Full name of responsible person**

Majid Mirmohammadkhani

#### **Street address**

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

#### **City**

Semnan

#### **Province**

Semnan

#### **Postal code**

3519899951

#### **Phone**

+98 23 3105 2120

#### **Email**

majidmirmohammadkhani@yahoo.com

#### **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

##### **Street address**

Faculty of Nursing, Semnan University of Medical Sciences, Km 6 Damghan Road

##### **City**

Semnan

##### **Province**

Semnan

##### **Postal code**

3513138111

##### **Phone**

+98 23 3365 4190

##### **Email**

aaghods@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Ali Asghar Ghods

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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**