

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Effect of two Oral Hygiene Learning Methods on Knowledge among the Last Elementary Class Students.

#### Protocol summary

##### Study aim

The purpose of this clinical trial study is to evaluate the role of the two oral hygiene methods (conventional method vs. educational film) on oral health promotion among students, as one of the important goal groups in society.

##### Design

In this randomized clinical trial study, 120 Students in the last elementary class in one of the schools in Tehran with inclusion criteria will participate and the classes will be randomly selected into the tests or control groups.

##### Settings and conduct

A questionnaire with 6 multiple choice questions will be answered by the students; the score will be assumed as the "pretest" score. Three weeks after intervention, the questionnaire will be answered again and the score will be recorded as "post test" score.

##### Participants/Inclusion and exclusion criteria

Boy students at the 6th elementary class who are volunteer to participate to the study.

##### Intervention groups

Test Group 1: Animation Film Group Test Group 2: Dentist with Artificial Model Group Control Group: Without Intervention

##### Main outcome variables

Knowledge change about oral hygiene.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140318017053N8**

Registration date: **2018-01-27, 1396/11/07**

Registration timing: **retrospective**

Last update: **2018-01-27, 1396/11/07**

Update count: **0**

##### Registration date

2018-01-27, 1396/11/07

##### Registrant information

###### Name

Ferena Sayar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2256 4571

###### Email address

f\_sayar@dentaliau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2017-11-29, 1396/09/08

##### Actual recruitment start date

2017-11-22, 1396/09/01

##### Actual recruitment end date

2017-11-29, 1396/09/08

##### Trial completion date

empty

##### Scientific title

Effect of two Oral Hygiene Learning Methods on Knowledge among the Last Elementary Class Students.

##### Public title

Effect of two Oral Hygiene Methods on Knowledge of Students at Elementary School.

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Male Students 6th elementary class

###### Exclusion criteria:

Discontent to participate

#### Age

From **11 years** old to **13 years** old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **120**

Actual sample size reached: **120**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Each class will be selected for one of the study groups by a sealed pocket.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

It is the first time in Iran we are going to use of animation film to promote oral hygiene knowledge among elementary students.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Islamic Azad University

##### Street address

9th Neyestan St., Pasdaran Ave., Dental School,  
Islamic Azad University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

19585175

#### Approval date

2017-11-12, 1396/08/21

#### Ethics committee reference number

IR.IAU.DENTAL.REC.1396,33

## Health conditions studied

### 1

#### Description of health condition studied

Knowledge about Oral Hygiene

#### ICD-10 code

## ICD-10 code description

## Primary outcomes

### 1

#### Description

Change in Knowledge.

#### Timepoint

Base line and 3 weeks after the interventions.

#### Method of measurement

Score of the questionnaire.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Test group 1: Educational Film Group.

#### Category

N/A

### 2

#### Description

Test group 2: Dentist with Artificial Model Group.

#### Category

N/A

### 3

#### Description

Control group: Without Intervention.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental School, Islamic Azad Medical Sciences

##### Full name of responsible person

Ferena Sayar

##### Street address

9th Neyestan, Pasdaran Ave.

##### City

Tehran

##### Province

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##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ferena Sayar

**Street address**

9th Neyestan, Pasdaran Ave, Islamic Azad Dental School

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**Grant name**

vice chancellor for research, Islamic Azad Dental School.

**Grant code / Reference number**

2279608130002

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Ferena Sayar

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Periodontics

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## Person responsible for scientific inquiries

#### Contact

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**Latest degree**

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## Person responsible for updating data

#### Contact

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Islamic Azad University

**Full name of responsible person**

Ferena Sayar

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**Latest degree**

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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