

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Dental Health Education program for 6-olds: A Cluster Randomized Controlled Trial

#### Protocol summary

##### Summary

Oral health is a reflection of general health and significantly influences the quality of life. Dental caries is one of the most common chronic diseases of childhood which may adversely affect physical, mental and social growth of children. Oral hygiene methods can effectively prevent orodental diseases and oral hygiene education plays an important role in this regard. The aim of the present study was then to assess the effect of oral hygiene education on the orodental health of 6-year-olds. A hundred sixty 6-year-old children from 4 pre-school centers were divided into two groups of case and control in this cluster randomized controlled trial. The students in the case group received orodental education in one session. The parents of the case group were also instructed in one session. The children and parents of the control group did not receive any instructions. Plaque index (PI): Turesky-Gilmore-Glickman and gingival index (GI): Loe & Silness were measured on 1) baseline, 2) 1.5 and 3) 6 months after the primary examination.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138812163484N1**

Registration date: **2010-04-20, 1389/01/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-04-20, 1389/01/31

##### Registrant information

###### Name

Nasrin Esfahanizadeh

###### Name of organization / entity

Azad University of Tehran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2276 5235

###### Email address

dr.n.esfahanizadeh@dental.iau.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Nasrin Esfahanizadeh

###### Expected recruitment start date

2008-04-08, 1387/01/20

###### Expected recruitment end date

2008-05-04, 1387/02/15

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Dental Health Education program for 6-olds: A Cluster Randomized Controlled Trial

###### Public title

The effect of Dental Health Education program on dental health

###### Purpose

Health service research

###### Inclusion/Exclusion criteria

Inclusion criteria: Children with 6 years old

###### Age

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

###### Gender

Both

###### Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 160

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Cluster randomized control trial

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Dental School, Azad University

##### Street address

10th Neyestan Street, Pasdaran Avenue,

##### City

Tehran

##### Postal code

1946853314

#### Approval date

2009-03-13, 1387/12/23

#### Ethics committee reference number

14045

## Health conditions studied

### 1

#### Description of health condition studied

Dental health

#### ICD-10 code

Z40-Z54

#### ICD-10 code description

Persons encountering health services for specific procedures and health care

## Primary outcomes

### 1

#### Description

Plaque index,

#### Timepoint

Base line, After 1.5 and 6 months

#### Method of measurement

based on the Turesky-Gilmore-Glickman

### 2

#### Description

Gingival index

#### Timepoint

Base line, After 1.5 and 6 months

#### Method of measurement

based on the Loe & Silness

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Dental Health education in case group

#### Category

Prevention

### 2

#### Description

No intervention in control group

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Rahimi Girl school

##### Full name of responsible person

Health teacher in school & Nasrin Esfehanizadeh

##### Street address

Srtict 4 in Tehran,

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Sadi girl school

##### Full name of responsible person

Health teacher in school & Nasrin Esfehanizadeh

##### Street address

Srtict 4 in Tehran

##### City

Tehran

### 3

#### Recruitment center

##### Name of recruitment center

Namjoo boy school

##### Full name of responsible person

Health teacher in school & Nasrin Esfehanizadeh

##### Street address

Srtict 4 in Tehran  
**City**  
Tehran

#### 4

##### **Recruitment center**

**Name of recruitment center**  
Khalegh boy school  
**Full name of responsible person**  
Health teacher in school & Nasrin Esfehanizadeh  
**Street address**  
Srtict 4 in Tehran  
**City**  
Tehran

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

**Name of organization / entity**  
Vice chancellor for Research, Faculty of Dentistry,  
Islamic Azad University  
**Full name of responsible person**  
Afshin Haraji  
**Street address**  
P.OBox: 19585/175  
**City**  
Tehran

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Vice chancellor for Research, Faculty of Dentistry, Islamic Azad University

##### **Proportion provided by this source**

100

##### **Public or private sector**

*empty*

##### **Domestic or foreign origin**

*empty*

##### **Category of foreign source of funding**

*empty*

##### **Country of origin**

##### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

##### **Contact**

**Name of organization / entity**  
Dental school of Azad University  
**Full name of responsible person**  
Nasrin Esfehanizadeh  
**Position**  
Implant fellowship, Assistant professor of Dental school of Azad University  
**Other areas of specialty/work**  
**Street address**

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**Web page address**

## **Person responsible for scientific inquiries**

##### **Contact**

**Name of organization / entity**  
Dental School, Azad University  
**Full name of responsible person**  
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DDS  
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## **Person responsible for updating data**

##### **Contact**

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**Full name of responsible person**  
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**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*

**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*