

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparative assessment of effect of traditional oral hygiene and halitosis-base education on oral hygiene indicators in 9-10 years old students

#### Protocol summary

##### Study aim

Comparison of the effect of the topic of education (health education with or without education about bad breath or gum and decay) in motivating the promotion of oral health indicators in a group of third grade elementary school students in Yazd

##### Design

Clinical trials with a control group, community-based and pragmatic

##### Settings and conduct

This study was performed on three types of health education in six primary schools of Yazd. Then 1 and 6 months later the training was repeated and in each of the three periods, the plaque index and the modified gingival index and bad breath were measured.

##### Participants/Inclusion and exclusion criteria

Entry requirements: Third grade elementary school students in Yazd. Conditions of non compliance: Disabling physical or mental illness, acute dental caries

##### Intervention groups

Bad Breath group: receive bad breath thematic education and oral health education  
Gum and Decoy group: receive Gum and Decoy thematic education and oral health education  
Control group: receive oral health education

##### Main outcome variables

Plaque index, Modified gingival index, Bad breath index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180526039842N1**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **retrospective**

Last update: **2018-09-26, 1397/07/04**

Update count: **0**

##### Registration date

2018-09-26, 1397/07/04

##### Registrant information

###### Name

Faezel Fotoohi ardekani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3625 5881

###### Email address

f.fotoohi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-09-21, 1395/06/31

##### Expected recruitment end date

2016-10-05, 1395/07/14

##### Actual recruitment start date

2016-09-21, 1395/06/31

##### Actual recruitment end date

2016-10-21, 1395/07/30

##### Trial completion date

2018-05-04, 1397/02/14

##### Scientific title

Comparative assessment of effect of traditional oral hygiene and halitosis-base education on oral hygiene indicators in 9-10 years old students

##### Public title

Comparison of the effect of oral health education in three different ways

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Third elementary student

### **Exclusion criteria:**

People with debilitating illnesses people who were not in one of the fallopian People with acute dental caries

## **Age**

From **9 years** old to **10 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **150**

Actual sample size reached: **136**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Randomization method: Simple randomization Random unit: cluster Randomization Tool: 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 of Shahid Sadoughi University of Medical Sciences, Yazd

##### **Street address**

Yazd, Shahid Bahonar Square

##### **City**

Yazd

##### **Province**

Yazd

##### **Postal code**

8914881167

#### **Approval date**

2017-02-20, 1395/12/02

#### **Ethics committee reference number**

IR.SSU.REC.1395.230

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Effect of the topic of oral health education

## **ICD-10 code**

K05.1

## **ICD-10 code description**

Chronic gingivitis

## **Primary outcomes**

### **1**

#### **Description**

Plaque index

#### **Timepoint**

Measuring plaque index at the beginning of the study (before intervention) and 1 and 6 months after the start of the study

#### **Method of measurement**

Calculate the ratio of dental plaque dental surfaces to total dental surfaces in the mouth (except the occlusal surface)

### **2**

#### **Description**

Modified gingival index

#### **Timepoint**

Measuring plaque index at the beginning of the study (before intervention) and 1 and 6 months after the start of the study

#### **Method of measurement**

0-Non-inflammation 1-Mild inflammation, slight changes in color and texture of each part except marginal and papillary gingivitis 2-Mild inflammation, slight changes in color and tissue that are involved in marginal and papillary gingivitis 3- Moderate inflammation, redness and edema, and gingival hypertrophy Marginal and papillary 4-severe inflammation, reddened edema and / or marginal and papillary gingivitis, spontaneous bleeding and ulceration

### **3**

#### **Description**

Halitosis

#### **Timepoint**

Measuring plaque index at the beginning of the study (before intervention) and 1 and 6 months after the start of the study

#### **Method of measurement**

Organoleptic test

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

First intervention group: Receive the theoretical lesson of bad breath and oral health education at the beginning of

the study and 6 months after the start of the study.

**Category**

Other

**2**

**Description**

Second intervention group: Receive the theoretical lesson of gum and tooth decay and oral health education at the beginning of the study and 6 months after the start of the study.

**Category**

Other

**3**

**Description**

Control group: Receive oral health education

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Education and training of Yazd

**Full name of responsible person**

Abbas Ali Danaei Far

**Street address**

Paknejad Blvd

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89195668

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**Email**

info@yazdedu.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Mahmoud Vakili

**Street address**

Shahid Bahrar Square

**City**

Yazd

**Province**

Yazd

**Postal code**

8916844933

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+98 35 3726 3733

**Email**

vakilim52@ssu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Faezeh Fotouhi Ardakani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

Dentistry

**Street address**

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**City**

Yazd

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**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**

Not applicable

**Data Dictionary**

Not applicable