

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparing the effect of three different oral hygiene instruction methods: brochure, educational video and lecture on plaque index of 8-9 years old children

#### Protocol summary

##### Study aim

Determining the effect of oral health education on 8-9 years old children by brochure, educational video and lecture on their plaque index

##### Design

Clinical trial, interventional, Includes 72 students in 3 parallel groups divided in comparative assignments

##### Settings and conduct

A girls' and a boys' school are randomly selected from the list of primary schools of Rasht city. Then, using blocking method, 72 second grade students (36 girls and 36 boys) are randomly and equally divided into the three groups: brochures, educational videos and lectures. Before the health education, the plaque index is recorded based on the Silness and Loe index. Then, training on how to brush and use dental floss are given to the corresponding groups, and the second and third plaque index are recorded on the next day and two weeks after the training. Then, these plaque indexes are measured with each other.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: - The age group is 9-8 years old - Having at least 10 permanent teeth listed in the study method - Parental consent for admission to study  
Exit criteria: - Excessive wear and destruction of the teeth studied - Failure to complete inactive teeth - The teeth have evolutionary anomalies. - The presence of any disease or evolutionary condition, such as physical-motor abnormalities or mental problems that disrupts the control of plaque control procedures for the child. - Parental unwillingness to continue the study during the study

##### Intervention groups

The intervention groups included: a training group with brochures, a training group with educational videos and a teaching group with lectures

##### Main outcome variables

Comparison of the effect of oral health education on the reduction of PI in children before, one day and two weeks after the use of brochures, educational film and lecture

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180624040221N1**

Registration date: **2018-10-27, 1397/08/05**

Registration timing: **prospective**

Last update: **2018-10-27, 1397/08/05**

Update count: **0**

##### Registration date

2018-10-27, 1397/08/05

##### Registrant information

##### Name

Anousheh Janani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3312 2360

##### Email address

Janania@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2018-12-06, 1397/09/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effect of three different oral hygiene instruction methods: brochure, educational video and lecture on plaque index of 8-9 years old children

**Public title**

Comparing the effect of three different oral hygiene instruction methods: brochure, educational video and lecture on plaque index of 8-9 years old children

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The age group is 9-8 years old Having at least 10 permanent teeth listed in the study method Parental consent for admission to study

**Exclusion criteria:**

Excessive tear and destruction of the teeth studied Failure to complete inactive teeth The teeth have evolutionary anomalies. The presence of any disease or evolutionary condition, such as physical-motor abnormalities or mental problems that disrupts the control of plaque control procedures for the child. Parental unwillingness to continue the study during the study

**Age**

From **8 years** old to **9 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The list of second grade students in the selected schools was prepared prior to the beginning of the study and seeing the students. Two lists of 36 were found, one for girls and one for boys. Then from each list, the first three students were assigned to the brochure group, the second three students to the film group and the third three student to the third group of lectures, and three to three students were divided accordingly.

**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 Guilan University of Medical Sciences

**Street address**

Gas field - Lacan Road - Saravan Gulf - 2 Km to Fouman - University Complex in Guilan University of Medical Sciences

**City**

Rasht

**Province**

Guilan

**Postal code**

73774-41941

**Approval date**

2018-06-02, 1397/03/12

**Ethics committee reference number**

IR.GUMS.REC.1397.073

**Health conditions studied****1****Description of health condition studied**

Dental decay and periodontal disease

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The plaque index score in the study of the effect of education through brochures, educational film and lecture

**Timepoint**

Measuring plaque index at baseline (before the study), one day after training and two weeks after training

**Method of measurement**

The measurement of the state of oral hygiene by Silness-Löe plaque index is based on recording both soft debris and mineralized deposits on the following teeth. Each of the four surfaces of the teeth (buccal, lingual, mesial and distal) is given a score from 0-3. The scores from the four areas of the tooth are added and divided by four in order to give the plaque index for the tooth with the following scores and criteria: 0\_No plaque, 1\_A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface, 2\_Moderate accumulation of soft deposit s within the gingival pocket, or the tooth and gingival margin which can be seen with the naked eye,

3\_Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

## Secondary outcomes

### 1

#### Description

The Effect of Health Education on Oral Health of Children

#### Timepoint

Measuring the plaque index before health education (first session), one day after training (second session), two weeks after training (third session)

#### Method of measurement

Silness and loe index

## Intervention groups

### 1

#### Description

First intervention group: Training group with brochure. - Second intervention group: Training group by educational film. - Third intervention group: Teaching group with lectures.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gas field - Lacan road - Saravan - 2 km to Fouman - University of Guilan University of medical scie

##### Full name of responsible person

Dr. Arash Ghafouri

##### Street address

Gas field - Lacan road - Saravan - 2 km to Fouman - University of Guilan University of medical sciences.

##### City

Rasht

##### Province

Guilan

##### Postal code

73774-41941

##### Phone

+98 13 3348 6406

##### Fax

+98 13 3348 6423

##### Email

dental@gums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Rasht University of Medical Sciences

#### Full name of responsible person

Dr.Arash Ghafouri

#### Street address

Gas field end of Lakan-Bandar-e-Saravan road - 2 km to Fouman - University of Guilan University of medical sciences.

#### City

Rasht

#### Province

Guilan

#### Postal code

73774-41941

#### Phone

+98 13 3348 6406

#### Fax

+98 13 3348 6423

#### Email

dental@gums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Rasht University of Medical Sciences

#### 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

Rasht University of Medical Sciences

##### Full name of responsible person

Dr. Arash Ghafouri

##### Position

Assistant Professor, Faculty of Dentistry, Gilan

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

##### Street address

Gas field end of Lakan road, Saravan belt, 2 km to Fouman, University of medical sciences, Guilan University of medical sciences

##### City

Rasht

##### Province

Guilan

##### Postal code

73774-41941

##### Phone

+98 13 3348 6406

**Fax**

+98 13 3348 6423

**Email**

dental@gums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Arash Ghafouri

**Position**

Assistant Professor, Faculty of Dentistry, Gilan

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Gas field end of Lakan road, Saravan belt, 2 km to Fouman, University of medical sciences, Guilan  
University of medical sciences

**City**

Rasht

**Province**

Guilan

**Postal code**

73774-41941

**Phone**

+98 13 3348 6406

**Fax**

+98 13 3348 6423

**Email**

dental@gums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Dr. Arash Ghafouri

**Position**

Assistant Professor, Faculty of Dentistry, Gilan

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Gas field end of Lakan road, Saravan belt, 2 km to Fouman, University of medical sciences, Guilan

University of medical sciences

**City**

Rasht

**Province**

Guilan

**Postal code**

73774-41941

**Phone**

+98 13 3348 6406

**Fax**

+98 13 3348 6423

**Email**

dental@gums.ac.ir

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The data includes the name and gender of the children as well as information on the three periods of measuring their plaque index scores.

**When the data will become available and for how long**

The start of the access period is 6 months after the results are printed.

**To whom data/document is available**

Researchers working in academic and scientific institutions and those involved in child health education.

**Under which criteria data/document could be used**

Certain other conditions are not currently available.

**From where data/document is obtainable**

Applicants can go to the email address provided here: Marvashabrang@gmail.com

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

After sending the email and requesting the data, the applicant must explain the reason for asking and explaining how the information is used and after one week his application will be reviewed and answered.

**Comments**