

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 -
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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.

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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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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