Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative assessment of effect of traditional oral hygiene and halitosis-base education on oral hygiene indicates 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)

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+98 35 3625 5881

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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 indicates 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 fallopians 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

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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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