

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of an oral health promotion intervention program including supervised tooth brushing in comparison with not receiving supervised tooth brushing on oral health status (caries, plaque index) of 6 to 7 years old school children

Protocol summary

Study aim

Evaluation of an oral health promotion intervention for 6- to 7- years old school children in Tehran

Design

The multistage cluster randomized sampling is applied including 6 to 7 years old children chosen from 19 districts of Tehran according to the Ministry of Education map. Sampling is adjusted according to the economic status in Tehran. In each strata, three district will be randomly selected and in each district, 4 schools including two girl's and two boy's schools, as intervention and control were chosen.

Settings and conduct

After obtaining informed consent, the oral health knowledge of parents will be assessed. Oral hygiene status and caries will be recorded using disposable instruments by two calibrated dentists. In the intervention group, an education workshop and a pamphlet will be delivered to parents. Also supervised brushing program will be performed at school setting after co-ordination with school officials. Free home package including toothbrush and toothpaste containing 1000 ppm fluoride will be given to students. Post-intervention evaluation of knowledge will be performed and oral hygiene will be assessed. After 1 year follow up data will be collected in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria; 1) Healthy 6- to 7- years old children, 2) Having signed parents' informed consent
Exclusion criteria; 1) Having allergy to fluoride, 2) Children with physical disability, 3) Having systemic diseases

Intervention groups

In the intervention group, an education package including educational workshop pamphlet will be delivered. Supervised tooth brushing program will be performed at school setting and free home package

including toothbrush and toothpaste containing 1000 ppm fluoride will be given to students.

Main outcome variables

Parents' knowledge of oral health; oral hygiene status and caries

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090307001749N4**

Registration date: **2019-02-14, 1397/11/25**

Registration timing: **retrospective**

Last update: **2019-02-14, 1397/11/25**

Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name

Afsaneh Pakdaman

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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pakdaman@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of an oral health promotion intervention program including supervised tooth brushing in comparison with not receiving supervised tooth brushing on oral health status (caries, plaque index) of 6 to 7 years old school children

Public title

Evaluation of a caries prevention program including supervised tooth-brushing for 6 to 7 years old school children

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy 6 to 7 years old children Having signed parents' informed consent

Exclusion criteria:

Having allergy to fluoride Children with physical disability Having systemic diseases

Age

From **6 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **720**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple cluster randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, data collectors and statistician are blind to allocation to case and control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Dental Research Center, Qods st., Eghelab Ave.

City

Tehran

Province

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Postal code

1439955991

Approval date

2015-08-23, 1394/06/01

Ethics committee reference number

IR.TUMS.REC.1394.1730

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

Caries enamel

ICD-10 code

K02.0

ICD-10 code description

Caries limited to enamel

2**Description of health condition studied**

Caries of dentine

ICD-10 code

K02.1

ICD-10 code description

Caries of dentine

Primary outcomes**1****Description**

Dental Plaque Index

Timepoint

At the beginning of the study (before the intervention) and 1 month and one year after the beginning of the intervention

Method of measurement

Oral and dental examination

2**Description**

Caries limited to enamel

Timepoint

At the beginning of the study (before the intervention) and one year after the intervention

Method of measurement

Oral and dental examination

Secondary outcomes

1

Description

Oral health knowledge

Timepoint

Pre- and post- intervention

Method of measurement

Questionnaire

2

Description

Dental caries

Timepoint

At the beginning of the study (before intervention) and 1 year after the intervention

Method of measurement

Oral examination

3

Description

Oral Hygiene Index

Timepoint

At the beginning of the study (before intervention), one month and 1 year after the intervention

Method of measurement

Oral examination

Intervention groups

1

Description

Supervised tooth-brushing for students and workshop for parents about proper tooth-brushing of teeth

Category

Prevention

2

Description

Control group: Routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Dr Pakdaman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, School of Dentistry, Tehran 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

Vice chancellor for research, School of Dentistry, Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr Azadeh Babaei
Position
DDS/PhD Candidate
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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PhD candidate

Latest degree

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Web page address

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

There is no more information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

There is not a plan to make this available.

When the data will become available and for how long

There is not a plan to make this available

To whom data/document is available

Editor-in-chief of Journales connected of articles

Under which criteria data/document could be used

By the request of Journal editor

From where data/document is obtainable

Department of Community Oral Health School of Dentistry Tehran University of Medical Science Azadeh Babaei a.babaei@razi.tums.ac.ir

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

E-mail

Comments