

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

The effect of two types of intervention (based on the principles of social marketing and traditional education) on increase in self-reported frequency and duration of tooth brushing of elementary school students: A controlled quasi-experimental study

Protocol summary

Study aim

The aim of this study was to evaluate the effect of social marketing approach versus the traditional method on promotion of tooth brushing habits in primary school students of Kahak and Jafariyeh, Qom

Design

This quasi-experimental controlled trial had a parallel design. The study was conducted in the cities of Kahak and Jafariyeh, Qom, Iran. Considering the relatively small number of students in the two cities, sampling was not done and the whole target population entered the census. 1318 students participated in the study and enrolled in February 2017 and followed one and half months.

Settings and conduct

Intervention Group (Kahak) In this city, intervention was done according to the social marketing approach. The SMART model was used to organize different phases of social marketing in the following order [6, 13]: Phase 1: Preliminary planning The main problem, to overcome which this study was designed, was lack of interest in tooth brushing with the proper length and frequency. Therefore, the main objective of the study was to improve tooth-brushing habits as at least two times a day for at least two minutes each time. The main method that was used for project assessment was a self-report checklist before and after the intervention and comparison of the checklists. Phase 2: Audience analysis Only the primary school students of the two cities were identified as the target population. To analyze the target population's beliefs and prioritization of the reasons for irregular or no tooth brushing from the perspective of themselves or their parents, a checklist was provided to all students and its results (Table 1) were used in designing the intervention tools. Phase 3: Channel analysis Since most of the students' time was spent at

home or school, communication channels that were appropriate for these environments like face-to-face training sessions, printed material for use in the school, training through parents, and the effect of parents on their children were considered. Phase 4: Market analysis In this study, one of the supporting factors was the performance of some teachers that considered a day of the week as the "tooth brush day". On this day, the teachers asked the students to bring their toothbrushes and brush their teeth under the teacher's supervision. One of the identified competitors was the parents' low level of oral health knowledge in Iran [14]. Another competitor was the common belief among the students that brushing the teeth once a day is enough [15]. The second part of market analysis was implementation of market mix principles or 4P as the following: 1. Product: The main product was prevention of tooth decay and the real product was tooth brushing two times a day for two minutes each time. 2. Price: The time spent in the class (about 30 minutes), time spent on brushing the teeth and commitment to completing the tooth brushing calendar were among the expenses that the participants met. 3. Place: The place that was considered for the intervention was the students' schools and houses because they were easily accessible. 4. Promotion: All the tools that were designed to persuade students to brush their teeth are placed in this group. These tools were planned based on the results of the first checklist. Phase 5: Development In this study, a sample of the tools was provided to school managers and health authorities to collect their comments. The intervention tools were approved in all schools and no comments were received. Phase 6: Implementation In this phase, the project was implemented as designed in the previous phases, and interventions were applied in the schools. At the beginning of this phase, a checklist containing questions on tooth-brushing habits was completed by the students to record their status before the intervention.

This checklist was completed by the parents of students in grades 1 to 3 and by the students in grades 4-6. After the checklists were collected, the intervention was continued for one and a half months. Phase 7: Evaluation In this study, considering the students' presence at school, it was possible to convey messages to the target population. On the other hand, due to the availability of teachers, they were requested to cooperate in the assessment of the project and review the main concepts of the project with the students and check the tooth-brushing calendar at least once a week. At the end of this phase, the students completed the tooth-brushing habits checklist for the second time to evaluate the changes following the intervention. Control Group (Jafariyeh) The students in Jafariyeh completed the tooth-brushing habits checklist before the intervention (similar to students in Kahak). After collecting the checklists, since this city was considered as the control group, a traditional intervention, i.e. pamphlet that was exactly similar to the pamphlet distributed in Kahak, was applied. Then, the changes were assessed through completing the checklist for a second time.

Participants/Inclusion and exclusion criteria

Entry requirements: All primary school students (grade 1 to 6) of Kahak and Jafariyeh in the 2016-2017 academic year
Non-entry requirements: Non-cooperation of the students and their parents' unwillingness

Intervention groups

Intervention group: All primary school students of Kahak city in the 2016-2017 academic year
Control group: All primary school students of Jafariyeh city in the 2016-2017 academic year

Main outcome variables

Duration of tooth brushing
Frequency of tooth brushing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016123131675N1**
Registration date: **2017-07-26, 1396/05/04**
Registration timing: **retrospective**

Last update: **2018-03-05, 1396/12/14**

Update count: **1**

Registration date

2017-07-26, 1396/05/04

Registrant information

Name

AliAsghar Habibi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 4039

Email address

dreamstar890@gmail.com

Recruitment status

Recruitment complete

Funding source

Funding of Tehran University of Medical Sciences for thesis and research projects

Expected recruitment start date

2017-02-25, 1395/12/07

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of two types of intervention (based on the principles of social marketing and traditional education) on increase in self-reported frequency and duration of tooth brushing of elementary school students: A controlled quasi-experimental study

Public title

The application of social marketing to promote good habits of brushing (at least twice a day, each time at least two minutes)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Students enrolled in grades of one to six in elementary schools of Kahak and Jafariye cities in the academic year 2016-2017

Exclusion criteria:

non-compliance or lack of consent of the student or parents

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1720**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Tehran University of Medical Sciences Ethics Committee

Street address

room No. 604, sixth floor, the Central Organization of Tehran University of Medical Sciences, St. Qods, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-10-25, 1395/08/04

Ethics committee reference number

IR.TUMS.VCR.REC.1395.852

Health conditions studied

1

Description of health condition studied

Oral health advice and education (tooth brushing habit)

ICD-10 code

Z72.9, Z71

ICD-10 code description

Problem related to lifestyle, unspecified---Other specified counselling

Primary outcomes

1

Description

Frequency of tooth brushing

Timepoint

Before and one month after intervention

Method of measurement

Answering checklist (self-reported)

2

Description

Duration of tooth brushing

Timepoint

Before and one month after intervention

Method of measurement

Answering checklist (self-reported)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention in intervention city (Kahak city): The use of social marketing principles such as use of adware, masterclass, distributed toothbrushes, timers, brochures, etc. based on the assessed needs of students with using of SMART (Social marketing assessment and response tool) model in order to promote good habits of brushing (at least twice a day and each time at least two minutes)

Category

Prevention

2

Description

Intervention in the control city (Jafariye city): The use of traditional methods such as distributing pamphlets to increase the frequency and duration of brushing

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari2 school of Kahak city

Full name of responsible person

Mr Esmaeily

Street address

Zeynabieh St.

City

Kahak

Province

Ghoum

Postal code

3735114640

Phone

+98 25 3422 3424

Email

name@domian.com

2

Recruitment center

Name of recruitment center

Motahhari1 school of Kahak city

Full name of responsible person

Mr Abarghooyi

Street address

Zeynabieh St.

City

Kahak

Province

Ghoum

Postal code

3735114641

Phone

+98 25 3422 7676

Email

name@domian.com

3

Recruitment center

Name of recruitment center

Fatemiye school of Kahak city

Full name of responsible person

Mrs Moosayi

Street address

Hazrat Abalfazl Blvd.

City

Kahak

Province

Ghoum

Postal code

3735114159

Phone

+98 25 3422 5464

Email

name@domian.com

4

Recruitment center

Name of recruitment center

Ansarolhossein1 school of Jafariyeh

Full name of responsible person

Mr Moosavi

Street address

Imam Ali St.

City

Jafariyeh

Province

Ghoum

Postal code

3744118884

Phone

+98 25 3627 3223

Email

name@domian.com

5

Recruitment center

Name of recruitment center

Ansarolhosein2 school of Jafariyeh

Full name of responsible person

Mr Jokar

Street address

Farhang St.

City

Jafariyeh

Province

Ghoum

Postal code

3744118875

Phone

+98 25 3627 5433

Email

name@domian.com

6

Recruitment center

Name of recruitment center

Bahonar school of Kahak city

Full name of responsible person

Mr Rahnama

Street address

Khamenei Blvd.

City

Jafariyeh

Province

Ghoum

Postal code

3744118864

Phone

+98 25 3627 4312

Email

name@domian.com

7

Recruitment center

Name of recruitment center

Jahad school of Jafariyeh

Full name of responsible person

Mrs Jafari

Street address

Imam ALi St.

City

Jafariyeh

Province

Ghoum

Postal code

3744118891

Phone

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Email

name@domian.com

8

Recruitment center

Name of recruitment center

Bagher Rabbani school of Jafariyeh

Full name of responsible person

Mrs Karimi

Street address

Moradi St.

City

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Ghoum

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3744118721

Phone

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9

Recruitment center

Name of recruitment center

Kowsar school of Jafariyeh

Full name of responsible person

Mrs Mirzayi
Street address
Hakim St.
City
Jafariyeh
Province
Ghoum
Postal code
3744118731
Phone
+98 25 3627 4456
Email
name@domian.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Younesian
Street address
room No. 605, sixth floor, the Central Organization of Tehran University of Medical Sciences, St. Qods, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1417713541
Phone
+98 21 8893 3766
Email
tumspr@tums.ac.ir

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, 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

Dentistry School of Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahdia Gholami

Position

Member of science committee of oral health and social dentistry department

Latest degree

Ph.D.

Other areas of specialty/work

Street address

School of Dentistry, after Energy-Atomi, North AmirAbad

City

Tehran

Province

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Postal code

1439955934

Phone

+98 21 8801 5960

Fax

Email

m_gholami@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dentistry School of Tehran University of Medical Sciences

Full name of responsible person

Dr. Mahdia Gholami

Position

PhD of oral health and social dentistry

Latest degree

Ph.D.

Other areas of specialty/work

Street address

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Dentistry faculty of Tehran University of Medical Sciences

Full name of responsible person

AliAsghar Habibi

Position

Dentistry student

Latest degree

Medical doctor

Other areas of specialty/work**Street address**

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City

Tehran

Province

Tehran

Postal code

1439957181

Phone

+98 25 3423 4155

Fax**Email**

dreamstar890@gmail.com

Web page address**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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifying people

When the data will become available and for how long

The start of access to data is 3 months after publishing the results

To whom data/document is available

Study data will be available to all individuals, including academic and industry researchers

Under which criteria data/document could be used

Access to data will be available for oral health promotion programs and any statistical analysis will be allowed.

From where data/document is obtainable

1. Dr Mahdia Gholami, Department of Community Oral Health, School of Dentistry, Tehran University of Medical Sciences, Tehran, Iran Call Phone: +982188015960 Email: m_gholami@sina.tums.ac.ir 2. Dr. Ahmadreza Shamshiri- Department of Community Oral Health, School of Dentistry, Tehran University of Medical Sciences, Tehran, Iran Call Phone: +982188015960 Email: ar_shamshiri@yahoo.com

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

The requester must send the application to the persons mentioned in previous section to receive the study data. It is expected to receive information within a week.

Comments