Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of a tooth brushing educational package on the improvement of tooth brushing and gingival health of 4-6 years children: an RCT

Protocol summary

Study aim
Evaluation of the effectiveness of a tooth brushing educational package on the oral health indices improvement among 5-6 years old children.
Design
this is a randomized , two-sided blinded , controlled clinical trail that will conducted among 90 participants. For random allocation of the groups, we used Lucky Ball.
Settings and conduct
Setting: Three kindergartens in regions with moderate to high SES in Isfahan City.
Participants/Inclusion and exclusion criteria
5-6 preschool children that are systematically healthy in private kindergarten of the Isfahan city.
Intervention groups
Group I: the whole package based on the COM-B model Group II: Educational video Group III: control
Main outcome variables
Plaque index Gingival Index Tooth brushing practice Tooth brushing duration The parents COM-b

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160822029476N2**
Registration date: **2023-06-02, 1402/03/12**
Registration timing: **prospective**

Last update: **2023-06-02, 1402/03/12**
Update count: **0**
Registration date
2023-06-02, 1402/03/12

Registrant information
Name
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-09-11, 1402/06/20
Expected recruitment end date
2023-10-12, 1402/07/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of a tooth brushing educational package on the improvement of tooth brushing and gingival health of 4-6 years children: an RCT

Public title
Effectiveness of a tooth brushing package on the tooth brushing improvement among children
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
5-6 preschool children that are systematically healthy in private kindergarten of the Isfahan city. . Their parents

should be alive. Mother education should be diploma or higher. The selection of kindergartens was in accordance to the Rehabilitation Organization located in the regions with moderate to high SES

Exclusion criteria:

Children with untreated inter-proximal dental caries, having space retainer or having oral breathing patterns

Age

From **5 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

From the proposed list of kindergartens, three will be selected randomly. Then based on the "lucky ball" randomization method, random allocation of the selected kindergartens into the three groups of Intervention I, Intervention II or control groups will be performed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participated children are not contaminated with other groups. Their teachers are not involved in the educations and not aware of the content of the interventions. The groups will be introduced to the data analyzer by English articles including A,B ,C and is not aware of the interventions contents.

Placebo

Not used

Assignment

Parallel

Other design features

After gaining ethical approvals from the Ethics Committee and signed inform consents from the parents, children will be examined to record plaque index and gingival index by one examiner (NA). The examiner will be trained by an oral public health expert and calibrated by examining 10 children before the study.Plaque index will be recorded using the Quigley-Hein index that scores the level of plaque accumulation from 0-6. The gingival index will be recorded using the (Loe Silness and Loe Gingival Index which scores the gums health from 0-3 based on the Ramford Teeth (No (5585و71و75و65و51و)). All the examinations will be performed using disposable mirrors and blunted scalers on the kindergarten chairs and using Head Light. Also, to evaluate the changes in the motivation, capability and opportunities of the parents, the checklist of COM-B self-assessment will be used. This checklist has 6 questions in 3 domains and the scoring system is based on VAS. In addition, the checklist of the oral health behavior including the time and frequency of tooth brushing, using tooth paste and duration of tooth bushing will be completed by the parents and the children, separately. Statistical Analysis: The data will be fed into SPSS 26 and using descriptive and analytical tests including Paired T-test, ANOVA, q-squared or their equivalent non-parametric tests will be analyzed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Commiitee of Isfahan University of Medical Sciences

Street address

Department of Oral Public Health, School of Dentistry Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2022-11-19, 1401/08/28

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.246

Health conditions studied

1

Description of health condition studied

oral health status

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Dental plaque index

Timepoint

1 month

Method of measurement

Teeth examination and record in information data sheet

Secondary outcomes

1

Description

COM-B scores of parents(Capability , Opportunity , Motivation Questionnaire)

Timepoint

1 month

Method of measurement

6-questions COM-B questionnaire (with questions in domains of Capability, Opportunity, Motivation) with Visual Analogue Scale

2

Description

Gingival index

Timepoint

1 month

Method of measurement

Visual examination of gingiva and recording its status in the data collection form

Intervention groups

1

Description

Intervention group I: In the main intervention group (Group I), The behavior changes will be conducted based on the principles of COM-B; for capability improvement, a short educational video will be prepared including the explanations about the process of dental caries, the role of dental plaque, and the ways parents could utilized to remove the dental plaque mechanically. In addition, the proper use of tooth brush and tooth paste will be educated by demonstrating on two 5 and 6 children. During the demonstration, two recommended methods of tooth brushing in this age group (horizontal and roll technique) will be educated. Also, the important role and responsibility of the parents regarding the necessity of direct or supervised tooth brushing will be emphasized. The validity of the prepared videos, regarding the attractiveness, relevancy and content, will be affirmed during an expert panel evaluation including experts from the Health Education, Dental public Health and dental Pediatric departments. To improve the “opportunity” domain among parents, in a virtual group encompassing parents of the selected children, parents were encouraged to ask their questions about the methods of the tooth brushing or any comments related to the video. Also, they were asked to record and share a short film of their child’s brushing and allow the PIs (principle Investigators) to help them find their practical pitfalls. In the third domain of the model, to give children and parents relative Motivations, a 2-miutes animation was sent to the parents. This motivative animation was developed by the OIs in a recent work (oral health promoting schools) and include two singing children (a boy and a girl) who speaks about the importance and method of tooth brushing and flossing. The duration of the animation is exactly as the recommended duration of brushing and was validated in our previous works. Parents were asked to motivate their children in the time of brushing by showing them this animation. This animation is accessible through https://t.me/OHPS.

Category

Behavior

2

Description

Intervention group2: In this group just the prepared educational video will be demonstrated

Category

Behavior

3

Description

Control group: no education will be provided.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

kindergartens in Isfahan City

Full name of responsible person

Bahareh Tahani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Bahareh Tahani

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
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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
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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data will be available upon the request from

corresponding author.

When the data will become available and for how long

Six months after the article publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For systematic analysis

From where data/document is obtainable

Contacting the corresponding author

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

Email and CV

Comments