Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Designing and evaluating a smart phone application in children's oral health and comparing the effectiveness of mothers' education through this application with common teaching methods

Protocol summary

Study aim

Designing and evaluating a learning smart phone application. Comparing the effectiveness of training mothers about child oral health care through this application with common teaching methods

Design

Clinical trial with control group ،not blinded، randomised

Settings and conduct

A smartphone app for improving oral health in mothers and their children is compared with common teaching methods. The study will be conducted in the special clinic of the Faculty of Dentistry, Tehran University of medical science. Mothers will be assigned randomly, to either common teaching methods group or app group .Before receiving the teaching method,with the help of the mothers of both groups, the knowledge, the attitude of oral health and self-report practice questionnaire on oral health of the mother and the child are completed through the interview.The modified microbial plaque index will be also examined and recorded on their children's teeth. After one and three months, the previous questionnaire will be filled out again by mothers.The plaque index will be evaluated. One researcher gives pre-test and post-test questionnaires to mothers and a second researcher performs statistical analysis. Both researchers are blind to the allocation of participants to groups.

Participants/Inclusion and exclusion criteria

Inclusion: Mothers and their children under the age of 6 years، mothers with smartphones, children under 6 tears old Exclusion:Children who have systemic diseases.

Intervention groups

Control group:Mothers who receive common teaching methods Case group:Mothers who receive an app about child oral health

Main outcome variables

Change in knowledge, attitude and practice of mothers

Change in plaque index of baby

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131102015238N3**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **prospective**

Last update: **2019-07-28, 1398/05/06**
Update count: **0**

Registration date

2019-07-28, 1398/05/06

Registrant information

Name

Simin Z. Mohebbi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 5960

Email address

smohebbi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluating a smart phone application in children's oral health and comparing the effectiveness of mothers' education through this application with common teaching methods

Public title

Evaluating the effect of a mobile smartphone software in child oral health and comparing its effectiveness with common teaching methods

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers who have smart phone. Children aged less than 6 years

Exclusion criteria:

Children who have systemic diseases

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomisation method, using an Excel spreadsheet: In the Excel spreadsheet the leftmost column shows the total number of participants, which in the current study will be 116. The next column indicates the group to which participants belong, with the top half in Group A and the bottom half in Group B. For the next column is filled using the" Rand() "function; this function generates random numbers for all individuals. Finally, we arrange the random numbers in ascending order, so the individuals will be randomly ordered within each of the two groups. Random unit: individual Randomization Tool: Software

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 Tehran University of Medical Sciences

Street address

Number 2, Dolatshahi alley, Naderi street, Keshavarz Boulvar, Virtual faculty

City

Tehran

Province

Tehran

Postal code

1417614418

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1397.196

Health conditions studied

1

Description of health condition studied

Knowledge, attitude and practice of mothers regarding oral health

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Microbial plaque

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mother's score in knowledge, attitude, and practice questionnaire

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

Knowledge, attitude and practice questionnaire on oral health

2

Description

Microbial Plaque

Timepoint

Before the intervention, one month after the intervention, three months after the intervention

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mothers who receive an app about child oral health.This app is designed with the Java programming language and for the Android operating system, including:Brushing movies, introducing caries, nutritional recommendations, use of fluoridated toothpaste and information about oral health.The app also sends a notification for brushing to mother's mobile every night at nine o'clock.
Category
Lifestyle

2

Description
Control group: Mothers who receive common teaching method Including Scrub brushing technique for children, Nutrition recommendations, use of fluoridated toothpaste and a pamphlet about oral health.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry, Tehran University of Medical Sciences
Full name of responsible person
Simin Z. Mohebbi
Street address
End of North Kargar Street, Adjacent to the Atomic Energy Organization, High School of Dentistry, Tehran University of Medical Sciences
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Email
smohebbi@tums.ac.ir
Web page address
http://dentistry.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Keshavarz Blvd, Ghods St, Central Organization of the University, Sixth Department of Research and Technology
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Phone
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Email
rmo@tums.ac.ir
Web page address
http://vcr.tums.ac.ir
Grant name
Tehran University of Medical Sciences, Research Deputy
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Simin Z. Mohebbi
Position
Head of Community Oral Health Dept
Latest degree
Ph.D.
Other areas of specialty/work
Dentistry
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End of kargar Street
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Web page address

Person responsible for scientific inquiries

Contact

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Tehran University of Medical Sciences

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Person responsible for updating data

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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
We are going to publish a paper from the study findings and all above mentioned may be included in appendix or sent to journal for public view.

When the data will become available and for how long
We are going to publish a paper from the study findings and all above mentioned may be included in appendix or sent to journal for public view.

To whom data/document is available
We are going to publish a paper from the study findings and all above mentioned may be included in appendix or sent to journal for public view.

Under which criteria data/document could be used
We are going to publish a paper from the study findings and all above mentioned may be included in appendix or sent to journal for public view.

From where data/document is obtainable
We are going to publish a paper from the study findings and all above mentioned may be included in appendix or sent to journal for public view

What processes are involved for a request to access data/document
We are going to publish a paper from the study findings and all above mentioned may be included in appendix or sent to journal for public view

Comments
We are going to publish a paper from the study findings and all above mentioned may be included in appendix or sent to journal for public view.