Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Evaluating the effect of gamified features in effectiveness of training mothers about child oral health care by smartphone application

Protocol summary

Study aim
- Designing a learning smartphone application - Evaluating the effect of gamified features in effectiveness of training mothers about child oral health care

Design
Experimental trial or pretest-posttest control experimental group، single blind، randomized

Settings and conduct
A smartphone app for improving oral health in mothers and their children is compared with an enriched app with gamified features. 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 a simple app group or an enriched app with gamified features.Before receiving the app, mothers in both groups would fill up the knowledge of oral health and self-report practice questionnaire on oral health of the mother and the child. The modified microbial plaque index will be also examined and recorded on their children's teeth. After a month, 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 Inclusion:Mothers with smartphones, children under 6 tears old Exclusion:Children who have systemic diseases.

Intervention groups
Control group:Mothers who receive a simple application Case group:Mothers who receive an enriched app with gamified features

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: **IRCT20131102015238N2**
Registration date: **2019-02-24, 1397/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-24, 1397/12/05**
Update count: **0**

Registration date
2019-02-24, 1397/12/05

Registrant information

Name
Simin Z. Mohebbi

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8801 5960

Email address
smohebbi@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-04, 1397/11/15

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of gamified features in effectiveness of training mothers about child oral health care by smartphone application

Public title
Evaluating the effect of a mobile smartphone software in child oral health

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

- Participant
- Data analyser

Sample size
Target sample size: **58**

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)
Single blinded

Blinding description
A person who gives pre-test and post-test questionnaires to mothers and the researcher who performs assessment and statistical analysis is blind to the allocation of groups.

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
2019-01-27, 1397/11/07

Ethics committee reference number
IR.TUMS.VCR.REC.1397.855

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

Method of measurement
Knowledge, attitude and practice questionnaire on oral health

2

Description
Microbial Plaque

Timepoint
Before the intervention, one month after the intervention

Method of measurement
Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Mothers will receive an enriched app with gamified features for improving the oral health of mothers and their children. Participants will be followed-up one month after the first intervention.
Category
Lifestyle

2

Description
Control group: Mothers who receive a simple application.Participants will be follow upped one month after intervention.
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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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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Web page address
http://vcr.tums.ac.ir
Grant name
Tehran University of Medical Sciences, Research Deputy
Grant code / Reference number
40116
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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Head of Community oral health Dept

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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

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.