

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Sep 2022

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 years 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)

Phone

+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 followed up 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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Email

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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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Contact

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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.