

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1439955991

##### Phone

+98 21 8801 5960

##### Fax

+98 21 8801 5961

##### 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Phone

+98 21 8163 3698

#### 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

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

##### Street address

End of Karger street

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##### Province

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**Email**

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## Person responsible for scientific inquiries

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Tehran University of Medical Sciences

**Full name of responsible person**

Simin Z. Mohebbi

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## Person responsible for updating data

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Tehran University of Medical Sciences

**Full name of responsible person**

Simin Z. Mohebbi

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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.