

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### evaluating the effect of a smartphone application on oral health indices and literacy of school-aged adolescents in Ahvaz

#### Protocol summary

##### Study aim

evaluating the effect of a smartphone application on oral health indices and literacy of school-aged adolescents in through a brief intervention in Ahvaz

##### Design

community based, parallel group, double blind, randomised controlled trial

##### Settings and conduct

health education for students, middle schools, clinical examinations and oral health instructions and questionnaire fulfillment students and data analyzer are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. individuals must be completely satisfied to participate in the study. 2. individuals must be 12-15 years old. 3. individuals must be have access to a smartphone. 4. individuals must be in permanent dentition. Exclusion criteria: 1. no presence of any diagnosed disease 2. unable to follow-up 3. relocating to another school 4. any disease that affects the study 5. orthodontics treatment

##### Intervention groups

randomly selecting to groups of students, face to face education of oral health for control group, smartphone-application-based education of oral health for intervention group

##### Main outcome variables

oral health observance; oral health literacy elevation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191016045128N1**

Registration date: **2019-10-29, 1398/08/07**

Registration timing: **prospective**

Last update: **2019-10-29, 1398/08/07**

Update count: **0**

##### Registration date

2019-10-29, 1398/08/07

##### Registrant information

###### Name

Samaneh Khanehmasjedi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3338 9516

###### Email address

khanehmasjedi.s@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

evaluating the effect of a smartphone application on oral health indices and literacy of school-aged adolescents in Ahvaz

##### Public title

evaluating the effect of a smartphone application on oral health in school-aged adolescents in Ahvaz

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

individuals must be completely satisfied to participate in the study. individuals must be 12-15 years old.  
 individuals must be have access to a smartphone.  
 individuals must be in permanent dentition.

**Exclusion criteria:**

presence of any diagnosed disease unable to follow-up  
 relocating to another school any disease that affects the  
 study orthodontics treatment

**Age**

From **12 years** old to **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **240**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

method of randomization in this study is block. unit of randomization is individual. sealed envelope is the tool used in randomization. the random sequence was built by throwing coins.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

in this study the participants, data analyzer and the main investigator are blinded. outcome collector and assessor is not blinded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

**Street address**

Unit 2, No 65, West Mihan street, Chamran avenue, Kianpars

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6155814885

**Approval date**

2019-05-05, 1398/02/15

**Ethics committee reference number**

IR.AJUMS.REC.1398.116

**Health conditions studied****1****Description of health condition studied**

dental caries

**ICD-10 code**

K02

**ICD-10 code description**

Dental caries

**Primary outcomes****1****Description**

The extent of people's health observance

**Timepoint**

4 months after intervention

**Method of measurement**

oral health literacy questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: a group of students that receive an educational smartphone application made by researcher, according to referenced textbooks.

**Category**

Prevention

**2****Description**

Control group: a group of students which receive the gold standard method of oral health education; face to face education.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

kowthar middle school

**Full name of responsible person**

Samaneh Khanehmasjedi

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**Recruitment center**

**Name of recruitment center**

setayesh middle school

**Full name of responsible person**

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**Recruitment center**

**Name of recruitment center**

middle school

**Full name of responsible person**

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**Recruitment center**

**Name of recruitment center**

shahid abbaspoor middle school

**Full name of responsible person**

Samaneh Khanehmasjedi

**Street address**

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

**Street address**

Vice-Chancellor for Research and Technology  
Development, Ahvaz Jundishapur University of  
Medical Sciences, Golestan Blvd

**City**

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**Province**

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6135715794

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**Grant name**

Research deputy of Ahvaz University of Medical Science

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Samaneh Khanehmasjedi

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Leila Bassir

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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basir-l@ajums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Samaneh Khanehmasjedi

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available