Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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
Khouzestan

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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2

Recruitment center

Name of recruitment center
setayesh middle school

Full name of responsible person
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3

Recruitment center

Name of recruitment center
middle school

Full name of responsible person
Samaneh Khanehmasjedi

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Recruitment center

Name of recruitment center
shahid abbaspoor middle school

Full name of responsible person
Samaneh Khanehmasjedi

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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

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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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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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