Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of a mobile application-based intervention on knowledge of oral care and oral health behavior of disadvantaged 12-year-old adolescents: A community-based trial

Protocol summary

Study aim

Effectiveness of a mobile application-based intervention on knowledge of oral care and oral health behavior of disadvantaged 12-year-old adolescents

Design

Field trial, with single groups, phase 2 on 312 patients

Settings and conduct

Determining the sample size is done using Morgan's table and Cochran's formula among girls' and boys' schools in the less privileged areas of Torbetjam city. Based on this formula, 312 12-year-old students enter the study in the sixth grade of these schools In order to carry out this study, the oral examination of the students is done first, and the dental status and oral hygiene of the students are measured using DMFT, PI (Plaque Index, Quiengly-Hein), (Bleeding On Probing) BOP, and (Modified Gingival Index). MGI is checked and recorded by the student who is calibrated for this purpose, then a pretest is conducted in person and during it, the students are asked about health behaviors and eating habits (frequency of eating foods containing added sugar) and the application Mobile phone, whose validity and reliability was previously conducted in the study "Design and Validation of Remote Oral Health Screening Application" is introduced to them. In this application, oral care training is given to them. At the end of the study, after 6 months, the students are examined again based on the same indicators and the post test is done in person.

Participants/Inclusion and exclusion criteria

6th grade elementary school students in low-income schools in Torbet Jam-having a mobile phone

Intervention groups

Teaching oral and dental health care through a mobile application

Main outcome variables

Measurable outcome: average correct answers of students to pre-test and post-test questions, DMFT and care index (F/DMF), restoration index (F/D), treatment index*100 (DMF/M+F), PI and MGI before and after from intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230817059173N1**
Registration date: **2023-09-09, 1402/06/18**
Registration timing: **prospective**

Last update: **2023-09-09, 1402/06/18**
Update count: **0**

Registration date

2023-09-09, 1402/06/18

Registrant information

Name

shima tarahomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5254 6279

Email address

sh.tarahomi91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-04-18, 1403/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of a mobile application-based intervention on knowledge of oral care and oral health behavior of disadvantaged 12-year-old adolescents: A community-based trial

Public title

Effectiveness of a mobile application-based intervention on knowledge of oral care and oral health behavior of disadvantaged 12-year-old adolescents: A community-based trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1- 6th grade primary school student in the underprivileged schools of Torbat Jam 2- Having a mobile phone

Exclusion criteria:

Age

From **12 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **312**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Musa-bin-Jafar 14

City

Torbat-jam

Province

Razavi Khorasan

Postal code

9571975437

Approval date

2023-04-09, 1402/01/20

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1401.149

Health conditions studied

1

Description of health condition studied

dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

2

Description of health condition studied

gingivitis and periodontal disease

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Mean difference of correct answers in pre-test and post-test

Timepoint

Six months

Method of measurement

Forms

2

Description

Care Index (F/DMF)

Timepoint

Six months

Method of measurement

Oral examination

3

Description

Restorative Index (F/D)

Timepoint

Six months

Method of measurement

Oral examination

4

Description
Treatment Index (F+M/DMF)
Timepoint
Six months
Method of measurement
Oral examination

5

Description
Plaque index
Timepoint
Six months
Method of measurement
Oral examination

6

Description
Modified Gingival Index
Timepoint
Six months
Method of measurement
Oral examination

7

Description
Bleeding On Probing (BOP)
Timepoint
Six months
Method of measurement
Oral examination

Secondary outcomes

1

Description
Diet modification
Timepoint
Six months
Method of measurement
Forms

2

Description
Dental appointment
Timepoint
Six months
Method of measurement
Post-test Forms

3

Description
Oral Hygiene instruction
Timepoint
Six months
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: 1- In the pre-exam, a form containing questions about oral hygiene habits and the use of snacks will be completed by students. 2- The method of brushing and flossing their teeth is observed. 3- Oral and dental care is explained by the researcher according to the guidelines for the prevention of caries and periodontal disease. 4- The students undergo a clinical oral examination by the researcher. After 6 months, 1- students complete the post-exam form 2- their brushing and flossing methods are observed. 3- Students are subjected to oral clinical examination by the researcher.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Torbet Jam primary schools
Full name of responsible person
shima tarahomi
Street address
Musa Bin Jafar
City
torbat jam
Province
Razavi Khorasan
Postal code
9571975437
Phone
+98 51 5254 6279
Email
sh.tarahomi91@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Amir Moin Taqavi
Street address
Vakil Abad Blvd
City
mashhad
Province
Razavi Khorasan
Postal code
13944 91388
Phone

+98 51 3841 2081

Email

p.relations@mums.ac.ir

Web page address

https://mums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Shima Tarahomi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

14 Musa bin Jafar, No. 16

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torbat jam

Province

Razavi Khorasan

Postal code

9571977887

Phone

+98 51 5254 6279

Fax

Email

sh.tarahomi91@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Shima Tarahomi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

shima tarahomi

Position

student

Latest degree

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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

The effectiveness of an intervention based on a mobile phone program on oral health behavior and oral care

awareness of 12-year-old adolescents

When the data will become available and for how long

After printing the results

To whom data/document is available

Working researchers

Under which criteria data/document could be used

Under the research conditions, the use of analyzes on the delivered data is allowed, the use of documentation is allowed

From where data/document is obtainable

Postal address, e-mail, application and phone numbers of Shima Tarhami and Mrs. Dr. Hadie Totoni

What processes are involved for a request to access data/document

After making a request through postal address, email, application and phone numbers, they will receive the data within three working days

Comments