

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Title: The effect of educational intervention based on self-efficacy theory on promoting adolescent oral health behaviors through a mobile application

Protocol summary

Study aim

determination effect of educational intervention based on self-efficacy theory on the promotion of behaviors related to oral and dental hygiene of adolescents through a mobile application

Design

A clinical trial with a control group. Randomized. Phase 2 for 40 people. A repeated random block method with 4 blocks is used for randomization.

Settings and conduct

The sampling stage among the teenagers who obtained low scores in relation to oral and dental hygiene behaviors in the descriptive stage will be invited to participate in the randomized clinical trial study. The sampling method in this research is simple random sampling. It; so that 4 schools are randomly selected from the urban girls' schools; during the implementation of the intervention, the control group will not receive any training; And finally, immediately, one month and three months after the intervention, questionnaires will be distributed in both groups and information will be collected.

Participants/Inclusion and exclusion criteria

1- Female students aged 13-15 years 2- Residents of Shushtar city 3- Do not have oral and dental diseases 4- Do not have underlying diseases 5- Are studying 6- Having a smartphone and the ability to use it 7- Having consent Consciously to participate in the study 8- Participation in most of the educational intervention sessions, not having any of the above items exclusion criteria

Intervention groups

40 students are present in the intervention group and they are trained using a mobile application designed for self-efficacy in oral and dental health promotion behaviors. The intervention group does not receive any training.

Main outcome variables

The average score of knowledge, attitude, self-efficacy, and performance related to oral and dental hygiene

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200120046204N1**

Registration date: **2022-10-13, 1401/07/21**

Registration timing: **prospective**

Last update: **2022-10-13, 1401/07/21**

Update count: **0**

Registration date

2022-10-13, 1401/07/21

Registrant information

Name

Seiedeh zahra Marashi

Name of organization / entity

Tarbiat modares university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-08, 1402/01/19

Expected recruitment end date

2023-06-09, 1402/03/19

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Title: The effect of educational intervention based on self-efficacy theory on promoting adolescent oral health behaviors through a mobile application

Public title
An educational intervention to promote behaviors related to oral and dental hygiene of adolescents

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female students aged 13-15 years - A resident of Shushtar city Do not have oral and dental disease Don't have any underlying disease They are studying Having a smartphone and the ability to use it Having informed consent to participate in the study Participating in most educational intervention sessions

Exclusion criteria:

Female students should not be 13-15 years old Do not live in Shushtar city. Have oral and dental disease Have a background knowledge are not studying Not having a smart phone and the skill to use it Lack of informed consent to participate in the study Failure to participate in most educational intervention sessions

Age
From **13 years** old to **15 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation of the samples will be done to maintain balance in the number of people assigned to the two control and test groups and to obtain the maximum power in the study by the method of repeated random blocks with blocks of 4. These repeating random blocks will be done for each floor separately. To implement this method, to maintain the randomness of the allocation of people, before starting the sampling, 6 combinations of four letters A (participant in the test group) and B (participant in the control group) are formed as follows: AABB ABAB ABBA BABA BBAA BAAB Then, using six-sided dice with the numbers 1 to 6 on each side, according to the number that appears on the dice each time, the order of assigning the participants to the test and control groups in each class is as follows: It is determined independently.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tarbiat Modares University of Medical Sciences

Street address

Tarbiat modares univercity., Bridge Nasr., Jalal Al Ahmad.,Tehran

City

Tehran

Province

Tehran

Postal code

111 -14115

Approval date

2022-09-24, 1401/07/02

Ethics committee reference number

IR.MODARES.REC.1401.125

Health conditions studied

1

Description of health condition studied

Promotion of behaviors related to oral and dental hygiene

ICD-10 code

Z00-Z13

ICD-10 code description

Persons encountering health services for examination and investigation

Primary outcomes

1

Description

The average score of knowledge related to oral and dental hygiene

Timepoint

in three time periods before the intervention, one month, and three months after the intervention

Method of measurement

Standard questionnaire of awareness

2

Description

The average score of attitude related to oral and dental hygiene

Timepoint

in three time periods before the intervention, one month, and three months after the intervention

Method of measurement

Standard questionnaire of attitude

3

Description

The average score of self-efficacy related to oral and dental hygiene

Timepoint

in three time periods before the intervention, one month, and three months after the intervention

Method of measurement

Standard questionnaire of self-efficacy

4

Description

The average score of performance related to oral and dental hygiene

Timepoint

in three time periods before the intervention, one month, and three months after the intervention

Method of measurement

Standard questionnaire of performance

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1- The amount of oral hygiene in the intervention group(13-15-year-old female students) is first measured by a questionnaire. Then, this group receives mobile- based training during six sessions. Each session is 45 minutes of training. Each session is based on the theory of self-efficacy. The first session: Familiarization of students with mouth and teeth and diseases caused by non-observance of oral and dental hygiene. The second session: introducing students to the importance of oral and dental hygiene. The third session: introducing students to the importance of believing in their ability to observe oral and dental hygiene and preventing future dental problems. The fourth session: familiarizing the students with the importance of mastery experience, and observational experience in the prevention of oral and dental diseases. The fifth session: The role of verbal persuasion, physical and emotional state in the prevention of oral and dental diseases. The sixth session: Questions and answers.

Category

Prevention

2

Description

Control group: The amount of oral hygiene information in this group is only measured by questionnaire and no training(intervention) in this group is presented

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

First secondary schools of Shushtar city

Full name of responsible person

Mustafa Abedipour

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Seyyed Mohammad Gulabi Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

The University of Tarbiat Modares

Full name of responsible person

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Position

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Latest degree

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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

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Demographic information of the target group will not be shared and only general statistics will be published.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be accessible to researchers

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Contact via email zahra73m@yahoo.com

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

There is no special condition. It will be answered as soon as possible

Comments

No description