OPEN ACCESS Freely available online

ISSN: 2247-2452
Oral Health and Dental Management

Research Article

Educational Intervention for the Promote Behaviors Related to Oral Health: A Randomized Controlled Trial Protocol

Seyedeh Zahra Marashi[1], Alireza Heidarnia[1*], Seyedeh Somayeh Kazemi[2], Fatemeh Zarei[1]

[1]Department of Health Education and Promotion, Tarbiat Modares University, Tehran, Iran; [2]Department of Public Health, Mazandaran University of Medical Sciences, Sari, Iran

ABSTRACT

Background: Oral health is an essential part of the overall health in infants, children, and adolescents because oral diseases have effect on growth performance and quality of life. Given that adolescence is associated with many changes, including physical, sexual and psychosocial changes, and on the other hand, nowadays many adolescents use mobile applications to monitor their lifestyle behaviors and improve their health. Therefore, the present study will be conducted with the aim of the effect of mobile app intervention based on the theory of self-efficacy on the promotion of behaviors related to oral health of adolescents.

Materials and methods: This is a randomized controlled trial that will be done in two steps. The first stage is related to a descriptive-analytical study at this stage determination the current status and educational need assessment of behaviors related to oral health and will be reviewed eligible individuals. The second stage is an experimental study. At this stage, eligible adolescents are divided into two groups of intervention and control based on randomized allocation. Then the interventions will be implemented by using of educational strategies based on the self-efficacy theory through the mobile application. Evaluations will be performed with a standard questionnaire of self-efficacy and behaviors related to oral health (knowledge, attitude, behavior).

Discussion: Adolescents who are in the early stages of permanent teeth and this unfavorable condition of the mouth and teeth can have negative effects on the longevity of permanent teeth.

Keywords: Mobile applications; Self-efficacy; Oral health; Health education; Adolescent

INTRODUCTION

Oral health is an essential part of the overall health in infants, children, and adolescents because oral diseases have effect on growth performance and quality of life [1]. Oral and dental care should be safe, consistent, diverse, accessible, affordable, and high quality that prevents or eliminates disease, pain, and infection. The most important index that shows the level of people suffering from caries is the DMFT index. To calculate the DMFT of a community, the number of decayed, filled, and missed teeth of the people of that community are counted and its average is calculated [2-6].

Dental caries and periodontal diseases are plaque-associated conditions that have a high global prevalence and are considered an important economic burden [7]. Also, tooth decay cannot be stopped by taking antibiotics, and this causes it to affect a large number of teeth in a short period of time. The World Health Organization (WHO) considers oral health as a lifelong prerequisite for maintaining public health and emphasizes the importance of this issue more than ever [8,9]. Unfortunately,

Correspondence to: Alireza Heidarnia, Department of Health Education and Promotion, Tarbiat Modares University, Tehran, Iran; E-mail: hidarnia@modares.ac.ir

Received: 28-Apr-2023, Manuscript No. OHDM-23-21161; **Editor assigned:** 01-May-2023, PreQC No. OHDM-23-21161 (PQ); **Reviewed:** 15-May-2023, QC No. OHDM-23-21161; **Revised:** 28-Jun-2023, Manuscript No. OHDM-23-21161 (R); **Published:** 05-Jul-2023, DOI: 10.35248/2247-2452.23.22.1078

Citation: Marashi SZ, Heidarnia A, Kazemi SS, Zarei F (2023) Educational Intervention for the Promote Behaviors Related to Oral Health: A Randomized Controlled Trial Protocol. Oral Health Dent Manag. 22:1078.

neglecting adolescent health care, including oral health care, has become commonplace [10,11].

Adolescence is associated with many changes, including physical, sexual and psycho-social changes, and in this period. Adolescents aged 12 to 15 are in the early stages of permanent teeth, and this unfavorable condition of the mouth have negative effects on the longevity of permanent teeth. Therefore, it is very important to develop good oral health habits and lifestyle habits to improve oral health during this period [12]. So that oral health is so important for people that the World Health Organization has declared tooth decay as one of the most important health problems in the world with a prevalence of 60% to 90% among school students also, oral diseases affect nearly 3.5 billion people [13-15]. In a study conducted in collaboration with the World Health Organization and the ministry of health, it showed that the DMFT index in Iran is 67.1%, girls had a higher index than boys, and half of the students refuse to brush their teeth. Another study in Ahvaz showed that tooth decay is more common among girls in Ahvaz and most students, especially boys, are at high risk of tooth decay [16-18].

In addition to non-behavioral factors (shape and form of teeth, placement of teeth, type of teeth, etc.) and genetics, hygiene behaviors in the field of oral health include brushing at least twice a day, using dental floss, using Mouthwash and dental examinations are very important for improving oral health, preventing and controlling tooth decay and other oral health (periodontal) diseases [19].

Schools are considered to be the best place to promote health behaviors, including oral health. One of the important health activities of schools is 'health education'. The purpose of health education is to raise the level of health knowledge and finally to create a favorable change in the behavior of students and transfer it to their families [20].

In relation to the appropriate platform of health education for people, especially teenagers, it can be mentioned that smartphones have become an integral part of daily life and many teenagers are now using mobile apps to monitor their lifestyle behaviors and improve their health, smartphones with content and games related to health behaviors may be a valuable platform to engage children, adolescents, and adults regarding nutritional behaviors, physical activity and prevention of chronic disease risk behaviors.

People's belief in their abilities in relation to performing health behaviors can be effective therefore, one of the theories of behavior change in the field of health behaviors, especially oral health, is self-efficacy theory. This theory refers to the ability of people to adopt relevant health behaviors to improve indicators and maintain proper health improving self-efficacy can effectively increase awareness of oral health care and promote good oral health-related behaviors. Self-efficacy theory tells us that people usually only try to do things they believe. They have to do it and if they believe that doing something will lead to failure, they will not try to do it. 25 in this regard, in the studies of Asgari, et al.; Fang Keren, et al., the role of self-efficacy in protective behaviors and its relationship with the number of times brushing teeth in teenagers have been pointed out, which shows the importance of the variable of self-efficacy and its effect on oral health behavior.

The theory of self-efficacy suggests that the understanding and feeling of efficiency are influenced by 4 factors

- **Mastery experience:** People believe that they can do new things when they have already done some similar things well. Acquiring such skills is considered the most effective way to strengthen people's self-efficacy.
- **Vicarious experience:** Another factor that is effective in understanding and feeling self-efficacy is observational experience, or in other words, observing the successes and failures of others, where you realize the similarity of your experiences and those people. Watching someone like you do something successfully will boost your self-efficacy. Conversely, seeing someone like you fail at something threatens and devalues self-efficacy.
- **Verbal persuasion:** The third factor affecting self-efficacy is verbal persuasion or social influence. When people are verbally encouraged before doing a task, they can gain mastery and skill in doing a task and responsibility and are more likely to do it.
- **Somatic and emotional states:** Physical and emotional states of people sswhen meditation and thinking about doing a task provide clues to the possibility of their failure or success. Stress, anxiety, worry and fear all harm a person's self-efficacy and can lead to a person's prediction and personal estimate of failure or inability to do fearful things.

It has been shown that self-efficacy about oral health is an important variable in predicting successful treatment, preventing health risks and encouraging health-promoting behaviors. In the field of oral health, the use of a self-efficacy scale is very important (Figure 1).

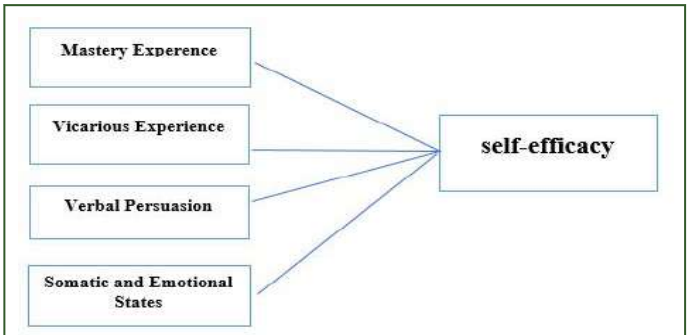

Figure 1: The constructs of self-efficacy theory.

Therefore, considering the low indicators of oral health behaviors, this study will be conducted with the aim of the effect of mobile app intervention based on the theory of self-efficacy on the promotion of behaviors related to oral health of adolescents.

MATERIALS AND METHODS

This protocol is a randomized clinical trial. The overall aim of this study is to develop and evaluate mobile app intervention based on self-efficacy theory on the promotion of behaviors

related to oral health in adolescents. An overview of the different phases containing aims, methods, and participants is depicted in Table 1. This study consists of two main phases: The first phase: Is a descriptive-analytical cross-sectional study to determine the current situation and educational needs assessment regarding behaviors related to oral health in qualified people. The needs assessment will be evaluated using the standard questionnaire for measuring awareness, attitude, and performance of adolescents about oral health and another the standard questionnaire for measuring self-efficacy about oral health. The second phase of the study includes the design and implementation of an educational intervention based on the theory of self-efficacy on the promotion of behaviors related to the oral health of adolescents through a mobile application. So that, the intervention group receives the training program through the mobile app, while the control group does not receive any training program. Participants will be assessed at three points in time: At the baseline, one and three months' follow-up. The study procedure from enrollment through follow-up data collection and analysis is shown in Figure 2.

Table 1: The study overview.

Phases and participants	Aim	Methods
Phase 1		
A descriptive-analytical cross-sectional study on adolescents.	**Step 1:** Determining the current situation and educational needs assessment regarding behaviors related to oral health.	Online design of the standard questionnaire
Phase 2		
Design interventions researcher.	**Step 1:** Intervention group training.	Based on mobile app.
Implementationa dolescent.	**Step 2:** Transfer educational content to the intervention group.	Based on mobile app.
Evaluation of intervention.	**Step 3:** Evaluate the program Identify the impact of the program on the intervention group.	Questionnaire.

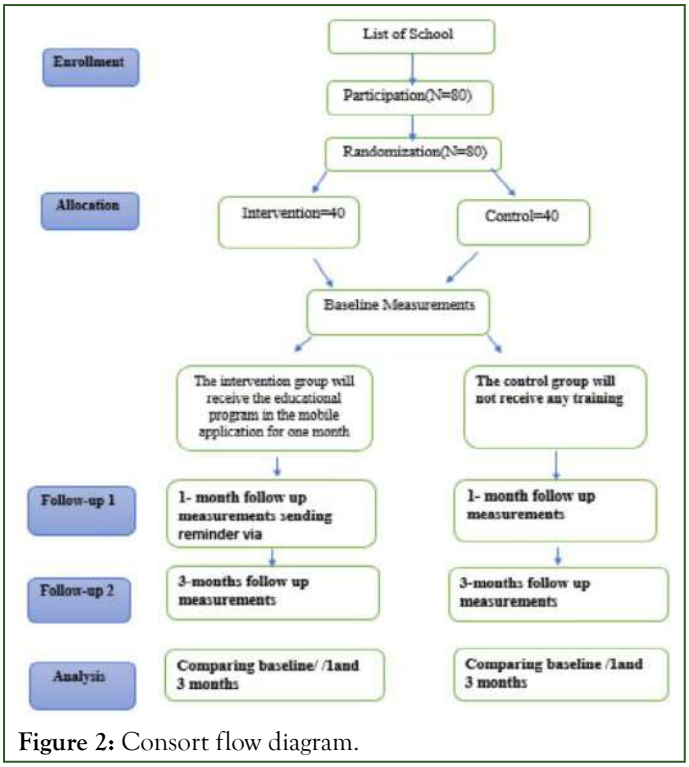

Figure 2: Consort flow diagram.

Study setting and sampling

This is a randomized controlled trial. The statistical population of Shushtar schools and the target group are students 13-15 years old. In the descriptive-analytical stage, the sample size is estimated according to Cochran's formula with a 10% drop in the sample size of 391 people. For sampling first, we will provide a list of all schools (27 schools), and 6 girls' schools will select randomly. Then according to the statistics of students and the total required sample, a certain number of students will be randomly entered into the descriptive study through their student numbers.

In the intervention phase, the sample size calculates based on a similar study and taking into account the confidence level of 95% and the test power of 80%, the number of samples required for each group (intervention and control) according to the Pocock formula, including 10% drop in number, 40 people is calculated for each group. So that 4 girls' schools are randomly selected from among 27 city schools the random allocation of the samples will be done to maintain the balance in the number of people assigned to the two control and test groups and to obtain the maximum power in the study, using the repeated random blocks method 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. Finally, by using a six-sided dice with the numbers 1 to 6 on each side, according to the number that appears on the dice each time it is thrown, the order of assigning the participants to the test and control groups on each floor is determined independently.

Consent or assent

An informed consent form will be completed online by all study participants.

Inclusion and exclusion criteria

The criteria for entering the study include female student's 13-15 years old studying, living in Shushtar city, not suffering from oral health diseases and underlying diseases, having a smartphone and the ability to use it, and having informed consent to participate in the study. It is a study. Regarding the exit criteria, it can be mentioned the absence of at least one of the above items.

Designing and developing educational intervention content

To design the technical features of the application and apply the maximum capabilities of the mobile application production field, a team of experts will be consulted. The main idea of the program will be discussed in joint meetings between specialized and technical teams and ambiguities will be resolved. Finally, considering that the main purpose of designing the application is to improve oral health behaviors, therefore, the mobile application will be designed to improve the oral health behaviors of 13-15 years old adolescents.

The mobile application will be designed with a simple and intuitive user interface that includes four main sections.

- **Training:** This section consists of a wide range of training: The content will include related written texts, animations, and dentist's recommendations regarding the importance of oral health in this section, educational materials, animations, medical recommendations, self-efficacy in oral health behaviors (self-efficacy in brushing, self-efficacy in flossing), ways to improve it, and attitude towards oral health behaviors. Will cover and emphasize three messages (brushing twice a day, using dental floss, and positive attitude toward oral health). After entering the application, teenagers can first receive training on the importance of brushing and the correct way of brushing, and then training on using dental floss. Finally, their last choice in this section will be to receive materials related to the field of attitude toward oral health behaviors. The training will be uploaded to the application within 3 days and after the training is completed, a group discussion session with questions and answers will be presented to the teenagers online in the presence of a researcher and a dentist. In general, all the training in the application can be downloaded and teenagers can access the content offline. Also, all content will be extracted from reliable sources. To improve the content in the next versions of the software, at the end of each media, the adolescent is asked to rate the content and help us in increasing the quality of the service.
- **Contacting the service provider:** In this section, the adolescent can contact the service providers and ask their questions.
- **Self-reporting of symptoms:** In this section, adolescent can report their oral health problems (Teeth decay, gum problems, etc.) to the service providers.
- **Biography of service providers:** This section includes the full introduction of service providers. The purpose of this section is to increase the adolescent's trust in service providers so that he can easily share his concerns and problems.

The questionnaire used and the scoring questionnaire in the study

The data collection tool will be included demographic information, and awareness standard questionnaires, attitude, performance and self-efficacy.

- **Demographic questions include:** Age, parents' education, economic status, teeth condition, number of times brushing, flossing and dental plaque.
- It is a standard questionnaire to measure the knowledge, attitude, and performance of teenagers about oral health. This tool has 36 questions and three areas of awareness (12 questions), attitude (10 questions), and performance (14 questions). The first part of the questionnaire includes 12 items related to students' knowledge about oral health behaviors, which will be given a score of one for the correct option and zero for the other options. The range of awareness scores is 0-12. A higher score will indicate more awareness in this field. The second part of the questionnaire contains 10 attitudinal items (alpha coefficient 0.82) and includes a 5-option Likert scale from completely agree (score 5) to completely disagree (score 1). The range of scores for this section is between 10-50 and a higher score will indicate a better attitude of students toward oral health. The last part of the questionnaire contains 14 performance items (alpha coefficient 0.89) which will be measured as options (yes, sometimes and no). The range of scores for this section is between 0-28, and a higher score will indicate a better performance of students regarding oral health. It should be mentioned that two questions were removed from the questions of this section due to the negative correlation between them. The validity and reliability of the questionnaire were also confirmed in the study of Yavari, et al.
- **The standard self-efficacy questionnaire about oral health:** This tool includes 3 parts to ensure the ability to brush your teeth, use dental floss and see a dentist. The self-efficacy questionnaire related to oral and dental hygiene has 3 parts. The first part related to brushing teeth has 10 questions, the second part related to using dental floss has 7 questions and the third part related to see the dentist also has 7 questions. In the self-efficacy questionnaire, the student is asked to indicate how much she has the ability on a four-point Likert scale (I am completely sure=4, I am somewhat certain=3, I am somewhat unsure=2 and I am not completely sure-1). He is confident in brushing his teeth, flossing, and to see the dentist in different situations. 10 questionnaire items are related to self-efficacy in brushing teeth (10-40 points), 7 items are related to self-efficacy in flossing (7-28 points) and 7 items are related to self-efficacy in going to the dentist (7-28 points). The reliability and validity of the questionnaire have been confirmed in the

study of Carranza, et al. In Iran, its reliability was reported in the study of Ardakani, et al. with Cronbach's alpha of 0.79. It should be noted that the reliability of the tools was also checked and confirmed in the present study (α>0.79).

Follow-up will be done at three points in time:

- At the baseline.
- One month.
- Three months after the intervention. According to the research ethics, at the end of the study, the educational content will be provided to the control group.

Public participation

In this research, the general participation of participants in the descriptive stage will be used to design an educational intervention based on a mobile application and evaluate its impact on promoting preventive behaviors.

Statistical analysis

The data will be analyzed using SPSS V.22. Descriptive statistics will include frequencies, means, and standard deviations. The Kolmogorov-Smirnov test will be used to check the normal distribution of data. Moreover, to compare the means between the two intervention and control groups, T-test will use. Also, Paired t-test will be used to compare the means in each group at two points in time, and ANOVA test will be used to compare the means in each group at three points in time. To analyze and evaluate the correlation between demographic variables, correlation tests (Pearson for parametric data and Spearman or Kendall for non-parametric data) and *chi-square* test will be used.

To analyze the primary outcome (behavior), the linear regression model will be used for predicting variables of awareness, attitude, and self-efficacy in brushing teeth, self-efficacy in flossing and self-efficacy in going to the dentist.

DISCUSSION

This study pays special attention to improving the health of adolescents in schools. This research examines the effects of interventions in improving behaviors related to oral health. The main framework of this study will be carried out a theory-based intervention using a mobile application to improve the oral health behaviors of adolescents. About this issue, we can refer to the teenage years and the formation of health behaviors such as brushing teeth, feeding, the need for encouragement to believe in their abilities, and also the tendency of teenagers to use mobile phones and various games. Therefore, the present study aims to evaluate the effect of self-efficacy as a predictor of oral health behaviors of adolescents through a mobile application.

Strengths and weaknesses of the research

Among the strengths of this research, we can mention the study based on self-efficacy theory as a predictor of health behaviors, interventions based on mobile applications for teenagers, and also the interaction of people with the researcher during the intervention.

One of the weak points of the study is the self-reporting methods of people regarding behaviors related to oral health. Another limitation of the study is the lack of time to collect data on 6 and 12 month follow-ups to determine its lasting effects, which should be considered in future studies.

Trial status

Date of registration in clinical trial is 2022-10-13. Trial ID is 65599. Expected recruitment start approximate date is 2023-04-08. Expected recruitment end approximate date is 2023-06-09.

Ethics and dissemination

- Obtaining a license from the faculty of medical sciences of Tarbiat Modares university with ID code (IR.MODARES.REC.1401.125).
- Registration in Iran clinical trial center with ID code (IRCT20200120046204N1).
- Obtaining a letter of introduction from of Tarbiat Modares university for the ministry of education in Tehran.
- Obtaining a license from the education organization of Khuzestan province, Shushtar.
- Obtaining informed consent from the participants in the study by the researcher.
- No need to the write first and last name on the questionnaires.
- Assuring participants that their information is confidential.
- Providing educational content to the control group after the end of the research.

CONCLUSION

Dissemination policy

The publication policy of the project's findings is welcomed in international journals. The authors would like to present the results of the program to teachers, families and other stakeholders in the ministry of education of Iran.

Ancillary and post-trial care

A dentist works with the researchers to provide oral care for the students in this study.

Ethics and dissemination

The Tarbiat Modares university of ethics committee for health research ethics (IR.MODARES.REC.1401.125) approved the study. Informed consent will be obtained from all participants. The data (when ready) will be available from the corresponding author on request.

Trial registration

Iranian Registry of Clinical Trial (IRCT) IRCT20200120046204N1. Registered on 24 September 2022 ethics code: IR.MODARES.REC.1401.125

ACKNOWLEDGMENTS

This paper is extracted from the Ph.D. thesis in the department of health education and health promotion, faculty of medical sciences, Tarbiat Modares university, Tehran, Iran. The authors would like to thank the teachers, students, and staff of potential schools and principals of the education ministry in Shushtar, Khuzestan, Iran

AUTHORS' CONTRIBUTIONS

Seyedeh Zahra Marashi was the main investigator who collected and analyzed the data and wrote the first draft of the manuscript. Alireza Heidarnia supervised the study and contributed to the writing process. Seyedeh Somayeh Kazemi and Fatemeh Zarei were the study advisor who contributed to the analysis and interpretation and provided the final draft. All authors read and approved the final manuscript.

FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not for profit sectors.

AVAILABILITY OF DATA AND MATERIALS

The data will be available from the corresponding author on request.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Written informed consent was obtained from each participant. The ethics committee of Tarbiat Modares university, Tehran, Iran, approved the study. The ethical code is IR.MODARES.REC.1401.125

CONSENT FOR PUBLICATION

All detailed data publication is most welcome.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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