

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 2026

evaluation of the effect of oral health education through skill-based and knowledge-based methods in 12-year-old students: a randomized controlled trial study

Protocol summary

Study aim

Determination of the effect of oral health education through skill-based and knowledge-based methods in 12-year-old students on self-efficacy: a randomized controlled trial study

Design

A Double-Blind, Parallel-Group, Randomized Controlled Trial with Two Intervention Groups (Knowledge-Based and Skill-Based) Conducted Among 220 Students in Schools. Schools were selected using stratified cluster random sampling, and students were randomly assigned through a lottery method.

Settings and conduct

All interventions and assessments will be conducted on students in schools. Baseline knowledge will be assessed through a valid and reliable questionnaire, hygiene behavior through a checklist, and plaque and decay indices will be evaluated. Interventions will be tailored to each group: in the knowledge-based group, education will be provided through pamphlets, while in the skill-based group, face-to-face and practical training will be delivered by the researcher. Then, after 3 months, the indices and behavioral and knowledge outcomes of the students will be measured for the second time. Both participants (students) and outcome assessors are blinded. Only one intervention (either knowledge-based or skill-based) will be implemented in each school, preventing participants from knowing their group assignment. Outcome assessors are unaware of group assignments and evaluate predetermined outcomes without bias.

Participants/Inclusion and exclusion criteria

Students who are 12 years old, either in the sixth grade or who have reached the age of 12 at the time of the study.

Intervention groups

1- Knowledge-Based (Use of a Uni-Media Educational

Approach) 2- Skill-based (Use of a Multi-Media Educational Approach)

Main outcome variables

Dental Caries; Knowledge and Behavior Score Based on the Constructs of the Theory of Planning Behavior Model; Dental Plaque Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240303061155N1**

Registration date: **2025-01-09, 1403/10/20**

Registration timing: **prospective**

Last update: **2025-01-09, 1403/10/20**

Update count: **0**

Registration date

2025-01-09, 1403/10/20

Registrant information

Name

Maryam Fazli

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-02, 1403/11/14

Expected recruitment end date

2025-05-04, 1404/02/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
evaluation of the effect of oral health education through skill-based and knowledge-based methods in 12-year-old students: a randomized controlled trial study

Public title
Evaluation of the effect of oral health education in students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Students who are 12 years old, either in the sixth grade or who have reached the age of 12 at the time of the study.
Exclusion criteria:
Reluctance to participate in the study Dental prophylaxis in the past month No systemic health issues

Age
From **12 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **220**

Randomization (investigator's opinion)
Randomized

Randomization description
A list of all public elementary schools in Zanjan County will be obtained from the local office of the Education Department. Then, three areas of Zanjan County (Area 1, Area 2, and the Rural Area) will be randomly selected. After that, a list of all girls' and boys' schools in each area will be written on paper and collected separately into different containers (Container 1: all girls' schools in Area 1, Container 2: all boys' schools in Area 1, Container 3: all girls' schools in Area 2, Container 4: all boys' schools in Area 2, Container 5: all girls' schools in the Rural Area, and Container 6: all boys' schools in the Rural Area). To avoid contamination, only one intervention (educational or skill-based) will be performed in each school. Two papers will be drawn from each container: the first paper will be assigned to the skill-based group, and the second paper will be assigned to the knowledge-based group. Thus, schools will be selected using a stratified cluster random sampling method, and based on the order in which schools' names are drawn from each container, they will be assigned to either Intervention Group 1 (Skill-Based) or Intervention Group 2

(Knowledge-Based). For example, from Container 1, which includes all girls' schools in Area 1 of Zanjan County, two papers will be randomly selected. The school on the first paper will be assigned to the skill-based group, while the school on the second paper will be assigned to the knowledge-based group. This process will be repeated in the same manner for the other five containers, resulting in the selection of 12 schools. Additionally, students from the selected schools will be randomly chosen through a lottery to participate in the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, to prevent contamination and side effects from different interventions, only one intervention (either knowledge-based or skill-based) is applied to each school. This ensures that participants are unable to discern which group (either knowledge-based or skill-based) they belong to, thus blinding at the participant level is fully achieved. Consequently, all students are exposed to similar conditions and do not have any specific knowledge about the type of intervention they received. Additionally, outcome assessors are also fully blinded. Assessors, without knowledge of the group assignment for each student, evaluate only the predetermined outcomes and are free from any bias in assessing the results. To achieve this, all data are provided to the assessors in an anonymous format, with no reference to intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

The skill-based intervention, based on the constructs of the Theory of Planning Behavior, will be conducted in 3 educational sessions lasting 50 to 60 minutes each. These sessions will include lectures and face-to-face teaching, focusing on directly educating individuals about attitudes, subjective norms, and perceived behavioral control to effectively improve oral health behaviors. In the first session, students will learn about their attitudes regarding the process of tooth decay, foods and beverages involved in the decay process, choosing the right toothbrush by comparing different types through touching the bristles of soft, medium, and hard toothbrushes, brushing time and frequency, common mistakes in oral hygiene, and finally, the proper technique for brushing and flossing using a dental kit demonstrated in front of the students, allowing them to repeat the correct method. In the second session, the construct of social norms from the Theory of Planning Behavior will be addressed, involving teachers and parents in encouraging and motivating students to engage in self-care behaviors with consideration of rewards and praise. This session will include general information about the role of oral health in students' overall health, the differences between deciduous and permanent teeth, and ways to prevent tooth decay. Teachers and parents will be shown the proper brushing and flossing techniques and informed on how they can

encourage their children to brush and floss by practicing these techniques alongside them. In the third session, the key points from the first session will be reviewed, and students will be taught how to deal with perceived behavioral control issues, focusing on the obstacles and difficulties they might face in performing self-care behaviors, and how to overcome these barriers. In Intervention Group 2, knowledge-based education will be delivered through a researcher-developed pamphlet, which is commonly used as an effective strategy in health education and promotion programs to provide information on various levels of health problem prevention. The educational section of this program will consist of a 2-hour training session for parents and teachers, and a 2-hour session for students. In these pamphlet-based sessions, designed according to the constructs of the Theory of Planning Behavior, the pamphlet will be given to students, parents, and teachers to read by themselves over a specified period. The pamphlet will start by explaining tooth decay, the associated process, foods that cause decay, the time and frequency of brushing, brushing techniques, and flossing techniques to improve the audience's knowledge and attitudes regarding oral health. Next, to address barriers to oral health, the pamphlet will include an image demonstrating how to select the right toothbrush and common mistakes encountered during brushing. Afterward, questions will be asked to ensure comprehension, such as "How will you brush your teeth tonight?" or "Can you tell me the minimum brushing time per session?" It should be noted that in this group, by involving coaches, teachers, and parents, the social norm construct regarding oral health education can strengthen students' intentions and health behaviors. At the outset of the study, all participants were provided with standardized oral hygiene kits, including Signal-brand toothbrushes and toothpaste (Unilever factory). This ensured consistency in intervention tools and minimized potential confounders related to resource variability. Participants were instructed to use the provided products exclusively throughout the three-month intervention period. Contingency plans were established with school administrators to replenish resources if needed, ensuring no additional financial burden was placed on families or schools.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical School

Street address

Zanjan, Azadi Square, Beginning of Jomhouri Eslami Boulevard, Central Headquarters of Zanjan University of Medical Sciences

City

zanjan

Province

Zanjan

Postal code

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Approval date

2024-12-02, 1403/09/12

Ethics committee reference number

IR.ZUMS.REC.1403.274

Health conditions studied

1

Description of health condition studied

Design, implementation, and evaluation of the effect of oral health education through skill-based and knowledge-based methods in 12-year-old students: a randomized controlled trial study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Knowledge and Behavior Score Based on the Constructs of the Theory of Planning Behavior Model

Timepoint

before the start of the intervention and 3 months after the start of the intervention

Method of measurement

Through a Valid and Reliable Questionnaire

Secondary outcomes

1

Description

The Attitude Construct of the Theory of Planning Behavior

Timepoint

Measurement before the start of the intervention and 3 months after the start of the intervention

Method of measurement

In this study, attitude refers to the students' belief regarding the positive or negative impact of adhering to or neglecting proper oral self-care behaviors. This is assessed based on their responses to the relevant questions in the questionnaire.

2

Description

The Subjective Norms Construct of the Theory of Planning Behavior

Timepoint

Measurement before the start of the intervention and 3 months after the start of the intervention

Method of measurement

In this study, subjective norms refer to the students' perceptions of the opinions of parents, peers, teachers, principals, and other significant individuals regarding adherence to proper oral self-care behaviors. These perceptions are assessed based on the students' responses to the relevant questions in the questionnaire.

3

Description

The Perceived Behavioral Control Construct of the Theory of Planning Behavior

Timepoint

Measurement before the start of the intervention and 3 months after the start of the intervention

Method of measurement

In this study, perceived behavioral control refers to the individual's perceived difficulty or ease and their perceived ability to perform proper oral self-care behaviors. This is assessed based on their responses to the relevant questions in the questionnaire.

4

Description

The Behavioral Intention Construct of the Theory of Planning Behavior

Timepoint

Measurement before the start of the intervention and 3 months after the start of the intervention

Method of measurement

In this study, behavioral intention refers to the individual's intention (or willingness) to adhere to proper oral self-care behaviors. This is assessed based on their responses to the relevant questions in the questionnaire

5

Description

Use of Dental Floss

Timepoint

before the start of the intervention and 3 months after the start of the intervention

Method of measurement

Check list (Yes/No)

6

Description

Use of Tooth brush

Timepoint

before the start of the intervention and 3 months after the start of the intervention

Method of measurement

Check list (Yes/No)

7

Description

The number of times using teeth brush

Timepoint

before the start of the intervention and 3 months after the start of the intervention

Method of measurement

Check list

8

Description

Dental Caries

Timepoint

Measurement before the start of the intervention and 3 months after the start of the intervention

Method of measurement

Clinical Examination through the assessment of the DMFT (the ratio of the number of restored teeth after the intervention to the number of decayed teeth before and after the intervention)

9

Description

Dental Plaque Index

Timepoint

Measurement before the start of the intervention and 3 months after the start of the intervention

Method of measurement

Specialized examinations using a periodontal probe and registration in the examination form

Intervention groups

1

Description

Intervention group: Skill-based (Use of a Multi-Media Educational Approach) - The skill-based intervention, based on the constructs of the Theory of Planning Behavior, will be conducted in 3 educational sessions lasting 50 to 60 minutes each. These sessions will include lectures and face-to-face teaching, focusing on directly educating individuals about attitudes, subjective norms, and perceived behavioral control to effectively improve oral health behaviors. In the first session, students will learn about their attitudes regarding the process of tooth decay, foods and beverages involved in the decay process, choosing the right toothbrush by comparing different types through touching the bristles of soft, medium, and hard toothbrushes, brushing time and frequency, common mistakes in oral hygiene, and finally, the proper technique for brushing and flossing using a dental kit demonstrated in front of the students, allowing them to repeat the correct method. In the second session, the construct of social norms from the Theory of Planning Behavior will be addressed, involving teachers and parents in encouraging and motivating students to engage in self-care behaviors with consideration of rewards and praise. This session will include general information about the role of oral health in students' overall health, the differences between deciduous and permanent teeth, and ways to prevent tooth decay. Teachers and parents will be shown the proper brushing and flossing techniques and informed on how they can encourage their children to brush and floss by practicing these techniques alongside them. In the

third session, the key points from the first session will be reviewed, and students will be taught how to deal with perceived behavioral control issues, focusing on the obstacles and difficulties they might face in performing self-care behaviors, and how to overcome these barriers.

Category

Prevention

2

Description

Intervention group: Knowledge-Based (Use of a Uni-Media Educational Approach) - In Intervention Group 2, knowledge-based education will be delivered through a researcher-developed pamphlet, which is commonly used as an effective strategy in health education and promotion programs to provide information on various levels of health problem prevention. The educational section of this program will consist of a 2-hour training session for parents and teachers, and a 2-hour session for students. In these pamphlet-based sessions, designed according to the constructs of the Theory of Planning Behavior, the pamphlet will be given to students, parents, and teachers to read by themselves over a specified period. The pamphlet will start by explaining tooth decay, the associated process, foods that cause decay, the time and frequency of brushing, brushing techniques, and flossing techniques to improve the audience's knowledge and attitudes regarding oral health. Next, to address barriers to oral health, the pamphlet will include an image demonstrating how to select the right toothbrush and common mistakes encountered during brushing. Afterward, questions will be asked to ensure comprehension, such as "How will you brush your teeth tonight?" or "Can you tell me the minimum brushing time per session?" It should be noted that in this group, by involving coaches, teachers, and parents, the social norm construct regarding oral health education can strengthen students' intentions and health behaviors.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected Primary Schools of Zanjan County

Full name of responsible person

Maryam Fazli

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Mahdavi Blv. Faculty of Dentistry, Department of Oral Health and Social Dentistry

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drfazli@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Azin nourian

Street address

Mahdavi St., Dentistry Department, Zanjan University of Medical Science

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Phone

+98 24 3314 8100

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azin.nourian@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

25

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

2

Sponsor

Name of organization / entity

Unilever Iran Factory

Full name of responsible person

Reza Safari

Street address

Qazvin, Alborz Industrial City, Sohrevardi Boulevard, Abu Reyhan Birooni Street

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qazvin

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3531944893

Phone

+98 28 3381 6000

Email

info@unilever.ir

Web page address

https://unilever.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Unilever Iran Factory

Proportion provided by this source

20

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

3

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Maryam Fazli

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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

Zanjan University of Medical Sciences

Proportion provided by this source

55

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Maryam Fazli

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Community oral health

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Maryam Fazli

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

All participant data can be shared after de-identification.

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

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

To receive the data and documents, send an email to Dr.Maryam Fazli Or contact the research office of Zanzan School of Dentistry. Dr.Maryam Fazli's email: drfazli@zums.ac.ir Zanzan Faculty of Dentistry research office phone number: +98-24-33148215

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

Data requests are usually answered after two working weeks.

Comments