

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 043 6943

##### Email address

drfazli@zums.ac.ir

##### 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 Zanzan County will be obtained from the local office of the Education Department. Then, three areas of Zanzan 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 Zanzan 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 Jomhuri Eslami Boulevard, Central Headquarters of Zanjan University of Medical Sciences

#### City

zanjan

#### Province

Zanjan

#### Postal code

۴۵۱۳۹۵۶۱۱۱

#### 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

##### Street address

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

##### City

zanjan

##### Province

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##### Postal code

4513956111

##### Phone

+98 912 043 6943

##### Email

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

##### City

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##### Province

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##### Postal code

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##### Phone

+98 24 3314 8100

##### Email

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

##### City

qazvin

##### Province

Qazvin

##### Postal code

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

**Street address**

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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

**Street address**

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## Person responsible for scientific 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 updating data

**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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**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**