Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of educational intervention based on Transtheoretical model in self-care behaviors of oral and dental health of students

Protocol summary

Study aim
Determining the effectiveness of educational intervention based on the Transtheoretical model in self-care behaviors of oral and dental health of students

Design
The clinical trial has two intervention and control groups, with parallel, single-blind and randomized groups, and the intervention is carried out on 88 students. A simple random method is used for sampling.

Settings and conduct
The present study will be conducted in 4 public primary schools for girls and boys in Shahreza city, which are selected by multi-stage sampling from all schools in Shahreza. The intervention will be conducted in the form of face-to-face training regarding self-care of oral and dental health based on a Transtheoretical model using a combination of teaching methods in the classroom. In this study, all people in the intervention and control groups are unaware of their placement in the intervention or control group and are considered as blind people.

Participants/Inclusion and exclusion criteria
Entry requirements: Being in the first three stages of preparation for change according to the Transtheoretical model Completing the informed consent form to participate in the study Non-entry conditions: Having underlying diseases according to the opinion of the dentist Age below 11 years and above 13 years

Intervention groups
The intervention of the present study includes oral and dental health self-care training based on a Transtheoretical model for the intervention group, while the control group will not receive any training.

Main outcome variables
frequency of cleaning behavior; frequency of use of each cleaning tool The final result: the amount of dental plaque

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241008063294N1**
Registration date: **2024-12-21, 1403/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-21, 1403/10/01**
Update count: **0**

Registration date
2024-12-21, 1403/10/01

Registrant information

Name
Negin Akbarpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5322 6074

Email address
neginakbarpoor79@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-15, 1403/09/25

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of educational intervention based on Transtheoretical model in self-care behaviors of oral and dental health of students

Public title
Investigating the effect of education on oral and dental health self-care behaviors of students

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Being in the first three stages of preparation for change according to the transtheoretical model Completing the informed consent form to participate in the study

Exclusion criteria:
Having underlying diseases according to the opinion of the dentist Age below 11 years and above 13 years

Age
From **11 years** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomness

Blinding (investigator's opinion)
Single blinded

Blinding description
In the present study, all the participants of the intervention and control groups, which include students aged 11 to 13 years, are considered as blind people.

Placebo
Not used

Assignment
Parallel

Other design features
The educational intervention of the present study is designed based on the Transtheoretical model.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences., Hezar Jerib Street., Isfahan

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2024-12-14, 1403/09/24

Ethics committee reference number
IR.MUI.DHMT.REC.1403.163

Health conditions studied

1

Description of health condition studied
Oral and dental health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Self-efficacy

Timepoint
Measuring self-efficacy at the beginning of the intervention (before the intervention), 2 and 6 months after the intervention

Method of measurement
Questionnaire created by a researcher to measure the constructs of the Transtheoretical model

2

Description
Perceived benefits

Timepoint
Measuring perceived benefits at the beginning of the intervention (before the intervention), 2 and 6 months after the intervention

Method of measurement
Questionnaire created by a researcher to measure the constructs of the Transtheoretical model

3

Description
Perceived barriers

Timepoint
Measuring perceived barriers at the beginning of the intervention (before the intervention), 2 and 6 months after the intervention

Method of measurement
Questionnaire created by a researcher to measure the constructs of the Transtheoretical model

4

Description
Frequency of cleaning behavior

Timepoint
Measuring the frequency of cleaning behavior at the beginning of the intervention (before the start of the intervention), 2 and 6 months after the intervention
Method of measurement
Questionnaire created by a researcher to measure the constructs of the Transtheoretical model

5

Description
The frequency of using each of the cleaning tools
Timepoint
Measuring the frequency of using each of the cleaning tools at the beginning of the intervention (before the intervention), 2 and 6 months after the intervention
Method of measurement
Questionnaire created by a researcher to measure the constructs of the Transtheoretical model

Secondary outcomes

1

Description
The amount of dental plaque based on the grouping of dental plaque index
Timepoint
Measurement of dental plaque at the beginning of the study (before the start of the intervention) and six months after the intervention
Method of measurement
Through a dentist's examination with direct observation and grouping based on dental plaque index

Intervention groups

1

Description
Intervention group: The researcher visits the selected schools at a specific time and with prior coordination and provides the parental consent form to the school principal to be sent and completed by the parents. After completing the parental consent forms, students who have the completed parental consent form will be included in the study. It should be noted that since the target group is elementary school students, verbal consent will be obtained from them to participate in the study. The educational program includes 4 sessions for students and 1 session for parents and teachers of the students, and each session is implemented for 45 to 60 minutes for the intervention group. The educational content is provided based on reliable sources from the Isfahan Provincial Health Office and the Faculty of Dentistry. The educational content mainly includes familiarizing students with the mouth and tooth structure, the benefits and obstacles of observing oral and dental hygiene, creating a sense of self-efficacy, tooth cleaning behaviors, and the correct use of oral and dental cleaning tools. In fact, the educational content of the study is determined and adjusted in accordance with the structures of the Transtheoretical model and the results of the pre-test. Training is conducted in groups using a combination of lecture, question and answer, practical demonstration, individual statements, brainstorming, and group discussion methods in each training session. During training classes, media such as pamphlets (distributed to all attendees in the class for home study), books, posters, educational films, and photographs are used to enhance learning.
Category
Behavior

2

Description
Control group: will not receive any educational intervention. The control group will not receive any educational intervention. The control group will have to wait to receive the intervention and, if the intervention has a positive result, will receive the written content of the educational sessions after the end of the study.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Four primary schools in Shahreza city
Full name of responsible person
Negin Akbarpour
Street address
Amiral Momenin school., Next to Farhangian Consumption Cooperative Company., Shahid Motahari Blvd., Shahreza
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
Street address
Research and Technology Vice-Chancellor., Building No. 4, Isfahan University of Medical Sciences and Healthcare Services., Hezar Jerib Street, Isfahan
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research@mui.ac.ir

Web page address
https://research.mui.ac.ir/fa

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Negin Akbarpour

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Health Promotion

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Isfahan University of Medical Sciences., Hezar Jerib St., Shiraz Gate., Isfahan

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Person responsible for scientific inquiries

Contact

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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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 data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Start access after printing the results

To whom data/document is available

All people working in academic, scientific and industrial sectors are able to receive data.

Under which criteria data/document could be used

1- Using information to conduct scientific and research studies 2- Not changing information and observing ethical standards

From where data/document is obtainable

1- Conductors and authors of the research project 2- Research vice-chancellor of the university and the relevant educational institution (Isfahan University of Medical Sciences). Ways of communication with the executors of the research project: 1- Ms. Negin Akbarpour, address: Subsection11., Hakim nasrollah Ave., Shahreza., Isfahan, contact number: 09210430855, email address: neginakbarpoor79@gmail.com 2- Dr. Hossein Shahnazi, Address: Department of Health Education., Faculty of Health., Isfahan University of Medical Sciences., Hezar Jerib Street., Isfahan, contact number: 09133360148, email address: h_shahnazi@yahoo.com.

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

After the person's request is made by calling or emailing the project organizers and checking the scientific and moral qualification of the applicant, the information will be provided to him in the shortest possible time.

Comments