Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Educational Intervention on oral health behaviors health and quality of life in covid 19 among elementary school students in schools promoting health : Based on the Theory of Planned Behavior

Protocol summary

Study aim

Determining the effect of education based on the planned behavior model in improving oral health behaviors of students

Design

Randomized control trial, parallel group of 2 primary schools for the control and intervention group are selected by lot. The selection of participants in the study will be by lottery. The sample size for each group is 50 people.

Settings and conduct

This study is done in Shazand city. First, the questionnaire is completed by students. After analyzing the information and examining the educational needs of students, the educational intervention in the intervention group is based on the planned behavior model and preferences are done through Shad virtual network. One month After the intervention, the questionnaires are completed again and the previous information and after the intervention are analyzed by SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: employment in the fifth and sixth grades, filling out the consent form by the students' guardians and having a minimum of 11 and a maximum of 12 years

Intervention groups

The present study is an educational intervention that is performed with the participation of 100 students in two experimental and control groups (50 people each). Controls will also receive routine school-based health-promoting training.

Main outcome variables

1- Awareness 2Attitude 3-Abstract norms 4-Controlling perceived behavior 5-Behavioral intention 6 Preventive behaviors 7Quality of life related to oral health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220404054412N1**
Registration date: **2022-05-24, 1401/03/03**
Registration timing: **retrospective**

Last update: **2022-05-24, 1401/03/03**
Update count: **0**

Registration date

2022-05-24, 1401/03/03

Registrant information

Name

Maryam Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3822 3148

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

2022-03-01, 1400/12/10

Actual recruitment end date

2022-03-06, 1400/12/15

Trial completion date

2022-04-14, 1401/01/25

Scientific title
The Effect of Educational Intervention on oral health behaviors health and quality of life in covid 19 among elementary school students in schools promoting health : Based on the Theory of Planned Behavior

Public title
The effect of education on oral health behaviors

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Employment to study in the fifth and sixth grades of primary schools in Shazand city and having a minimum age of 11 years and a maximum of 12 years Filling in the consent form by the student guardian

Exclusion criteria:
Students drop out before interventions Immigrating to another school and not participating in the educational program

Age
From **11 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be clustered randomly. After coordination with Shazand city education, to determine the samples, first 4 schools are randomly selected from the health promotion schools of Shazand region (6 primary schools of health promoters), then two schools are in the control group and two schools are in the intervention group. And then 50 people from each school will be randomly selected from the list of students for the control and intervention group.

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 Arak University of Medical Sciences

Street address
Arak, Shahid Shiroudi Street, Alam al-Huda Street

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2022-02-21, 1400/12/02

Ethics committee reference number
IR.ARAKMU.REC.1400.314

Health conditions studied

1

Description of health condition studied
Oral health behaviors among students

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Awareness about oral health

Timepoint
Before training and one month after training

Method of measurement
Researcher-made questionnaire

2

Description
Attitudes about oral health

Timepoint
Before training and one month after training

Method of measurement
Researcher-made questionnaire

3

Description
Abstract norms about oral health

Timepoint
Before training and one month after training

Method of measurement
Researcher-made questionnaire

4

Description
Controlling perceived behavior regarding oral health

Timepoint
Before training and one month after training

Method of measurement
Researcher-made questionnaire

5

Description
Behavioral intention about oral health
Timepoint
Before training and one month after training
Method of measurement
Researcher-made questionnaire

6

Description
Oral health behaviors
Timepoint
Before training and one month after training
Method of measurement
Researcher-made questionnaire

7

Description
Quality of life related to mouth and tooth
Timepoint
Before training and one month after training
Method of measurement
Researcher-made questionnaire

Secondary outcomes

1

Description
Quality of life related to mouth and tooth
Timepoint
Before and one month after training
Method of measurement
Researcher-made questionnaire

Intervention groups

1

Description
Intervention group:
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Health promoting schools covered by shazand county education
Full name of responsible person
Dr. Raheleh Soltani
Street address
Jihad Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Raheleh Soltani
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr. Raheleh Soltani
Position
Associate Professor, School of Public Health, Arak University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion

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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available