

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 86 3822 3148

Email address

maryammohammadi2510@gmail.com

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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Shazand

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381963345

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Email

maryammohammadi2510@gmail.com

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 scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Postgraduate Student

Latest degree

Bachelor

Other areas of specialty/work

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Email

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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