

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The Effect of planned behavioral theory training on behaviors that associated with mouth and tooth health in primary students

Protocol summary

Summary

Objective: provide simple administrative solutions in order to create attitudes and behavior in order of importance of oral health. Field of study: randomized, double-blind, placebo-uncontrolled, multi-center, one phase of clinical trial. A) Study population: male and female students in primary schools (fourth, fifth and sixth) at saveh city. Inclusion criteria: willingness to participate in the study; fourth to sixth primary school students; without learning disorders such as ADHD and autism; Without attending similar training. Exclusion criteria: reluctance to continue to participate in the study; school managers opposing to participate of students in the study; reluctance of parents to participate of students in the study. Sample size: 520, with the possibility of sample loss. B) Intervention study: the effect of planned behavioral theory training on behaviors that associated with mouth and tooth health in primary students C) The study period: from 10 March 2017 to 30 May 2017. D) The primary outcome: the creation of a positive attitude about the importance of oral health.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017012831522N5**

Registration date: **2017-02-20, 1395/12/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

Vahid Naseri Salahshour

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Saveh University of Medical Sciences

Expected recruitment start date

2017-02-28, 1395/12/10

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of planned behavioral theory training on behaviors that associated with mouth and tooth health in primary students

Public title

The effect of education According to planned behavioral theory on mouth and tooth health in primary students

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study; fourth to sixth primary school students; without learning disorders such as ADHD and autism; without attending

similar training. Exclusion criteria: reluctance to continue to participate in the study; school managers opposing to participate of students in the study; reluctance of parents to participate of students in the study; irregular participation in training classes.

Age

From **9 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **520**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The samples were randomly placed in two groups. If the first sample is girl, the sample placed in intervention group and after the samples alternative (one to one) placed in control and intervention groups and if the first sample is boy, the sample placed in control group and after the samples alternative (one to one) placed in intervention and control groups

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Saveh University of Medical Sciences

Street address

Saveh University of Medical Sciences, Madar Sq, SHariati St, Saveh

City

Saveh

Postal code

3918698786

Approval date

2015-07-26, 1394/05/04

Ethics committee reference number

IR.SAVEHUMS.REC139407

Health conditions studied

1

Description of health condition studied

Mouth and tooth health

ICD-10 code

Z41.8

ICD-10 code description

Other procedures for purposes other than remedying health state

Primary outcomes

1

Description

Observance of mouth and tooth health

Timepoint

The questionnaire immediately after the intervention and one month after it is completed by samples of two experimental and control groups

Method of measurement

The seven-part questionnaire including: knowledge, attitude, subjective norm, perceived behavioral control, intention and behavior

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groups: The samples of intervention group training at 3 sessions of 40 minutes in the form of lectures, group discussions and practical view. Educational content classes includes: First session: raising awareness and attitude, Second session: the importance of perceived behavioral control on empowerment And third Session: Practical showing the correct way of brushing and flossing and practice on themselves.

Category

Behavior

2

Description

Control group: samples of the control group as well as samples of the intervention group (without participation in the educational classes) to complete the questionnaires.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Saveh city primary schools
Full name of responsible person
The managers of saveh city primary schools
Street address
Saveh city department of education, Fajr town
entrance, SHahid Beheshti Blvd, Saveh.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Saveh University of
Medical Sciences
Full name of responsible person
Hamidreza Baradaran, Vice Chancellor for research of
Saveh University of Medical Sciences
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Saveh University of Medical Sciences, Madar Sq,
SHariati st, Saveh
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Saveh
Grant name
-
Grant code / Reference number
-
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice Chancellor for research of Saveh University of
Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty