

# 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

+98 86 3417 3505

##### Email address

v.naserisalahshour@arakmu.ac.ir

##### 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.  
**City**  
Saveh

Saveh  
**Postal code**  
3918698786  
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+98 86 4230 1291  
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**Email**  
v.naserisalahshour@arakmu.ac.ir  
**Web page address**  
-

## 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  
**Street address**  
Saveh University of Medical Sciences, Madar Sq,  
SHariati st, Saveh  
**City**  
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**  
Saveh University of Medical Sciences  
**Full name of responsible person**  
Vahid Naseri Salahshour, MSc of Nursing Education in  
Medical Surgical Field  
**Position**  
MSc of Nursing Education in Medical Surgical Field  
**Other areas of specialty/work**  
**Street address**  
Saveh University of Medical Sciences, Madar Sq,  
SHariati st, Saveh  
**City**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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## Person responsible for updating data

#### Contact

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**Web page address**

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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*