

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of educational intervention based on protection-motivation theory on oral health literacy promotion among female high school students

Protocol summary

Summary

This study is an educational randomized controlled trial. The purpose of this study is to determine the effect of educational intervention based on protection motivation theory on oral health literacy promotion. 180 students are selected by a multistage cluster sampling from four secondary schools of the zone 2 and 4 of Shiraz education after elimination of special schools (gifted, non-profit and exceptional) and assign into experimental and control groups. The data is obtained by using oral health literacy and protection motivation theory questionnaire before and after the educational intervention. Inclusion criteria are being female students studying at ninth grade of high school in Shiraz and willingness to participate in the study and exclusion criteria are unwillingness to continue participating in research, absence in the pre-test or post-test, absence of more than one session in educational classes and incomplete filling of questionnaires. Educational intervention include four educational sessions of 45 to 60 minutes once a week based on booklet " be the best friend of your teeth" Which has been prepared by reviewing of the literature and the results of pre-test questionnaire analysis and are perform by lecture, question and answer, group discussion, role playing, video playback, training booklet and poster in intervention group. Primary research outcomes are oral health literacy, behavior and teeth plaque index, and secondary outcome are Protection Motivation Theory components (perceived vulnerability, perceived severity, self-efficacy, response efficacy and response costs) and knowledge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702176261N16**

Registration date: **2017-07-12, 1396/04/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-12, 1396/04/21

Registrant information

Name

Mohammad Hussein Kaveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences, Governmental

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention based on protection-motivation theory on oral health literacy

promotion among female high school students

IR.SUMS.REC.1395.166

Public title

The effect of educational intervention on oral health literacy promotion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: female students studying at the base of the ninth school Junior High School Shiraz willingness to cooperate in the study Exclusion criteria: study in special schools (gifted, non-profit and exceptional), unwillingness to cooperate, participate in the pre-test or post-test; absence of more than one meeting during the classes, withdrew from the study, a questionnaire corruption due to incomplete answer.

Age

From **14 years** old to **15 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The samples were divided into intervention and control groups using closed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice chancellor for research, seventh floor, Shiraz University Center Building, Zand Avenue

City

Shiraz

Postal code

7134814336

Approval date

2017-01-08, 1395/10/19

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Oral Health Literacy

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

Oral Health Literacy

Timepoint

Before the intervention and one month after educational intervention

Method of measurement

Oral Health Literacy questionnaire

2

Description

Plaque Index

Timepoint

Before the intervention and one month after intervention

Method of measurement

silness loe plaque index

3

Description

Oral health behavior

Timepoint

Before the intervention and one month after educational intervention

Method of measurement

Self-Made Protection Motivation Theory questionnaire

Secondary outcomes

1

Description

Perceived vulnerability

Timepoint

Before the intervention and one month after intervention

Method of measurement

Self-Made Protection Motivation Theory questionnaire

2

Description

perceived severity

Timepoint

Before the intervention and one month after intervention

Method of measurement

Self-Made Protection Motivation Theory questionnaire

3

Description

Self-efficacy

Timepoint

Before the intervention and one month after intervention

Method of measurement

Self-Made Protection Motivation Theory questionnaire

4

Description

Response Efficacy

Timepoint

Before the intervention and one month after intervention

Method of measurement

Self-Made Protection Motivation Theory questionnaire

5

Description

response costs

Timepoint

Before the intervention and one month after intervention

Method of measurement

Self-Made Protection Motivation Theory questionnaire

6

Description

Knowledge

Timepoint

Before the intervention and one month after intervention

Method of measurement

Self-Made Protection Motivation Theory questionnaire

Intervention groups

1

Description

Intervention group: educational intervention included 4 educational sessions of 45 to 60 minutes once a week based on booklet " Be the best friend of your teeth" and are performed by lecture, question and answer, group discussion, role playing, video playback, training booklet and poster.

Category

Behavior

2

Description

Control group: In the control group, educational intervention does not take place. These group will participate in the pre-test and post-test.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Narjes girls' High School

Full name of responsible person

Fatemeh Movasseghi

Street address

Nasr Blvd, Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Enghelab Eslami girls' High School

Full name of responsible person

Fatemeh Movasseghi

Street address

Saheli Sharghi Avenue, Shiraz

City

Shiraz

3

Recruitment center

Name of recruitment center

Shahid Nematolahi girls' High School

Full name of responsible person

Fatemeh Movasseghi

Street address

Zakaolmolk Avenue, Shiraz

City

Shiraz

4

Recruitment center

Name of recruitment center

Olum va Maaref girls' High School

Full name of responsible person

Fatemeh Movasseghi

Street address

Parvaneh Alley, Zand Avenue, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Sayed Basir Hashemi

Street address

Vice chancellor for research, seventh floor, Shiraz

University Center Building, Zand Avenue
City
 Shiraz
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 Shiraz 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
 Shiraz University of Medical sciences
Full name of responsible person
 Fatemeh Movasseghi
Position
 Master Student of Health Education
Other areas of specialty/work
Street address
 Health education and health promotion, School of Public Health, Shiraz University of Medical sciences
City
 Shiraz
Postal code
 14336 71348
Phone
 +98 71 3725 1001
Fax
Email
 stud2296951880@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Shiraz University Of Medical Sciences
Full name of responsible person
 Mohamad Hosein Kaveh

Position
 Associate Professor
Other areas of specialty/work
Street address
 Health education and health promotion, School of Public Health, Shiraz University of Medical sciences
City
 Shiraz
Postal code
 14336 71348
Phone
 +98 71 3725 1001
Fax
Email
 kaveh@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Shiraz University of Medical Sciences
Full name of responsible person
 Fatemeh Movasseghi
Position
 Master Student of Health Education
Other areas of specialty/work
Street address
 Health education and health promotion, School of Public Health, Shiraz University of Medical sciences
City
 Shiraz
Postal code
 14336 71348
Phone
 +98 71 3725 1001
Fax
Email
 stud2296951880@sums.ac.ir
Web page address

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