

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The impact of a theory based educational intervention on sexual behavior and its determinants among public high school girl students

Protocol summary

Study aim

Investigate the effect of the theory based educational intervention on sexual health behaviors and determinants among female students

Design

Two arm parallel group randomised controlled trial, with 120 people sample size in each group are selected by random cluster sampling; 2 schools are selected from 2 educational districts by simple random sampling, case and control groups are allocated randomly to each school. Then 2 classes are selected by simple random sampling in each school.

Settings and conduct

The research environment is public girl high schools in Shiraz. The research population is the eleventh grade girl students of Shiraz schools in the year 1397. 240 students are selected by cluster random sampling and allocation to experimental (120) and control (120) group is done. researcher-made standardized questionnaire will be used for pre test. 6 educational Intervention sessions will be implemented and after 6 weeks post test in both two groups (experiment and control groups) will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: eleventh grade female student
Non-Inclusion criteria: marriage; participation in previous similar session; unwillingness to participation; Parents' disagreement of her participation

Intervention groups

Case group: after pretest, 6 educational workshops are conducted through 90-second sessions using interactive lecture, group discussion and question answering methods. Possibly, individual or group learning tasks are done, also a virtual group for text, video and audio message transmission is produced. After 6 weeks, post test is taken; Control group: no intervention, only pre and post test is taken.

Main outcome variables

Attitude toward healthy sexual behavior; subjective norm, perceived behavioral control and intention related

to sexual behavior; healthy sexual behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110423006261N18**

Registration date: **2019-03-25, 1398/01/05**

Registration timing: **retrospective**

Last update: **2019-03-25, 1398/01/05**

Update count: **0**

Registration date

2019-03-25, 1398/01/05

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

Expected recruitment start date

2019-02-18, 1397/11/29

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Sciences
Scientific title	Street address
The impact of a theory based educational intervention on sexual behavior and its determinants among public high school girl students	Vice chancellor for research, seventh floor, Shiraz University Center Building, Zand Avenue
Public title	City
The impact of education on sexual behavior among girl students	Shiraz
Purpose	Province
Education/Guidance	Fars
Inclusion/Exclusion criteria	Postal code
Inclusion criteria:	7134814336
Eleventh grade high school student female sex	Approval date
Exclusion criteria:	2018-10-27, 1397/08/05
student is married Participation in previous similar course unwillingness to participation Parents' disagreement of her participation	Ethics committee reference number
Age	IR.SUMS.REC.1397.699
From 16 years old to 17 years old	Health conditions studied
Gender	<u>1</u>
Female	Description of health condition studied
Phase	sexual behavior
N/A	ICD-10 code
Groups that have been masked	ICD-10 code description
No information	Primary outcomes
Sample size	<u>1</u>
Target sample size: 240	Description
Randomization (investigator's opinion)	sexual behavior
Randomized	Timepoint
Randomization description	Before the intervention and 6 weeks after intervention
Simple randomization is using In this study. For case and control random allocation, random number table is used. 2 schools are selected separately from each of the two education districts as clusters. (Selecting 2 districts from 4 districts is proposed by education officials).Then for each district, by using random number table two classes are selected for case group in one school and two classes for control group in the other school.	Method of measurement
Blinding (investigator's opinion)	Researcher-made standardized questionnaire
Not blinded	Secondary outcomes
Blinding description	<u>1</u>
Placebo	Description
Not used	Attitude
Assignment	Timepoint
Parallel	Before the intervention and 6 weeks after intervention
Other design features	Method of measurement
In order to prevent information leakage, random allocation is doing in level of schools not students.	Researcher-made standardized questionnaire
Secondary Ids	2
empty	Description
Ethics committees	Perceived behavioral control
<u>1</u>	Timepoint
Ethics committee	Before the intervention and 6 weeks after intervention
Name of ethics committee	Method of measurement
Ethics committee of Shiraz University of Medical	Researcher-made standardized questionnaire
	3
	Description
	Subjective norm
	Timepoint
	Before the intervention and 6 weeks after intervention
	Method of measurement

Researcher-made standardized questionnaire

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Description

Intention

Timepoint

Before the intervention and 6 weeks after intervention

Method of measurement

Researcher-made standardized questionnaire

Intervention groups

1

Description

Intervention group: 120 eleventh grade high school girl students are selected according to the sampling process. After pre-test, using a researcher-made questionnaire, educational intervention is carried out in at least six 90 minutes training sessions. Topics include an introduction to puberty, physical and sexual health in adolescents, sexual transmitted diseases, friendship and dating, beliefs and values in life, problem solving skills, skills of assertiveness and risks of virtual space on sexual issues. These topics are based on reliable and related sources. Overall strategy include interactive methods such as interactive lectures, small group techniques, group discussion, questions and answers and home based assignments and self-teaching materials for pamphlets and booklets that runs by the researcher. Also if it is possible to expand and deepen learning in cyberspace, a group is created for text and video and audio messages. In addition, the duration and number of training sessions may increase based on the capacity, the willingness, the conditions of the participants in the class and other factors. Six weeks after the completion of the training, a post-test will be held.

Category

Behavior

2

Description

Control group: students in control group will experience no intervention but only routine school curricula .

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Girl High Schools

Full name of responsible person

Fateme Badiei

Street address

Health Education and Health Promotion Group, School of Public Health, Razi Blvd, Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

14336 71348

Phone

+98 71 3725 1001

Email

Badiei1970@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

DR Syed Basir Hashemi

Street address

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

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kaveh@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Kaveh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Health Education and Health Promotion Group, School of Public Health, Razi Blvd, Shiraz, Iran.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Kaveh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Web page address**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

fateme badiei

Position

Master Student of Health Education and Health Promotion

Latest degree

Master

Other areas of specialty/work

Health Promotion

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City

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Person responsible for updating data**Contact**