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, with120 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)

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+98 71 1725 1001

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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

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

Public title
The impact of education on sexual behavior among girl students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Eleventh grade high school student female sex
Exclusion criteria:
student is married Participation in previous similar course unwillingness to participation Parents' disagreement of her participation

Age
From **16 years** old to **17 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **240**

Randomization (investigator's opinion)
Randomized

Randomization description
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.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In order to prevent information leakage, random allocation is doing in level of schools not students.

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

Province
Fars

Postal code
7134814336

Approval date
2018-10-27, 1397/08/05

Ethics committee reference number
IR.SUMS.REC.1397.699

Health conditions studied

1

Description of health condition studied
sexual behavior

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
sexual behavior

Timepoint
Before the intervention and 6 weeks after intervention

Method of measurement
Researcher-made standardized questionnaire

Secondary outcomes

1

Description
Attitude

Timepoint
Before the intervention and6 weeks after intervention

Method of measurement
Researcher-made standardized questionnaire

2

Description
Perceived behavioral control

Timepoint
Before the intervention and6 weeks after intervention

Method of measurement
Researcher-made standardized questionnaire

3

Description
Subjective norm

Timepoint
Before the intervention and6 weeks after intervention

Method of measurement

Researcher-made standardized questionnaire

4

Description
Intention
Timepoint
Before the intervention and6 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
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Postal code
14336 71348
Phone
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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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Person responsible for scientific inquiries

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Associate Professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
fateme badiei
Position
Master Student of Health Education and Health Promotion
Latest degree
Master
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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