

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Study of The effect of educational smoking prevention program on smoking refusal self-efficacy of senior high school females

Protocol summary

Study aim

To increase refusal smoking self-efficacy with smoking prevention program in girl adolescents

Design

54 tenth grade girls in high school were chosen purposefully and a code was allocated to each one of them. Then, students were randomly divided into two control and intervention groups.

Settings and conduct

This experimental study is aimed to assess the effect of an educational program on refusal smoking self-efficacy in students. The target population includes 16-year-old students in the tenth grade in public senior high schools, Mashhad, Iran. Two schools with similar socioeconomic status (to be comparable) and from each, one class with at least 27 students will be selected. Then they will randomly be assigned to intervention and control groups. Then, for pre-test both groups will be asked to fill in the refusal smoking self-efficacy questionnaire. This pre-test is done to assess the comparability of the two groups and further adjustment if necessary. After that control group will continue having their ordinary educational program. However, the intervention group will take part in five 90 minute smoking preventive educational sessions, held in their schools and within five consecutive weeks. Instruction methods include lecture, group discussion, showing video, pamphlets, and role modelling with focus on short- and long-term harmful effect of smoking, as well as stress management, assertiveness, effective communication, and decision-making skills. The eight following activities are implemented in each session: (1) "Sharing experience/brainstorming" (discussion and brainstorm participant's self-knowledge and self-experience about smoking), (2) "Knowledge about smoking" (ingredients of cigarettes, short-term effects of smoking on body and health, long-term effects of smoking on body and health, increasing awareness about consequence of smoking to passive smokers or second-hand smokers and understanding of myth and

fact about smoking), (3) "Stress management for teenager" (stress management and lesson about stress, emotion experience, psychological stressor, strategies to handle stress situation, created positive mood and reduced stress in daily), (4) "Assertive communication and smoking refusal skill" (Training and role play to refuse cigarette offered by watching the video), enhancing awareness and motivate to refuse cigarette), (5) "Decision making skills" (Knowledge to make decision related to smoking behavior and practice decision making skill in group), .6)Role playing in situation that needs to say no.Four weeks after completion of intervention, both groups will be asked to fill in the refusal smoking self-efficacy questionnaire. The time frame of study was determined in accordance with the similar ones to increase the feasibility of the study. Data analysis will be done using Stata to see if there is a significant difference between two groups regarding the refusal smoking self-efficacy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- female students in grade 10 in governmental schools, exclusion criteria: 1- not having used smoke, 2- not having used psychiatric medicine

Intervention groups

the intervention group will take part in five 90 minute smoking preventive educational sessions, held in their schools and within five consecutive weeks. Instruction methods include lecture, group discussion, showing video, pamphlets, and role modelling with focus on short- and long-term harmful effect of smoking, as well as stress management, assertiveness, effective communication, and decision-making skills. The eight following activities are implemented in each session: (1) "Sharing experience/brainstorming" (discussion and brainstorm participant's self-knowledge and self-experience about smoking), (2) "Knowledge about smoking" (ingredients of cigarettes, short-term effects of smoking on body and health, long-term effects of smoking on body and health, increasing awareness about consequence of smoking to passive smokers or second-hand smokers and understanding of myth and fact about

smoking), (3) "Stress management for teenager" (stress management and lesson about stress, emotion experience, psychological stressor, strategies to handle stress situation, created positive mood and reduced stress in daily), (4) "Assertive communication and smoking refusal skill" (Training and role play to refuse cigarette offered by watching the video), enhancing awareness and motivate to refuse cigarette), (5) "Decision making skills" (Knowledge to make decision related to smoking behavior and practice decision making skill in group), (6) Role playing in situation that needs to say no.

Main outcome variables

Refusal smoking self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171016036814N1**

Registration date: **2018-02-11, 1396/11/22**

Registration timing: **retrospective**

Last update: **2018-02-11, 1396/11/22**

Update count: **0**

Registration date

2018-02-11, 1396/11/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 3006

Email address

rafieez2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2018-04-18, 1397/01/29

Actual recruitment start date

2017-11-01, 1396/08/10

Actual recruitment end date

2017-12-11, 1396/09/20

Trial completion date

empty

Scientific title

Study of The effect of educational smoking prevention program on smoking refusal self-efficacy of senior high school females

Public title

The effect of smoking prevention program on smoking refusal self-efficacy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female Had willingness to participate Had permission from the parents or guardians to join in the program Non-smoker

Exclusion criteria:

smoker Students with depression condition

Age

From **16 years** old to **16 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **27**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: simple, unit of randomization: school, method: of the two schools that are randomly selected, one will assigned to intervention and the other will be taken as control. this procedure will be done by Excel program. Concealment is not applicable to the present study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

No. 18, university Ave., mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9188615381

Approval date

2017-10-07, 1396/07/15

Ethics committee reference number

R.MUMS.REC.1396.167

Health conditions studied

1

Description of health condition studied

prevention of smoking in adolescents

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

smoking refusal self-efficacy

Timepoint

At the beginning of study, Four weeks after completion of intervention

Method of measurement

The self-efficacy scale for adolescents smoking by lawrence

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

The intervention group: the intervention group will take part in five 90 minute smoking preventive educational sessions, held in their schools and within five consecutive weeks. Instruction methods include lecture, group discussion, showing video, pamphlets, and role modelling with focus on short- and long-term harmful effect of smoking, as well as stress management, assertiveness, effective communication, and decision-making skills. The eight following activities are implemented in each session: (1) "Sharing experience/brainstorming" (discussion and brainstorm participant's self-knowledge and self-experience about smoking), (2) "Knowledge about smoking" (ingredients of cigarettes, short-term effects of smoking on body and health, long-term effects of smoking on body and health, increasing awareness about consequence of smoking to passive smokers or second-hand smokers and understanding of myth and fact about smoking), (3) "Stress management for teenager" (stress management and lesson about stress, emotion experience, psychological stressor, strategies to handle stress situation, created positive mood and reduced stress in daily), (4) "Assertive communication and smoking refusal skill" (Training and role play to refuse cigarette offered by watching the video), enhancing awareness and motivate to refuse cigarette), (5) "Decision making skills" (Knowledge to make decision

related to smoking behavior and practice decision making skill in group), .6)Role playing in situation that needs to say no.

Category

Prevention

2

Description

Control group: the control group receive no intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rahrovan Zienab high school

Full name of responsible person

Dr fatemeh heshmati nabavi

Street address

No. 25, Emamt Ave., mashhad Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

zienab Rafiee

Position

nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

fatemeh heshmati nabavi

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zeinab rafiee

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data except for identity information could be available to researchers

When the data will become available and for how long

six months after publishing the research paper

To whom data/document is available

Researchers

Under which criteria data/document could be used

research affairs

From where data/document is obtainable

Dr Fatemeh Heshmati Nabavi, Scientific responsible of the research project

What processes are involved for a request to access data/document

A research proposal which is approved by a formal

organization and is confirmed by Mashhad University of Medical Sciences and then correspondence with Dr Fatemeh Heshmati Nabavi, Scientific responsible of the

research project
Comments