

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Explaining the process of smoking in girls' adolescents, Implementing and evaluating this process to prevent cigarette smoking

Protocol summary

Study aim

Determining the effect of educational intervention program to preventive cigarette smoking on female high school students

Design

Based on the results of the qualitative part of the study, the study was designed and performed on 300 adolescent girls in two control groups (n=150) and intervention (n=150) without randomization and blindness. Data collection will be performed using a researcher-made questionnaire (valid and reliable) based on the results of the qualitative section. The data will be analyzed using SPSS statistical software version 22 using descriptive and inferential methods. Significant levels in all tests will be determined to be less than 0.05. The statistical population studied will be selected by a multi-stage sampling method. First, a list of all high school girls will be prepared, and then the samples will be randomly divided into two groups of intervention and control.

Settings and conduct

This study will be performed on female high school students in Mashhad.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The student is in the second grade of high school, resident of Mashhad, and willing to participate in the study. Exclusion criteria: Having one or more session absentee at training sessions, students who participated in the pre-test but were not present in the post-test, and changing their schools.

Intervention groups

In this intervention study, a training program on cigarette smoking was conducted for 4 sessions of 2 hours for students in the experimental group for a maximum of one month.

Main outcome variables

Determine the average score of students' preventive behaviors in relation to cigarette smoking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040559N5**

Registration date: **2020-06-19, 1399/03/30**

Registration timing: **prospective**

Last update: **2020-06-19, 1399/03/30**

Update count: **0**

Registration date

2020-06-19, 1399/03/30

Registrant information

Name

Alireza Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3851 4548

Email address

jafaria962@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-05-08, 1400/02/18

Actual recruitment start date

2020-08-09, 1399/05/19

Actual recruitment end date

2020-10-11, 1399/07/20

Trial completion date

2021-05-10, 1400/02/20

Scientific title

Explaining the process of smoking in girls' adolescents,
Implementing and evaluating this process to prevent
cigarette smoking

Public title

The effect of educational intervention program to
preventive cigarette smoking on female high school
students

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The student is in the second grade of high school
Resident of Mashhad Willing to participate in the study

Exclusion criteria:

Having one or more session absentee at training
sessions Students who participated in the pre-test but
were not present in the post-test Changing their schools

Age

From **15 years** old to **19 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Actual sample size reached: **300**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Mashhad university of medical sciences

Street address

School of Health, Daneshgah Avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Approval date

2019-08-03, 1398/05/12

Ethics committee reference number

IR.MUMS.REC.1398.153

Health conditions studied

1

Description of health condition studied

The preventive of cigarette smoking

ICD-10 code

305.1

ICD-10 code description

Tobacco use disorder

Primary outcomes

1

Description

The preventive cigarette smoking

Timepoint

One month after the meeting and after the test made by
questionnaire, the two groups will be measured

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, training
program was performed with 4 sessions of 120 minutes

Category

Prevention

2

Description

Control group: No intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Female high school

Full name of responsible person

Alireza Jafari

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School of Health, Daneshgah Avenue, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Alireza Jafari
Street address
School of Health, Daneshgah Avenue, Mashhad
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jafari.ar94@gmail.com
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
Alireza Jafari
Position
PhD student
Latest degree
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Other areas of specialty/work
Health Promotion
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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+98 51 3851 4548
Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Potential data is shareable after distinguishing people

When the data will become available and for how long

Start the access period one month after the publication of result

To whom data/document is available

Start the access period one month after the publication of result

Under which criteria data/document could be used

Researchers working in academia

From where data/document is obtainable

Data is sent through an official request and by email

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

Alireza Jafari: jafaria962@mums.ac.ir

Comments