

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Development and Effectiveness of cognitive, behavioral and social interventions on smoke use prevention (CIPS) among adolescents (15-19 Years Old) pirkakran city: a community-based Mixed method Study

Protocol summary

Study aim

Determination and comparison of mean scores of cognitive variables one and six months after the intervention - Determining and comparing the mean scores of social variables one and six months after the intervention - Determination and comparison of smoking behavior in adolescents one month and six months after the intervention

Design

Samples were categorized into two sexes and each category 2 high school and secondary school will consider as a cluster. The proportion of each school will determine by the sample size(73 persons). Since the samples studied one and six months after the intervention are not necessarily the same as those before the intervention (73 persons), the researcher and the other team members have no information about the sample.

Settings and conduct

The intervention is a community-based without a control group that will take about two months. Educational intervention in the form of a city-wide exhibition on the outcomes of smoking, sending educational messages, designing educational reference sites, holding paintings on the outcomes of smoking in schools, educational sessions, etc. for some adolescents and their parents.

Participants/Inclusion and exclusion criteria

Residing in Pirkakran, Adolescents age 15-19 years

Intervention groups

The intervention is a community-based without a control group that will take about two months. Educational intervention in the form of a city-wide exhibition on the outcomes of smoking, sending educational messages through social networks, establishing banners in the environment, designing educational reference sites, holding paintings on the outcomes of smoking in schools, educational sessions, etc.

Main outcome variables

using smoking, Outcome expectancy, Self-regulation, Self-efficacy, Self-esteem, Family and School Function

General information

Reason for update

Acronym

CIPS

IRCT registration information

IRCT registration number: **IRCT20200101045980N1**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

hajar rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3744 2638

Email address

h.rezaee@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-27, 1398/04/06

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Development and Effectiveness of cognitive, behavioral and social interventions on smoke use prevention (CIPS) among adolescents (15-19 Years Old) pirkakran city: a community-based Mixed method Study

Public title
Development and Effectiveness of cognitive, behavioral and social interventions on smoke use prevention (CIPS) among adolescents (15-19 Years Old): a community-based Mixed method Study

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Residing in Pirkakran city adolescents 15-19 Years Old
Exclusion criteria:
Questionnaires are incomplete

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **73**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
This study is a community-based study without a control group. All participants receive educational intervention directly and indirectly.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
First Floor., The Second Door., Left Hand Beside The

Aqueduct., Alley Hosseinieh., Main Ave., Bagh Abrisham., Abrisham City
City
Isfahan
Province
Isfahan
Postal code
8178963539
Approval date
2019-05-15, 1398/02/25
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.116

Health conditions studied

1

Description of health condition studied
smoking
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cigarette smoking behavior
Timepoint
Before intervention, one and six months after intervention
Method of measurement
research-made questionnaire

2

Description
Outcome expectancy in a research-made questionnaire from a Mixed Study
Timepoint
Before intervention, one and six months after intervention
Method of measurement
research-made questionnaire from a Mixed Study

3

Description
Outcome expectation in a research-made questionnaire from a Mixed Study
Timepoint
Before intervention, one and six months after intervention
Method of measurement
research-made questionnaire from a Mixed Study

4

Description
Self-regulation in a research-made questionnaire from a Mixed Study
Timepoint

Before intervention, one and six months after intervention

Method of measurement

research-made questionnaire from a Mixed Study

5

Description

Self-efficacy in a research-made questionnaire from a Mixed Study

Timepoint

Before intervention, one and six months after intervention

Method of measurement

research-made questionnaire from a Mixed Study

6

Description

Self-esteem in a research-made questionnaire from a Mixed Study

Timepoint

Before intervention, one and six months after intervention

Method of measurement

research-made questionnaire from a Mixed Study

7

Description

Family Function in a research-made questionnaire from a Mixed Study

Timepoint

Before intervention, one and six months after intervention

Method of measurement

research-made questionnaire from a Mixed Study

8

Description

School Function in a research-made questionnaire from a Mixed Study

Timepoint

Before intervention, one and six months after intervention

Method of measurement

research-made questionnaire from a Mixed Study

Secondary outcomes

empty

Intervention groups

1

Description

Educational intervention in the form of a city-wide exhibition on the outcomes of smoking, sending educational messages through social networks, drawing competitions on the consequences of smoking and secondhand smoke in schools, designing educational

reference websites, holding educational sessions. It will do for some adolescent and parents.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Pir Bakran City Schools

Full name of responsible person

Hajar Rezaei

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h.rezaee@hlth.mui.ac.ir

Web page address

http://nocigarette.blogfa.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Isfahan University of Medical Sciences., Hezar Jerib Ave

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Isfahan

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8174673461

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Email

research@mui.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hajar Rezaei
Position
PhD Candidate, Health Education and Health Promotion, Department of Health Education and Promotion
Latest degree
Master
Other areas of specialty/work
Health Promotion
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Person responsible for updating data

Contact

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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

Participants' data file, consent form, codes used in the analysis, data classification system, and statistical analysis plan will provide to the responsible persons if necessary for accuracy of the information and... The study protocol will publish as a rational model of

education to prevent smoking in adolescents The results of this study and the clinical trial report will publish in the form of an article.

When the data will become available and for how long

From the second half of the year 1399

To whom data/document is available

Research committees and responsible for the journal to verify the results of the study

Under which criteria data/document could be used

- Considering the development of the questionnaire the use of this questionnaire in future studies - the use of interventions to prevent smoking in adolescents

From where data/document is obtainable

E-mail the Research Committees and the journal responsible for the validity of the study results

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

Valid e-mail-related research organizations

Comments