

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect of Educational Program Based on Theory to reduce hookah smoking among High Schools Male Students in Hamadan City: Exploratory Mixed Method Design

Protocol summary

Summary

This study is a randomized controlled trial. The aim of this study will be to determine the effect of educational programs designed to reduce hookah smoking among high school male students in Hamadan. Design: in the first stage, using quantitative and qualitative methods, a needs assessment will be to reduce hookah smoking of behavioral problems students. According to the results of the needs assessment, 2 schools with high prevalence of hookah have identified and randomly assigned to experimental and control groups. Blinding the study was done only for students. Setting and conduct: In the intervention stage production of educational material tailored to the culture and characteristics of the target population as well as the intervention stage is based on active learning and the educational intervention to try to ensure that hookah smokers actively in the training program have activities teaching-learning with their contribution to the brand. Exclusion Criteria: to use of tobacco in the last month, High Schools Male Students (ninth, tenth and eleventh grade). Outcome measure: assess will be for effectiveness of interventions related between the intervention and control groups for determine expected outcomes in two three periods before, immediately and three months after intervention. The primary outcome is the reduction of hookah smoking among students.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042333592N1**

Registration date: **2017-05-14, 1396/02/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-14, 1396/02/24

Registrant information

Name

Hamid Abasi

Name of organization / entity

Hamadan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 81 3254 9481

Email address

h.abasi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan university of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Educational Program Based on Theory to reduce hookah smoking among High Schools Male Students in Hamadan City: Exploratory Mixed Method Design

Public title

The effects of intervention program to reduce hookah smoking among students

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: to use of tobacco in the last month, High Schools Male Students (ninth, tenth and eleventh grade), lack of physical or mental illness and the participants and their parents are happy to participate in the intervention. Exclusion criteria for this study include the absence of training sessions for participants twice as well when completing the questionnaire, immediately and 3 months after the training program are not available.

Age

From **14 years** old to **18 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 the Hamadan University of Medical Science

Street address

Martyr Fahmideh Street, Hamadan University of Medical Science

City

Hamadan

Postal code

6517838736

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.UMSHA.REC.1396.21

Health conditions studied

1

Description of health condition studied

Nicotine Dependence

ICD-10 code

F17.2

ICD-10 code description

Dependence- due to - tobacco

Primary outcomes

1

Description

Frequency of Water pipe smoking use

Timepoint

Before the Study, Immediately after intervention and 3 Months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Constructs of combined health education and health promotion model

Timepoint

Before study, Immediately the intervention and Three Months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention for the intervention group consisted of: Perform educational program during two sessions, distribute educational booklet, Follow-up and evaluation for 2 months to reduce the use of Water Pipe smoking and completing the questionnaire before intervention, Immediately after intervention and 3 months after intervention.

Category

Behavior

2

Description

Intervention in the control group: The control group did not receive. Contemporary, the experimental group completed the questionnaire 3 times.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

The first and second grades high schools male

Full name of responsible person

Hamid Abasi

Street address

Hamadan University of Medical Science

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- Chancellor of Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Vice- Chancellor of Research and Technology,
Hamadan University of Medical Sciences

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice- Chancellor of Research and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Science

Full name of responsible person

Hamid Abasi

Position

PhD Student of Health Education and Health
Promotion

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty