

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of education in the regard of the secondhand smoke on smoker men on the exposure of their pregnant wives

Protocol summary

The number of cigarettes that women have been exposed to it, The Cotinine saliva in pregnant women;

Study aim

Determine the effect of training on secondhand smoke in smoker men on the exposure of their pregnant wives

Design

140 smoker men who have a pregnant wife are divided randomly into two groups of intervention and control. In the pre-test stage, the questionnaires were completed, and the number of cigarettes that pregnant women encountered during a week have been questioned. Then the educational program is given to the members of the intervention group. After two months and in the post-test stage, the questionnaires were completed again and the number of cigarettes that pregnant women encountered for a week have been questioned. In addition, the sample of saliva in pregnant women is taken in order to measure the amount of cotinine in it.

Settings and conduct

Participants are smoker men who have a pregnant wife and are referred to health centers in Isfahan. The tool used is the researcher- made questionnaire on knowledge, attitude, and practice of smoker men. The number of cigarettes that women have been exposed to it and Salivary cotinine in pregnant women is measured.

Participants/Inclusion and exclusion criteria

Entry: Smoker men who have a pregnant wife, and have consumed at least one cigarette around the pregnant wife
Non-arrival: 1. The smoker men who are not at home for more than one week, 2. Termination of the pregnancy

Intervention groups

Intervention group: smoker men who have a pregnant wife and receive the educational program, that includes an educational pamphlet on the regard of the secondhand smoke, as well as 8 short messages, which will be sent as a reminder via a mobile phone, and a photo of a fetus in smoke with one sentence that demands from his father to please do not smoke.

Main outcome variables

The knowledge, attitude and practice of smoker men,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040555N1**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Zohreh Karimiankakolaki

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3336 1047

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education in the regard of the secondhand smoke on smoker men on the exposure of their pregnant wives

Public title

Design, implementation, and evaluation of the educational programs about secondhand smoke in smoker men on the exposure of their pregnant wives

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All smoker men who have a pregnant wife The men who smoke at least one cigarette daily beside their pregnant wives

Exclusion criteria:

The smoker men who are not with their pregnant wives for more than one week Termination of the pregnancy.

Age

From **15 years** old to **49 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling based on the table of random numbers

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 Shahid Sadoughi University of Medical Sciences, Yazd

Street address

School of Public Health, Daneshjou Blvd, Alem Square

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Postal code

8915173160

Approval date

2017-12-20, 1396/09/29

Ethics committee reference number

IR.SSU.SPH.REC.1396.133

Health conditions studied**1****Description of health condition studied**

Exposure to secondhand smoke in pregnant women

ICD-10 code

Z58.7

ICD-10 code description

Exposure to tobacco smoke

Primary outcomes**1****Description**

The mean score of knowledge, attitude, and practice of smoker men toward the secondhand smoke

Timepoint

Before the intervention and two months after the end of intervention

Method of measurement

Researcher-made Questionnaire of Knowledge, Attitude and Practice of Smoker Men

2**Description**

The number of cigarettes that pregnant women are exposed to it over a week

Timepoint

Before the intervention and two months after the end of intervention

Method of measurement

question

3**Description**

Saliva cotinine levels in pregnant women after the end of intervention

Timepoint

two months after the end of intervention

Method of measurement

kit Saliva cotinine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: smoker men who have a pregnant wife and receive the educational program. The educational program includes an educational pamphlet on the regard of the secondhand smoke that will be given to the members of the intervention group as well as 8 short messages, which will be sent as a reminder via a mobile phone, and a photo of a fetus in smoke with one sentence that demands from his father to please do not smoke in order to be exposed to men.

Category

Behavior

2

Description

Control group: Smoking men have a pregnant wife who does not take the training program

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Health Centers of Isfahan

Full name of responsible person

Zohreh Karimian Kakolaki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

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Dr Masoud Mirzaei

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd 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

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Person responsible for general inquiries

Contact

Name of organization / entity
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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable