

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of education based on health belief model of men on pregnant women's tobacco smoke exposure level

Protocol summary

Summary

The harmful effects of tobacco smoke exposure on health of mothers and fetuses are documented and the aim of this double blind experimental study is evaluation of the effect of education, based on health belief model, to men on smoker men's health belief and the level of pregnant women's tobacco smoke exposure. The target population is smoker men in Rafsanjan. Having pregnant wife is the inclusion criteria. After random sampling the sixty men allocate in intervention and control group. In the intervention group the face to face education based on health belief model about the harms of tobacco smoke on the health of mother and fetus will be offered. In the intervention group the education based on health belief model about the harms of tobacco smoke on the health of mother and fetus will be offered. In control group the education about the personal and social benefits of benefit of cigarette smoke quitting will be offered. the duration of education is 45 minute for each person. Before, immediately and 6 week after education the level of health belief constructs will be measured . Also, before education and 6 week after education the level of pregnant women's tobacco smoke exposure will be evaluated. during study all participants and questioner will be blinded about the name of groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706142857N5**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on health belief model of men on pregnant women's tobacco smoke exposure level

Public title

The effect of education of men on pregnant women's tobacco smoke exposure

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: men; smoker exclusion criteria: lack of contact with cigarette smoke among their wife

Age

No age limit
Gender
Male
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Isfahan university of Medical Sciences

Street address

Isfahan university of Medical Sciences

City

Isfahan

Postal code

Approval date

2015-05-22, 1394/03/01

Ethics committee reference number

IR.MUI.REC.1393.3.678

Health conditions studied

1

Description of health condition studied

tobacco smoke exposure

ICD-10 code

Z58.7

ICD-10 code description

Exposure to tobacco smoke

Primary outcomes

1

Description

Health belief constructs

Timepoint

before intervention

Method of measurement

filling questionnaire

2

Description

the level of pregnant women's tobacco smoke exposure

Timepoint

before intervention, 6 week after intervention

Method of measurement

filling questionnaire

Secondary outcomes

1

Description

health belief constructs

Timepoint

immediately and 6 week after intervention

Method of measurement

filling questionnaire

2

Description

pregnant women's tobacco smoke exposure level

Timepoint

6 weeks after intervention

Method of measurement

filling questionnaire

Intervention groups

1

Description

Control group: The education about personal and social health benefits of quitting smoking

Category

Lifestyle

2

Description

Intervention group: The education based on health belief mode about harmful effect of tobacco smoke exposure on health of mothers and fetuses

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center in Rafsanjan

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical sciences

Full name of responsible person

Shahnaz Kohan

Street address

Isfahan University of Medical sciences.

City

Isfahan

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

Yes

Title of funding source

Isfahan 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

Isfahan University of medical Sciences

Full name of responsible person

Ashraf Kazemi

Position

PhD

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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