Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Reduction of Secondhand Smoke Exposure in Healthy Infants

Protocol summary

Summary

This study, a two group randomized controlled trial, investigates whether an intervention for parents would persuade them to enforce smoking bans inside the home and in other locations. A total of 130 parents with children aged 12 months or younger will be recruited. Each group (n=65) will complete a baseline and follow up questionnaire. Urine samples from the infants will be collected to measure the amount of cotinine, a metabolite of nicotine. The parent-report and infant's urinary cotinine measures will be obtained at baseline and at a 3-month follow-up. In the intervention group, parents will be given three counseling sessions. For mothers, one being face to face and two telephone counseling and for fathers we will conduct three telephone counseling. The control group receives no intervention. Both groups will also complete a Fagerstrom test for nicotine dependence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801171791N1**
Registration date: **2009-08-08, 1388/05/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-08-08, 1388/05/17

Registrant information

Name

Azam Baheiraei

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 21 6692 7171

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2008-06-21, 1387/04/01

Expected recruitment end date

2009-06-01, 1388/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Reduction of Secondhand Smoke Exposure in Healthy Infants

Public title

Reduction of Secondhand Smoke Exposure in Healthy Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Families with healthy infants under 12 months of age, the infant resides with at least one smoking parent, parents being able to speak Persian and having a telephone Exclusion criteria: Parent(s) reporting consumption of other addictive substances, parent(s) in smoking cessation treatment

Age

To **1 year** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **130**
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

1

Registry name
The U.S. National Institues of Health
Secondary trial Id
NCT00821639
Registration date
2009-01-11, 1387/10/22

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences and Health Services
Street address
Tehran University of Medical Sciences and Health Services
City
Tehran
Postal code
15745-1453
Approval date
empty
Ethics committee reference number
6870

Health conditions studied

1

Description of health condition studied
Effect of intervention on smoker parents on home, car and outside of home and car smoking bans status and Infant's urinary cotinine levels
ICD-10 code
Z58.7
ICD-10 code description
Passive smoking

Primary outcomes

1

Description
Home smoking bans status
Timepoint
3 months
Method of measurement
Face to face interview; questionnaire consists of three parts, demographic characteristic, home situation and smoking situation

Secondary outcomes

1

Description
Car smoking bans status
Timepoint
3 months
Method of measurement
Face to face interview

2

Description
Parental cigarette consumption
Timepoint
3 months
Method of measurement
Face to face interview

3

Description
Infant's urinary cotinine levels
Timepoint
3 months
Method of measurement
The urine will be analyzed in laboratory of the Tarbiat Modarres University

Intervention groups

1

Description
Counseling sessions, one face to face counseling for both parents, two telephone counseling for mother and three telephone counseling for father and an educational pamphlet and a sticker
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Ayat child health center affilliated with Tehran

University of Medical Sciences and Health se

Full name of responsible person

Dr Kianoosh Kiaei

Street address

In front of Shariati park, Shariati street, Shariati city, behind padegan Ghale morghi

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Dr Azam Baheiraei

Street address

Tehran University of Medical Sciences and Health Services

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences and Health Services

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

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Full name of responsible person

Dr Azam Baheiraei

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Assistant Professor, MPH in Health Promotion, 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