

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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)

##### Phone

+98 21 6692 7171

##### Email address

baheiraei@tums.ac.ir

##### 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 Institutes 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 affiliated 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

**Phone**  
+98 21 6692 2221 ext. 292  
**Fax**  
+98 21 6690 4252  
**Email**  
abaheiraei@gmail.com  
**Web page address**

## 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**  
Tehran University of Medical Sciences and Health  
Services  
**Full name of responsible person**  
Dr Azam Baheiraei  
**Position**  
Assistant Professor, MPH in Health Promotion, PhD  
**Other areas of specialty/work**  
**Street address**  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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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*