Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of a Theory- based educational intervention to change air pollution exposure behaviors among pregnant women

Protocol summary

Summary

Objective: The aim of this study is to evaluate a Theory-based educational intervention to change air pollution preventive behaviors among pregnant women in Tehran. Design: A controlled clinical trial Setting: Prenatal care services in Tehran. Participants and eligibility criteria: 104 women with singleton pregnancy, 18-35 years old, gestational age less than 36 weeks and pregnancy without any complication will classified into intervention and control groups, randomly. Intervention: A Transtheoretical Model (TTM)-based educational program consisted of three components: one- session motivational interviewing, a pamphlet and daily Short Message Service (SMS). The intervention will be implemented for intervention group; after one-month, follow up the data will be gathered through standard questionnaires. Main outcome variables: Constructs of TTM; the stages of change, self-efficacy and perceived benefits and barriers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091010804N1**
Registration date: **2012-10-25, 1391/08/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-10-25, 1391/08/04

Registrant information

Name

Marzieh Araban

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

تهران

Email address

m.araban@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tarbiat Modares University

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-11-27, 1391/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of a Theory- based educational intervention to change air pollution exposure behaviors among pregnant women

Public title

Evaluation of a Theory- based educational intervention to change air pollution exposure behaviors among pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Main inclusion criteria: singleton pregnancy؛ maternal age age between 18-35 years old؛ gestational age less than 36 weeks؛ uncomplicated pregnancy Main exclusion criteria:complicated pregnancy (Preeclampsia؛ gestational hypertension؛ gestational diabetes؛ preterm labor؛ bleeding)

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Tarbiat Modares University

Street address

South east Gisha bridge, Tarbiat Modares University, number 1 building

City

Tehran

Postal code

1411713116

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

5271065

Health conditions studied

1

Description of health condition studied

behavioral intervention for pregnant women

ICD-10 code

O94-O99, O

ICD-10 code description

Other obstetric conditions, not elsewhere classified, Maternal care related to the fetus and amniotic cavity and possible delivery problems

Primary outcomes

1

Description

TTM constructs(including: perceived benefits and barriers, stage of change and self-efficacy)

Timepoint

1 month

Method of measurement

questionnaire

Secondary outcomes

1

Description

none

Timepoint

none

Method of measurement

none

Intervention groups

1

Description

The intervention consisted of three components: one-session motivational interviewing, a pamphlet and daily Short Message Service (SMS).

Category

Behavior

2

Description

Control group will receive routine prenatal care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Najmiyeh hospital

Full name of responsible person

Marzieh Araban

Street address

Hafez- Jomhouri cross section, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tarbiat Modares University

Full name of responsible person

Seddigheh sadat Tavafian

Street address

Number 1 building,Tarbiat Modares University, south east Gisha bridge,Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tarbiat Modares University

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Seddigheh sadat Tavafian

Position

Ph.D, Associate proffesor

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