

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluating the Effectiveness of Pregnant Women Empowerment Program on Elements of Empowerment and Their Satisfaction of Prenatal Cares.

#### Protocol summary

##### Summary

Objective: to investigate the effectiveness of pregnant women empowerment program on elements of empowerment and their satisfaction of prenatal cares.

Design : a clinical trail with an intervention group (group antenatal care) and a control group (traditional antenatal care). The sample size: the total number of samples by using of OpenEpi software, and related article was chosen 70 person. In each group will be 35 person. The sampling is easy And allocation of sampels in each intervention and control groups will be randomly.

Participation: potential participants for either group have to be healthy pregnant women, without medical or obstetric complications of pregnancy, between the ages 18 and 35, and Iranian person. Those who do not fit these criteria are excluded. Method: the empowerment program abolishes routine prenatal care by bringing women out of examination rooms and into groups for their care\_ risk assessment, education , and support\_ into one entity. Women are placed into groups of 8 to 9 based on estimated dates of delivery and meet for five 120-minute prenatal visits at regular intervals that begin when women are 13 weeks pregnant, and end when women are 36 weeks pregnant. In each session women measure their own blood pressure, weight themselves and record these results in their charts. Then, women are taken individually to a corner of the group room for fundal and fetal heart tone checks. During this time, each woman has the opportunity to build community with other pregnant women, learn self-care skills, get assurance about the progression of her pregnancy, and gain knowledge about pregnancy, birth, and parenting.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138904142248N5**

Registration date: **2011-12-31, 1390/10/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-12-31, 1390/10/10

##### Registrant information

###### Name

Fereshteh Jahdi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

00982188773073,00982182471404

###### Email address

f.jahdi@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran university of Medical Science

##### Expected recruitment start date

2011-12-26, 1390/10/05

##### Expected recruitment end date

2012-07-22, 1391/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the Effectiveness of Pregnant Women Empowerment Program on Elements of Empowerment and Their Satisfaction of Prenatal Cares.

##### Public title

Effectiveness of Pregnant Women Empowerment Program on Their Empowerment and Satisfaction.

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

Criteria for entry into the study: 1- Iranian- pregnant women 2- Women with gestational age age 13 weeks. 3- Without known physical and mental illnesses. 4- Ages 18 to 35 years. 5- Able for reading and writing. 6- Singleton pregnancy. 7- If she has a history of childbirth, natural childbirth. Exclusion criteria from the study: 1- During the study, mothers who are involved in adverse events such as death of loved ones. 2- During the study, mothers who are involved by complication of pregnancy such as: Abortion, hypertension, toxemia of pregnancy, gestational diabetes, intrauterine fetal death, premature labor. 3- Mothers who don't desire to continue. 4- Mothers who didn't attend at least in two sessions of training sessions.

### **Age**

From **18 years** old to **35 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **70**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Single

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Tehran university of medical science

##### **Street address**

keshavarz boulevard

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2011-12-24, 1390/10/03

#### **Ethics committee reference number**

1796

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

normal pregnancy

#### **ICD-10 code**

z34.8

#### **ICD-10 code description**

supervision of other normal pregnancy

## **Primary outcomes**

### **1**

#### **Description**

pregnant women empowerment

#### **Timepoint**

36 gestational age

#### **Method of measurement**

pregnant women empowerment questionair

## **Secondary outcomes**

### **1**

#### **Description**

saticfaction of care

#### **Timepoint**

36 gestational age

#### **Method of measurement**

Adams and litelfild saticfaction questionnaire

## **Intervention groups**

### **1**

#### **Description**

in the intervention group, prenatal care and education will be held in five group session. each session is 120 minutes which has two parts. care part is 30 minutes that will be done by pregnant women who already have learned how to measure weight and vital signs. education part is 90 minutes that will be done into group discusion.

#### **Category**

Other

### **2**

#### **Description**

There is not any intervention in control group. care and education to be done individually.

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

**Name of recruitment center**  
Prenatal clinic, Akbarabadi Hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Tehran

**City**  
kerman  
**Postal code**  
**Phone**  
+98 34 1321 9886  
**Fax**  
**Email**  
mahinbalouchi@ymail.com  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran university of medical science, vice chancellor  
for research  
**Full name of responsible person**  
Dr. Akbar Fotuhi  
**Street address**  
khods street, keshavarz boulevard  
**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 science, vice chancellor for  
research  
**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 science, school of  
midwifery and nursing  
**Full name of responsible person**  
Mahin Balouchi Mahani  
**Position**  
Master of midwifery  
**Other areas of specialty/work**  
**Street address**  
Vali asr Alley ,south sheikh Ahmad kaffi street

#### Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Tehran university of medical science, school of  
midwifery and nursing  
**Full name of responsible person**  
Fereshte Jahdi  
**Position**  
Master of midwifery  
**Other areas of specialty/work**  
**Street address**  
Tohid squar, school of midwifery and nursing  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 2242 6076  
**Fax**  
**Email**  
jahdi\_fr@yahoo.com  
**Web page address**

#### Person responsible for updating data

##### Contact

#### 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*