

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of education of foetal movement counting on maternal-fetal attachment in primiparous women

#### Protocol summary

##### Summary

Objectives: The aim of this study was to determine the effect of fetal movement counting education on maternal fetal attachment in Iranian primigravida women. Study design: This clinical trial study was conducted in two intervention and control groups. Setting and conduct: Selective sampling was done on the base of major inclusion criteria in Isfahan selected health care centers. Then selected subjects were randomly assigned into control and intervention groups. Intervention: In addition to prenatal care, Intervention group was taught to count their fetal movement after consuming breakfast for 30 minutes in left lateral position for 1 month from 24 weeks of pregnancy. In the control group, the usual education about prenatal care and fetal movements were done. Main outcome measure: At the beginning and end of the study, both groups completed the fetal attachment questionnaire. The main outcome of this study was the maternal fetal attachment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201610183936N2**

Registration date: **2016-11-27, 1395/09/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-27, 1395/09/07

##### Registrant information

##### Name

Kobra Salehi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 33 4243 2929

##### Email address

k\_salehi@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2014-04-29, 1393/02/09

##### Expected recruitment end date

2014-09-01, 1393/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of education of foetal movement counting on maternal-fetal attachment in primiparous women

##### Public title

The effect of education of foetal movement counting on maternal-fetal attachment

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Major eligibility criteria: Iranian women; first time pregnancy; being 18-35 years old; Having Literacy; having no medical problem during pregnancy or a history of mental disorders; normal pregnancy without use of ART; singleton pregnancy and gestational age between 22-20 weeks Major exclusion criteria: life threatening event during last 6 months; pregnancy with assisted reproductive treatment; multiple pregnancy; substances

abuse before and during pregnancy

### Age

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

### Gender

Female

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **50**

### 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

Isfahan University of Medical Sciences, Ethics Committee

##### Street address

Hezar Jerib St, Isfahan

##### City

Isfahan

##### Postal code

##### Approval date

2014-09-23, 1393/07/01

##### Ethics committee reference number

293259

## Health conditions studied

### 1

#### Description of health condition studied

emotional relationship between mother and fetus

#### ICD-10 code

O99.3

#### ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

## Primary outcomes

### 1

#### Description

Maternal fetal attachment

#### Timepoint

before and after intervention

#### Method of measurement

Cranly Maternal fetal attachment questionnaire

## Secondary outcomes

### 1

#### Description

Effect of fetal movement counting education on receiving prenatal care

#### Timepoint

Before and After intervention

#### Method of measurement

Assessment of prenatal care folder

## Intervention groups

### 1

#### Description

Control: In the control group, the usual education about prenatal care and fetal movements were done.

#### Category

N/A

### 2

#### Description

Intervention: In addition to prenatal care, Intervention group was taught to count their fetal movement after consuming breakfast for 30 minutes in left lateral position for 1 month from 24 weeks of pregnancy.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amirieh Health Care Center

##### Full name of responsible person

Kobra Salehi

##### Street address

Amirieh Health Care Center, 4 th St, Amirieh Valley, Isfahan

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Vice Council of Research

**Full name of responsible person**

Dr Nematbakhsh M.

**Street address**

Isfahan University of Medical Sciences, Vice Council of Research, Hezar Jerib St, Isfahan

**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, Vice Council of 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**

Isfahan University of Medical Sciences, Nursing and Midwifery School, Midwifery and Reproductive Health

**Full name of responsible person**

Kobra Salehi

**Position**

PHD student of Reproductive Health

**Other areas of specialty/work**

**Street address**

Hezar Jerib St, Isfahan

**City**

Isfahan

**Postal code**

**Phone**

+98 31 5243 2929

**Fax**

**Email**

k\_salehi@nm.mui.ac.ir; salehik1364@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Isfahan University of Medical Sciences, Nursing and Midwifery School, Midwifery and Reproductive Health

**Full name of responsible person**

Kobra Salehi

**Position**

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## Person responsible for updating data

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**Name of organization / entity**

Isfahan University of Medical Sciences, Nursing and Midwifery School, Midwifery and Reproductive Health

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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*