

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of Self-efficacy based Consultation on the fear of childbirth among nulliparous women

#### Protocol summary

##### Summary

The aim of this study is the effects of self-efficacy-based consultation on fear of childbirth of nulliparous women. Doing Interviews with pregnant women with gestational ages 28 to 30 weeks and Explaining the purpose of the study if they would like will be invited . All participants will complete fear of childbirth questionnaires . To choose samples, the cases related to women with qualification entrance of this study were investigated and to select the test and control group will be used Random permutation block method. In this research, the related population comprises of nulliparous pregnant women referred to health and care centers of Tuyserkan city. Inclusion criteria of the study: first pregnancy, planned pregnancy, the lack of medical and and gynecological problems based on medical records, gestational age 28 to 30 weeks of pregnancy, the literacy . Exclusion criteria of the study: have any risk medical conditions in pregnancy during the study, not participation in more than one training session . The sample size included 53 people in the experimental group and 53 people in the control group. In the test group, the necessary training will be done during 6 sessions by a researcher using lecture , and educational pamphlets. The main outcome variable in the study is the fear of childbirth.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015101623640N4**  
Registration date: **2016-06-01, 1395/03/12**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-01, 1395/03/12

#### Registrant information

##### Name

Farzaneh Soltani

##### Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 813220683

##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research and technology of Hamadan University of Medical Sciences

#### Expected recruitment start date

2015-10-23, 1394/08/01

#### Expected recruitment end date

2016-02-20, 1394/12/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of Self-efficacy based Consultation on the fear of childbirth among nulliparous women

#### Public title

The effect of consultation on the fear of childbirth among nulliparous women

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: first pregnancy; wished pregnancy; the lack of medical and gynecological problem based on medical records; gestational age 28 to 30 weeks of the

pregnancy; literacy. Exclusion criteria: have any risk medical conditions in pregnancy during the study; not participate in more than one training session.

#### **Age**

No age limit

#### **Gender**

Female

#### **Phase**

N/A

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

No information

#### **Sample size**

Target sample size: **106**

#### **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**

Hamadan University of Medical Sciences

##### **Street address**

Shahid Fahmideh Avenue

##### **City**

Hamedan

##### **Postal code**

6516845977

#### **Approval date**

2015-09-26, 1394/07/04

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

IR.UMSHA.REC.1394.303

### **Health conditions studied**

#### **1**

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

The relationship Self-efficacy based Consultation with fear of childbirth among nulliparous

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

P96.8

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

Other specified conditions originating in the perinatal period

### **Primary outcomes**

#### **1**

#### **Description**

Fear of childbirth

#### **Timepoint**

Before and after the intervention

#### **Method of measurement**

Childbirth Attitude Questionnaire(CAQ)

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

#### **Description**

Groups: the experimental group trained for 5 groups of 11-10 people in 6 sessions, each session lasting 45 to 60 minutes, will be taught. Training topics: The first session: Understanding the Physiology and Anatomy female reproductive system, vaginal and cesarean delivery difference in the second session: exposure to successful experiences available through the target, thereby, increasing the possibility of achieving performance In the third session, verbal persuasion and encouragement for successful performance. In the fourth session, adding experience successor pregnant women, the fifth session: providing alternative ways of dealing with irrational beliefs and rational thoughts . Sixth session: increasing the vital strength enhancing physiological arousal through sports program and muscle relaxation training will be. In this case, educational leaflets will be available to experimental group.

#### **Category**

Lifestyle

#### **2**

#### **Description**

control group: In order to regard the ethical principles in the control group, after the completion of training, they will be given educational pamphlet.

#### **Category**

Prevention

### **Recruitment centers**

#### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Health Network tuserkan

##### **Full name of responsible person**

Zahra Eskandari

##### **Street address**

Tuserkan city

##### **City**

Tuserkan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeed Bashirian

**Street address**

School of Nursing and Midwifery, Vice chancellor for research and technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan

**City**

Hamedan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Farzaneh Soltani

**Position**

PhD in Reproductive Health / Education, School of Nursing and Midwifery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Zahra Eskandari

**Position**

Bachelor of Midwifery, Master student of Midwifery Counselling

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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*