

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### The effect of individual consultation on the reduced fear of childbirth among nulliparous women

#### Protocol summary

##### Summary

Objectives: The effect of an individual- based consultation program on the fear of childbirth of nulliparous women Design: A clinical trial on 96 pregnant women attended Setting and conduct: A clinical trial on 96 pregnant women attended in health centers of Mashhad in order to investigate Major Inclusion and Exclusion criteria: citizenship of Iran, age of 18-35, the first pregnancy, total score of 38-84 in Wijma Fear Questionnaire, version A. Intervention: Intervention group: Three consultation sessions of 45-60 minutes will be conducted once two weeks during weeks 28-30, 30-32, and 32-34 of pregnancy. Control group: The control group will be under usual cares of health center. The fear of childbirth will be evaluated and compared again during weeks 34-36 of pregnancy main outcome measures: The fear of childbirth.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016042827653N1**

Registration date: **2016-09-02, 1395/06/12**

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

Last update:

Update count: **0**

##### Registration date

2016-09-02, 1395/06/12

##### Registrant information

###### Name

Nafise Androun

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3501 2534

##### Email address

androunn931@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice President of Research Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-03-02, 1394/12/12

##### Expected recruitment end date

2017-01-01, 1395/10/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

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

##### Public title

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

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: the Iranian 18-35 years old women from Mashhad who show their informed consent to participate in this study: to have (herself or one of his family members) a phone number to contact ; 26-28th Gestational week based on EDC or sonography; singleton pregnancy; 5th grade of education or more; low-risk pregnancy; and their total score of Wijma Fear Questionnaire:version A is 38-84. Exclusion criteria : the past or present clinical disease;; past or present mental illness; taking special medications influencing on the

mother's mind; rug abuse or taking narcotics:psychotropic or ecstasy drugs and alcohol drinking:unpleasant or stressor events during the past 6 months before the study:history of infertility:score higher than 29 in Beck Depression Questionnaire and or cases requiring referral to a psychiatrist:score greater than 29 in Beck Anxiety Questionnaire and or cases requiring referral to a psychiatrist: speech: hearing or accent disorders which inhibit establishment a relationship between researcher and subject:obvious embryonic disorders in sonography test of the first three months of pregnancy:score higher than 85 in Wijma Fear Questionnaire and or cases requiring referral to a Psychiatrist

**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: **96**

**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 Mashhad University of Medical Sciences

**Street address**

Mashhad University of Medical Sciences, Daneshgah Street, Mashhad, Khorasan Razavi, Iran

**City**

Mashhad

**Postal code****Approval date**

2016-03-02, 1394/12/12

**Ethics committee reference number**

IR.MUMS.REC.1394.720

**Health conditions studied****1****Description of health condition studied**

fear

**ICD-10 code**

F40.2

**ICD-10 code description**

Phobias restricted to highly specific situations such as proximity to particular animals, heights, thunder, darkness, flying, closed spaces, urinating or defecating in public toilets, eating certain foods, dentistry, or the sight of blood or injury. Though

**Primary outcomes****1****Description**

fear of childbirth

**Timepoint**

weeks 28-30 of pregnancy and then weeks 34-36

**Method of measurement**

Wijma Fear Questionnaire, Version A

**Secondary outcomes****1****Description**

choosing childbirth method

**Timepoint**

weeks 28-30 and 34-36 of pregnancy

**Method of measurement**

Question

**2****Description**

attitude toward childbirth

**Timepoint**

weeks 28-30 of pregnancy and then weeks 34-36

**Method of measurement**

Question

**3****Description**

conflict in decision making

**Timepoint**

weeks 28-30 of pregnancy and then weeks 34-36

**Method of measurement**

Question

**4****Description**

self efficacy of choosing delivery method

**Timepoint**

weeks 28-30 of pregnancy and then weeks 34-36

**Method of measurement**

Question

## 5

### **Description**

social support

### **Timepoint**

weeks 28-30 of pregnancy and then weeks 34-36

### **Method of measurement**

Question

## 6

### **Description**

depression

### **Timepoint**

weeks 28-30 of pregnancy and then weeks 34-36

### **Method of measurement**

questionnaire bek

## 7

### **Description**

anxiety

### **Timepoint**

weeks 28-30 of pregnancy and then weeks 34-36

### **Method of measurement**

questionnaire bek

## **Intervention groups**

## 1

### **Description**

The intervention group will be administered individual face to face consultation by the researcher based on the content of the consultation model in addition to usual care. Intervention will be performed through three sessions (45-60 minutes) every two weeks based on the mothers reference days to healthcare center during weeks 28-30, 30-32 and 32-34. Then, during weeks 34-36 of pregnancy questionnaires will be completed again by intervention and control.

### **Category**

Behavior

## 2

### **Description**

Control group will be administered by usual cares of the healthcare center. Then, during weeks 34-36 of pregnancy questionnaires will be completed again by intervention and control.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

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

Daneshamooz healthcare center

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

Mrs. Moradi

### **Street address**

Daneshamooz Street, Vakilabad Blvd, Mashhad, Khorasan Razavi, Iran.

### **City**

Mashhad

## 2

### **Recruitment center**

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

: Najafi healthcare center

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

Mrs. Bakhshi

#### **Street address**

: Khaqani 4, Piroozi 18, Piroozi Blvd. Mashhad, Khorasan Razavi, Iran

#### **City**

Mashhad

## 3

### **Recruitment center**

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

Rezashahr

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

Mrs. Tavakkol

#### **Street address**

Khaqani 10, Khaqani Street, Rezashahr Street

#### **City**

Mashhad

## 4

### **Recruitment center**

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

Ab & Bargh

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

Mrs. Ramezani

#### **Street address**

Villa Street, 7th Tir Blvd. Vakilabad Blvd

#### **City**

Mashhad

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Mashhad University of Medical Sciences

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

Dr. Mohsen Tafaghodi

#### **Street address**

Research Vice President of Mashhad University of Medical Sciences Daneshgah Street

#### **City**

Mashhad

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Mashhad 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**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Nafise Andaroun  
**Position**  
Master of counseling in midwifery  
**Other areas of specialty/work**  
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**Email**  
androunn931@mums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

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Masome kordi  
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## Person responsible for updating data

### Contact

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nafise androun  
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**Email**  
androunn931@mums.ac.ir  
**Web page address**

## 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*