

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Clinical trial comparing the effectiveness of desensitization integration in preparation for childbirth classes to pregnant women anxiety that participate in regular classes in preparation for childbirth

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effectiveness of the integration of systematic desensitization of anxiety in pregnant women for childbirth preparation classes. This study, consultation on 76 patients (38 patients per group) of nulliparous mothers attending antenatal classes 22Bahman Hospital in the city Gonabad 20th week of pregnancy will be done. This randomized study with a control group without blinding done. How to target qualified individuals and how the study will be explained. The four blocks are divided in two groups and the informed consent form is completed. Inclusion criteria consisted of: Causing the first being about 20 weeks gestational age, age between 20 and 35 years, the same anxiety (STAL score of 20 to 69 in Scale anxiety, including anxiety is mild to moderately severe), lack of medical-surgical diseases ( Blood pressure, diabetes), No history of psychiatric or mental illness, and the normal healthy fetus in the first trimester graphic examination (without any fetal abnormalities, the normal location of the placenta, normal cervical length). No apparent obstacles for normal delivery at the time of sampling, any contraindications to vaginal delivery, having the symptoms of threatened abortion, have at least read and write, singleton pregnancy, non-smoking, drugs and alcohol, single spouse, Lack of recurrent miscarriage and infertility. Exclusion criteria: absence of more than two sessions, moved, and the unavailability of pregnant women and pregnancy termination for any reason before the end of counseling, the creation of any indication for cesarean delivery. The sample size for each group of 30 is estimated. Including 20 percent chance of attrition number of samples in each group of 38 people considered to be. In addition to participating in the intervention group mothers in childbirth preparation classes for eight sessions is that desensitization techniques used in the class also will (That include

relaxation training in first 4 sessions are completely if the mother is unable to properly use this approach to the next stage And the last four sessions that are related to desensitization techniques). Control group will attend classes in preparation for childbirth. Desensitization sessions in the intervention group for subgroups will be 4 to 6 persons. This parallel sessions and will integrate in its class content done. Finally, using the Spielberger anxiety in two groups compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016060428240N1**

Registration date: **2016-06-16, 1395/03/27**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-06-16, 1395/03/27

##### Registrant information

###### Name

Fatemeh Yaghoobi Moghadam Bilondi

###### Name of organization / entity

Shahroud University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3239 4499

###### Email address

yaghoobi@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

University of Medical Sciences Shahroud

**Expected recruitment start date**

2016-06-21, 1395/04/01

**Expected recruitment end date**

2016-11-21, 1395/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial comparing the effectiveness of desensitization integration in preparation for childbirth classes to pregnant women anxiety that participate in regular classes in preparation for childbirth

**Public title**

Antenatal classes on pregnancy anxiety, desensitization integration in nulliparous women

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria consisted of: Causing the first being about 20 weeks gestational age, age between 20 and 35 years, the same anxiety (Business forget of 20 to 69 in Scale anxiety, including anxiety is mild to moderately severe), lack of medical-surgical diseases ( Blood pressure, diabetes),No history of psychiatric or mental illness, and the normal healthy fetus in the first trimester graphic examination (without any fetal abnormalities, the normal location of the placenta, normal cervical length).No apparent obstacles for normal delivery at the time of sampling, any contraindications to vaginal delivery, having the symptoms of threatened abortion, have at least read and write, singleton pregnancy, non-smoking, drugs and alcohol, single spouse, Lack of recurrent miscarriage and infertility. Exclusion criteria: absence of more than two sessions, moved, and the unavailability of pregnant women and pregnancy termination for any reason before the end of counseling, the creation of any indication for cesarean delivery.

**Age**From **20 years** old to **35 years** old**Gender**

Female

**Phase**

2

**Groups that have been masked***No information***Sample size**Target sample size: **76****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****1****Registry name**

-

**Secondary trial Id**

-

**Registration date**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the University of Medical Sciences anymore

**Street address**

Central building of Shahroud University of Medical Sciences, "Tir" Square,Shahroud.Semnan.

**City**

Shahroud

**Postal code**

3614773955

**Approval date**

2016-04-12, 1395/01/24

**Ethics committee reference number**

IR.SHMU.REC.1395.17

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

Anxiety

**ICD-10 code**

f41

**ICD-10 code description**

Other anxiety disorders

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

Anxiety

**Timepoint**

Before intervention, 4 months after treatment

**Method of measurement**

Spielberger questionnaire

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

Behavior change  
**Timepoint**  
Before intervention.Delivery time  
**Method of measurement**  
Information delivery

## Intervention groups

### 1

**Description**  
In the intervention group, in addition to previous training in preparation for childbirth classes given Desensitization in the course of the fifth to the eighth session done.

**Category**  
Behavior

### 2

**Description**  
In the control group of mothers in childbirth preparation classes according to their past.

**Category**  
Behavior

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Health centers in Gonabad University of Medical Sciences  
**Full name of responsible person**  
Fateme yaghoobi moghadam bilondi  
**Street address**  
Gonabad university of medical sciences.Gonabad  
**City**  
Gonabad

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Vice Chancellor for research; Shahroud University of Medical Sciences  
**Full name of responsible person**  
Dr Mohammadhasan Emamian  
**Street address**  
Central building of Shahroud University of Medical Sciences," Tir" Square,Shahroud.  
**City**  
Shahroud  
**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; Shahroud 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**  
Shahroud university of medical sciences  
**Full name of responsible person**  
Fateme yaghoobi moghadam bilondi  
**Position**  
Master science of student counseling midwiferys  
**Other areas of specialty/work**  
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**Web page address**

## Person responsible for scientific inquiries

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Afsaneh keramat  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahroud university of medical sciences

**Full name of responsible person**

Fateme yaghoobi moghadam bilondi

**Position**

Master science of student counseling midwiferys

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**Fax****Email**

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**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*