

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Effectiveness of Cognitive-Behavioral Group Therapy focused on Self-esteem on Fear of Childbirth in Nulliparous women

#### Protocol summary

##### Summary

The number of the women who want to have a cesarean due to the fear of childbirth has increased. Cognitive Behavioral Therapy (CBT) seems to be a good method to overcome or reduce the fear of childbirth. This study was aimed at determining the effectiveness of CBT on the primary fear of childbirth among nulliparous women in a random environment. The inclusion criteria were low-risk pregnancy and the fear of childbirth score  $\geq 28$ . The exclusion criteria were the lack of cooperation, perinatal death or stillbirth during pregnancy, referral or treatment for other problems which the research participants faced, and severe anxiety and depression. This study is a clinical trial consisting of 24 nulliparous women. The fear of childbirth was assessed using the Childbirth Attitudes Questionnaire (CAQ). Nulliparous women with low-risk pregnancies who were in the second trimester of pregnancy and their fear of childbirth score was  $\geq 28$  were randomly placed into two groups (case and control). Each group included 12 members. The case group underwent 8 cognitive-behavioral group therapy sessions, and the control group received routine pregnancy care. In this study, the intervention method used to control the fear of childbirth in nulliparous women was a cognitive-behavioral group therapy focused on self-esteem, which was held in eight 90-minute sessions. Each group therapy session had a specific structure. Two weeks after the last session of group therapy, the Childbirth Attitudes Questionnaire was filled out by the female participants, and the results were compared with each other. The primary outcome of this study was reducing fear of childbirth among nulliparous women in terms of the score obtained from the Childbirth Attitudes Questionnaire.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120920259N1**

Registration date: **2015-07-29, 1394/05/07**

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

Last update:

Update count: **0**

##### Registration date

2015-07-29, 1394/05/07

##### Registrant information

###### Name

maryam pourjandaghi

###### Name of organization / entity

arak university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4495 0786

###### Email address

m.pourjandaghi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2015-07-11, 1394/04/20

##### Expected recruitment end date

2015-08-11, 1394/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of Cognitive-Behavioral Group Therapy focused on Self-esteem on Fear of Childbirth in Nulliparous women

**Public title**

Effect of Cognitive-Behavioral Group Therapy focused on Self-esteem on Fear of Childbirth in Nulliparous women

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criterias: fill out the form of informed consent; eighteen to thirty five years old; high school diploma; single pregnancy; nulliparity; gestational age is twenty to twenty four weeks; low risk pregnancy and normal BMI; lake of depression and anxiety according to the Beck questionnaire; not using psychiatric drugs; childbirth fear score is 28 or more; self -esteem score is lower than zero; wanted pregnancy and no history of infertility; non-family conflicts. Exclusion criteria: willingness to participate in the other treatment and non-cooperation; continuous absence in cognitive behavioral therapy sessions; not fill out the follow-up questionnaire; perinatal death or stillbirth.

**Age**

From **76 years** old to **59 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**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**

Arak University of Medical Sciences

**Street address**

Sardasht Avenue, Basij Square, Arak, Markazi Province, Iran

**City**

Arak

**Postal code**

38481-7-6941

**Approval date**

2015-03-16, 1393/12/25

**Ethics committee reference number**

93-176-7

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

Fear of childbirth

**ICD-10 code**

F40

**ICD-10 code description**

Phobic anxiety disorders A group of disorders in which anxiety is evoked only, or predominantly, in certain well-defined situations that are not currently dangerous. As a result these situations are characteristically avoided or endured with dread. The pa

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

Fear of childbirth

**Timepoint**

Before intervention; two weeks after intervention

**Method of measurement**

Childbirth attitude questionnaire

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

Self-esteem

**Timepoint**

Before intervention; two weeks after intervention

**Method of measurement**

Rosenberg self-esteem questionnaire

**Intervention groups****1****Description**

The control group receive routine antennal care

**Category**

N/A

**2****Description**

The intervention group attend eight cognitive-behavioral therapy sessions. The intervention method is cognitive behavioral group therapy focused on self-esteem. Eight group sessions is held during second trimester. Each ninety minutes session has a certain structure

**Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Milad hospital

**Full name of responsible person**

maryam pourjandaghi, senior student of consultation in midwifery

**Street address**

Milad hospital, Before Chamran Bridge, Hemmat Expressway, Tehran, Iran

**City**

tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Catayon Vakilain, phd of reproductive health, Assistant professor Of Arak University Of Medical Sci

**Street address**

Sardasht Avenue, Basij Square, Arak, Markazi Province, Iran

**City**

Arak

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Catayon Vakilian

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Phd of reproductive health

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

maryam pourjandaghi

**Position**

Senior student of consultation in midwifery

**Other areas of specialty/work**

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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*