Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 ≥ 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 ≥ 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)

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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 questionaire

Secondary outcomes

1

Description
Self-esteem
Timepoint
Before intervention; two weeks after intervention
Method of measurement
Rosenberg self-esteem questionaire

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 Vkilain, 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
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Person responsible for updating data

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maryam.pourjandaghi@arakmu.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