Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Cognitive behavior therapy based on self-management on the fear, anxiety and delivery outcome in nulliparous women

Protocol summary

Summary

The number of the women who want to have a cesarean due to the fear and anxiety of childbirth has increased. And on the other hand, based on the studies, there is relation between fear and anxiety during pregnancy and outcome childbirth. Cognitive Behavioral Therapy (CBT) seems to be a good method to overcome or reduce the fear and anxiety of childbirth. This study was aimed at determining the effect of Cognitive behavior therapy with a With a Focus on self-care on fear, anxiety and delivery outcome in nulliparous women. The inclusion criteria are the pregnant women 28-30 w, age 18 to 35, with no history of congenital malformations, singleton pregnancy, without the background of the disease, no history of infertility, The ability to read and write, fear score higher than 85 and finally anxiety higher than 25 , no indication for cesarean delivery. Exclusion criteria consisted of: Stillbirth, prenatal death, Known mental illness, not wanting to continue the study, pregnant women, and the risk of pregnancy poisoning, drugs that can cause symptoms of depression. This study is a clinical trial consisting of 64 nulliparous women. The fear of childbirth will assess using the Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ). And anxiety of childbirth will assess using BAI anxiety questionnaire. The samples randomly will divide into two groups (case and control). Each group included 32 members. The intervention group will receive eight sessions of cognitive behavioral therapy with a focus on self-care and control group will received prenatal care. During labor the fear and anxiety score groups will evaluate using questionnaires fear and anxiety, and Birth outcomes in both groups will record. And finally fear and anxiety scores and delivery outcomes will compare in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082429506N1**
Registration date: **2016-09-20, 1395/06/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-20, 1395/06/30

Registrant information

Name

Sakineh Ghalehkhani Safat

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Science Dr Behzad Sharif Makhmal - - Golestan Blvd, Ahvaz Jundishapur University of Medical Science Ahvaz Khuzestan Iran, Islamic Republic Of 15794-61357 00986133738071 - - http://www.ajums.ac.ir ; research@ajums.ac.ir

Expected recruitment start date

2016-08-06, 1395/05/16

Expected recruitment end date

2016-10-07, 1395/07/16

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Cognitive behavior therapy based on self- management on the fear, anxiety and delivery outcome in nulliparous women

Public title
The effect of Cognitive behavior therapy with a based on self- management on fear, anxiety and delivery outcome in nulliparous women
Purpose
Treatment
Inclusion/Exclusion criteria
The inclusion criteria are the pregnant women 28-30 w, age 18 to 35, with no history of congenital malformations, singleton pregnancy, without the background of the disease, no history of infertility, The ability to read and write, fear score higher than 85 and finally anxiety higher than 25 , no indication for cesarean delivery. Exclusion criteria consisted of: Stillbirth, prenatal death, Known mental illness, not wanting to continue the study, pregnant women, and the risk of pregnancy poisoning, drugs that can cause symptoms of depression
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: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomized using random numbers generated by the computer

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Department of Research and Information Technology University of Medical Sciences, Ahvaz Jundishapour, Ground Floor, City University
City
Ahvaz
Postal code
Iran
Approval date
2016-07-19, 1395/04/29
Ethics committee reference number
IR.AJUMS.REC.1395.260

Health conditions studied

1

Description of health condition studied
Fear and anexiety of childbirth
ICD-10 code
f40
ICD-10 code description
Fear and anexiety of childbirth

Primary outcomes

1

Description
Anxiety of childbirth
Timepoint
Before intervention, in labor
Method of measurement
BAI questionnaire

2

Description
Fear of childbirth
Timepoint
Before intervention, in labor
Method of measurement
Wijma Delivery Expectancy/Experience Questionnaire(W-DEQ)

Secondary outcomes

1

Description
Satisfaction of labor process
Timepoint
Postpartum
Method of measurement
Self made Questionnaire

2

Description
Labor pain
Timepoint
In labor
Method of measurement
Scal vaz

3

Description
Duration of delivery
Timepoint
In labor
Method of measurement
Self made Questionnaire,observation

4

Description
Induction of delivery
Timepoint
In labor
Method of measurement
Self made Questionnaire,observation

5

Description
Type of delivery
Timepoint
During childbirth
Method of measurement
Self made Questionnaire,observation

6

Description
Apgar score
Timepoint
Postpartum
Method of measurement
Self made Questionnaire,observation

Intervention groups

1

Description
The intervention group attends eight cognitive-behavioral therapy sessions. The intervention method is cognitive behavioral group therapy with a based on self-care. Eight group sessions is held during third trimester. Each 45 minutes session has a certain structure
Category
Behavior

2

Description
The control group only received prenatal care
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
East's number one health center in Ahvaz
Full name of responsible person
Sakineh Ghalehkhani safat
Street address
Ayatollah Behbahani superhighway,7 tir park opposite
City
Ahvaz

2

Recruitment center
Name of recruitment center
East's number two health center in Ahvaz
Full name of responsible person
Sakineh Ghalehkhani safat
Street address
Asiabad,Street Number Eight
City
Ahvaz

3

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Sakineh Ghalehkhani safat
Street address
Amanyeh
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahvaz JundiShapur University of Medical Sciences
Full name of responsible person
Dr Behzad Sharief Makhmal
Street address
Ahvaz Jundishapur University of Medical Sciences, opposite the central building, Vice Chancellor for Research, Ahvaz University of Medical Sciences
City
Ahvaz
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, Ahvaz JundiShapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sakineh Ghalehkhani safat

Position

Student Master of consultation in Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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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