

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 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

Country

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

AgeFrom **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 Jundishapur,
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**Street address**

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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