Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Gonabad20th 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)

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Recruitment status

Recruitment complete

Funding source

University of Medical Sciences Shahrood

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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Afsaneh keramat

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Person responsible for updating data

Contact

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f.yaghoobi.m@gmail.com;yaghoobi@shmu.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