

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The Effect of group educations based on Cognitive-Behavioral Techniques on fear of childbirth in primiparous mothers,

#### Protocol summary

##### Study aim

Determine the effect of group training based on cognitive-behavioral techniques on fear of of Childbirth in Nulliparous Women

##### Design

Field trial with one control group and two parallel intervention groups

##### Settings and conduct

This study will be done at health centers in Gorgan city. Nulliparous mothers with a FOB score higher than 55, based on mother tendency to participate in training sessions were divided into intervention and control groups. The women in the intervention group who had tendency to participation in training class were randomly assigned to two subgroups. The first intervention group passed eight sessions of pregnancy training class and the second intervention group passed eight sessions of cognitive behavioral therapy education, and control groups were people who didn't Participation receive any training.

##### Participants/Inclusion and exclusion criteria

Nulliparous Women aged 18 to 35 years old! Gestational age 20 to 28 Week! The desire to participate in the study! Medium fear of birth score (55 and more)

##### Intervention groups

The first intervention group will pass the traditional pregnancy training programs. The second intervention group, will pass eight sessions of 90 minute weekly cognitive behavioral therapy. The third groups don't have any educational sessions.

##### Main outcome variables

fear of Childbirth

#### General information

##### Reason for update

Change in date and number of realized sampling and random assignment was not done due to ethical consideration and assigned two groups (intervention

,control) based on Personal desire

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171026037015N3**

Registration date: **2018-06-16, 1397/03/26**

Registration timing: **retrospective**

Last update: **2021-06-27, 1400/04/06**

Update count: **3**

##### Registration date

2018-06-16, 1397/03/26

##### Registrant information

###### Name

Houri Alijani

###### Name of organization / entity

Golestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3243 0360

###### Email address

alijani@goums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Golestan University of Medical Sciences, Faculty of Nursing, Midwifery of Boyeh

##### Expected recruitment start date

2017-11-16, 1396/08/25

##### Expected recruitment end date

2018-06-15, 1397/03/25

##### Actual recruitment start date

2017-11-16, 1396/08/25

##### Actual recruitment end date

2018-05-15, 1397/02/25

##### Trial completion date

2018-05-15, 1397/02/25

## Scientific title

The Effect of group educations based on Cognitive-Behavioral Techniques on fear of childbirth in primiparous mothers,

## Public title

The Effect of group educations based on Cognitive-Behavioral Techniques on fear of childbirth in primiparous mothers

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

low risk Nulliparous Women ages between 18 to 35 years old Gestational age between 20 to 28 weeks The desire to participate in the study Score questionnaire 55 and above

### Exclusion criteria:

Participate in psychological training classes

## 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: **108**

Actual sample size reached: **104**

## Randomization (investigator's opinion)

Not 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

Ethics Committee of Golestan University of Medical Sciences

##### Street address

Hirkan Blvd., The Shast kola Ave., Deputy of research and technology., Golestan University of Medical Sciences., Gorgan Town

##### City

Gorgan city

##### Province

Golestan

##### Postal code

4934174515

##### Approval date

2017-10-17, 1396/07/25

##### Ethics committee reference number

IR.GOUMS.REC.1396.143

## Health conditions studied

### 1

#### Description of health condition studied

The effect of group educations based on Cognitive-Behavioral Techniques on fear of childbirth in primiparous mothers

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

fear of birth

#### Timepoint

Before of the intervention and 8 week after intervention

#### Method of measurement

WDEQ (Wijma Delivery Expectancy, Experience Questionnaire)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first Intervention group: Includes nulliparous pregnant mothers who passed routine pregnancy training. These training was conduct in eight weekly sessions and in accordance with the Ministry of Health protocol in group of 6 to12 pregnant mothers and includes the first session; anatomy and physiology, common complaints during pregnancy, second session; nutrition, third session; personal and mental health, fourth session; Signs of danger during pregnancy, fifth session; planning for delivery, cesarean or normal vaginal delivery, Solutions for reducing labor pain, Sixth Session; Maternal actions during childbirth , The seventh session; postpartum care and the eighth session; neonatal care and lactation. Each session consisted of 45 minutes of theory training, half an hour of exercise and 20 minutes of relaxation.

#### Category

Behavior

### 2

#### Description

The second Intervention group: Includes nulliparous pregnant women who passed cognitive behavioral training. These training was conducted in eight weekly sessions, according to the Wijma 2017 protocol, pregnant mothers will be trained in groups of 5 to 7 mothers. Content of the first session: the first trimester of natural pregnancy, welcome, an overview of the rules and regulations of group counseling sessions, meet the members together, ask questions, the uncertainties and concerns of members about group meetings and consultants guidance, assessing the goals and expectations of members from counseling sessions, an attempt to create a safe and consensual space with the aim of accelerating the change process. Content of the second session: natural pregnancy In the second trimester, teaching ABCDE concepts in cognitive behavioral approach, listing fears, concerns and anxieties associated with pregnancy and childbirth, identifying methods to deal with anxiety situations and thoughts, feelings and behaviors associated with it, provides psychological information about the nature of anxiety and fear and how to Body responses when anxiety occurs. The content of the third session includes: natural third trimester pregnancy, self control exercises (scanning your thoughts, feelings and behaviors in anxious situations), respiratory retraining training, relaxation training (calming). The content of the fourth and fifth sessions includes: natural delivery, relief of pain, preparation and start of the training of controlling the anxious thoughts through Cognitive Restructuring Techniques (Such as: disaster, thinking stopping technique, and pay attention) and positive self reflection. The content of the sixth session includes: the first and second stages of normal delivery, internal exposure, with the aim of consciously and deliberately creating anxiety emotions to reject false evaluations of these feelings and silence of anxiety response. Contents of the 7th session: labor and natural delivery, critical situations of internal exposure with the aim of consciously and deliberately creating anxious emotions to reject false evaluations of these feelings and silence of anxiety response. Content of the 8th session: labor and natural delivery of the third stage, identification of factors that may be barrier the effectiveness of treatment, solutions for the relapse of fear, concerns and anxieties, describing individuals from their expectations of labor and delivery imminent, summarizing the content presented in the meetings.

**Category**

Behavior

**3**

**Description**

Control group: The pregnant Women who do not participate in any educational classes.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Health centers of Gorgan city

**Full name of responsible person**

Houri Alijani

**Street address**

Kalantari 13., Shahid Rajaei Ave., Gorgan Health Center , Gorgan Town

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Honarvar

**Street address**

Shast kola Ave., Hirkan Blvd., Deputy of research and technology., Golestan University of Medical Sciences., Gorgan Town

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**Email**

info@goums.ac.ir

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Gorgan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

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borghei@goums.ac.ir

**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Houri Alijani

**Position**

Master's student in midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Shast kola Ave., Hirkan Blvd., Faculty of Nursing  
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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Houri Alijani

**Position**

Master's student in midwifery counseling

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Narjes Sadat Borghei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive health

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Midwifery., Golestan University of Medical Sciences.,  
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4913815739

**Phone****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Information on the main outcome or the like can be shared.

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Data will be available to researchers working in academic and academic institutions

**Under which criteria data/document could be used**

The data will be available for scientific research with reference to the research. In order to access the data, they can reply to the person's email address.

**From where data/document is obtainable**

responsible person's email address: Hourii Alijan

alijani@goums.ac.ir alijani1349@gmail.com

**What processes are involved for a request to access data/document**

Applicants can respond to the email of the respondent and receive a response within a week.

**Comments**

If you do not reply to the first email address, please send a second email.