

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effectiveness of group counseling with a solution- focused approach on childbirth fear, pregnancy, anxiety and cesarean preference in women participating in physiologic delivery training classes

#### Protocol summary

##### Study aim

The purpose of the study was to determine the effect of group counseling with a solution- focused approach on childbirth fear, pregnancy anxiety, and cesarean preference in women participating in physiologic delivery training classes in Mobini hospital in 1398

##### Design

A randomized controlled trial is conducted on 132 pregnant women with 28 weeks of gestational age referred to physiologic delivery training classes in Mobini hospital. Samples are selected through convenience sampling and randomly allocated to two test (66 people) and control (66 people) groups. The data will be collected using a demographic characteristics checklist, Wijma fear of childbirth questionnaire (version A) and pregnancy anxiety before and after intervention.

##### Settings and conduct

This study will be conducted on pregnant women referring to physiologic delivery training classes in the Mobini hospital of Sabzevar city. Participants will be randomly assigned into two groups of counseling and control through block randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 28-36; Willingness to participate in research; Have reading and writing skills; First pregnancy; Age range 18-45; Single pregnancy; Wanted pregnancy  
Non entry criteria: Chronic disease such as heart disease, hypertension, diabetes mellitus; History of abortion; Bleeding; Placenta previa; Use of certain drugs; Mental illness during the last year; Drug addiction and cigarette smoking

##### Intervention groups

In the intervention group, group counseling with a solution- focused approach runs in four, 90-minute sessions starting from the 28th week to the 36th week of pregnancy. The control group, only attend in physiologic delivery training classes in Mobini hospital

#### Main outcome variables

Fear of childbirth; Cesarean preference; Pregnancy anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170827035934N3**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **prospective**

Last update: **2019-05-09, 1398/02/19**

Update count: **0**

##### Registration date

2019-05-09, 1398/02/19

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4466 9189

##### Email address

maryammehrabady@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2020-01-21, 1398/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The effectiveness of group counseling with a solution-focused approach on childbirth fear, pregnancy, anxiety and cesarean preference in women participating in physiologic delivery training classes

**Public title**  
The effectiveness of group counseling solution- focused on childbirth fear, pregnancy, anxiety and cesarean preference

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Gestational age 28-36; Willingness to participate in research; Have reading and writing skills; First pregnancy; Age range 18-45; Single pregnancy; Wanted pregnancy  
**Exclusion criteria:**

Chronic disease such as heart disease, hypertension, diabetes mellitus; History of abortion; Use of certain drugs; Bleeding; Placenta Previa; Mental illness during the last year; Drug addiction and cigarette smoking

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  

- Data analyser

**Sample size**  
Target sample size: **132**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization will be conducted using the website www.random.org and through blocking with block sizes of six and an allocation ratio of 1: 1 to the two groups of counseling and control

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this study, statistician was blinded. He analyzed the data while he did not know the assignment of patients to the groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

##### Street address

Campus of the University of Medical Sciences, after Grave of Unknown Martyrs, Tohid Shahr boulevard

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

#### Approval date

2019-03-17, 1397/12/26

#### Ethics committee reference number

IR.MEDSAB.REC.1397.119

## Health conditions studied

### 1

#### Description of health condition studied

Fear of Childbirth

#### ICD-10 code

F40.8

#### ICD-10 code description

Other phobic anxiety disorder

### 2

#### Description of health condition studied

cesarean preference

#### ICD-10 code

O82

#### ICD-10 code description

Single delivery by caesarean section

### 3

#### Description of health condition studied

pregnancy anxiety

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Fear of Childbirth

#### Timepoint

Before intervention, after intervention

#### Method of measurement

Wijma fear of childbirth questionnaire, A version

## Secondary outcomes

### 1

#### Description

childbirth method selection

#### Timepoint

Before intervention, after intervention

#### Method of measurement

childbirth method selection questionnaire

### 2

#### Description

Anxiety pregnancy

#### Timepoint

Before intervention, after intervention

#### Method of measurement

Anxiety pregnancy questionnaire

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, group counseling with a solution- focused approach are performed in the form of four ninety-minute sessions ranging from 28 weeks to 36 weeks of gestation.

#### Category

Prevention

### 2

#### Description

For the control group, only delivery training classes will be held.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

physiologic delivery training classes in Sabzevar  
Mobini hospital

##### Full name of responsible person

Maryam Mehrabadi

##### Street address

Unit One, No. 30, Farhangian 10 Alley, Farhangian  
Avenue

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9618745111

##### Phone

+98 51 4466 9189

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Dr Fereshteh Ghorat

##### Street address

Campus of the University of Medical Sciences, after  
Grave of Unknown Martyrs, Tohid Shahr boulevard

##### City

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##### Province

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##### Postal code

9613873136

##### Phone

+98 51 4401 1300

##### Email

info@medsab.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sabzevar 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

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Maryam Mehrabadi

##### Position

MSc in Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

Unit One, No 30, Farhangian10 Alley, Farhangian  
Avenue

##### City

Sabzevar

##### Province

Razavi Khorasan  
**Postal code**  
9618745111  
**Phone**  
+98 51 4466 9189  
**Email**  
maryammehrabady@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Forough Mortazavi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery  
**Street address**  
Campus of the University of Medical Sciences, after  
Grave of Unknown Martyrs, Tohid Shahr boulevard  
**City**  
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**Province**  
Razavi Khorasan  
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frmortazavi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sabzevar University of Medical Sciences  
**Full name of responsible person**  
Maryam mehrabadi  
**Position**  
MSc in Midwifery  
**Latest degree**  
Master

**Other areas of specialty/work**  
Midwifery  
**Street address**  
Unit One, No 30, Farhangian10 Alley, Farhangian  
Avenue  
**City**  
Sabzevar  
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Razavi Khorasan  
**Postal code**  
9618745111  
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+98 51 4466 9189  
**Email**  
maryammehrabady@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Data of participants are privacy.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

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

The results of clinical study will be published as article.

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

Immediately after publishing the results.

### To whom data/document is available

All researchers

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

Scientific using with citation to article.

### From where data/document is obtainable

Email: frmortazavi@yahoo.com

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

Maximum one week after the communication by email.

### Comments