

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

maryammehrabady@gmail.com

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
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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr Fereshteh Ghorat

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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

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Unit One, No 30, Farhangian10 Alley, Farhangian
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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
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Person responsible for updating data

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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