

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of cognitive behavioral group counseling on self efficacy of pregnant women to choose normal vaginal delivery compared with routine pregnancy care program.

Protocol summary

Summary

Objectives: This study aimed to determine the effect of cognitive behavioral group counseling approach on self-efficacy in pregnant women for choosing of natural childbirth. Design: single blinded trial. Setting and conduct: in this study, 60 women that will be candidate for physiological delivery, after a filling a informed consent, allocate in two groups according to a permuted block randomization method. Major inclusion and exclusion criteria: women who have not had the experience of labor and delivery, and are candidate for physiological childbirth. Intervention: group counseling with cognitive-behavioral approach, for three weeks. Every session will be implemented with 6 till 10 subjects weekly. Intervention will conducted with participation of a physiatrist, psychologist and a consultant midwife. The control group will receive the routine prenatal care in health centers. Main outcome measures variables: a standard self-efficacy questionnaire were designed with the researcher and were validated in another study. This questionnaire will complete by both groups, before and after of intervention, again in the last month of pregnancy (39 weeks of pregnancy). We will expect, after the counseling sessions, pregnant women be able to choose the type of delivery with their own informed choices.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015063022983N1**

Registration date: **2016-02-03, 1394/11/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-03, 1394/11/14

Registrant information

Name

Farideh Ghasemi

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive behavioral group counseling on self efficacy of pregnant women to choose normal vaginal delivery compared with routine pregnancy care program.

Public title

The effect of counseling on self efficacy of pregnant

women to choose normal vaginal delivery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Pregnant women without experience of a childbirth, 15 until 49 years olds, no history of infertility, candidates for physiological delivery, womens with no experience of any underlying physical illness or complications in pregnancy, no history of mental illness in pregnancy, women with at least primary education level, Pregnant women in their third trimester of pregnancy, urban pregnant women, be not a participants of childbirth preparation classes, without any embryonic disease and had not decided for type of delivery.
Exclusion criteria: pregnant women who have experienced childbirth, women who are not candidates for physiological delivery.

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahroud University of Medical Sciences

Street address
Central Building of Shahroud University of Medical Sciences, Hafte-Tir Square

City
Shahroud

Postal code
3614773955

Approval date
2015-06-20, 1394/03/30

Ethics committee reference number
IR.SHMU.REC.1394.41

Health conditions studied

1

Description of health condition studied
Selfefficacy

ICD-10 code
094099

ICD-10 code description
094099

Primary outcomes

1

Description
Self efficacy of selecting vaginal delivery

Timepoint
Before intervention, after intervention, 39 week of gestational age

Method of measurement
Self efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital

Full name of responsible person
Ghasemi farideh

Street address
Zanjan Province , Khodabandeh city , Amiralmomenin Hospital

City
Khodabandeh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Ghasemi farideh

Street address
No. 3 , Alley haghghat , Imam Khomeini Ave

City
Khodabandeh

Grant name

Grant code / Reference number

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

Title of funding source
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
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Position
MSc Midwifery counselling

Other areas of specialty/work

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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