

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of couples counseling based on problem solving approach on the childbirth fear, childbirth self-efficacy and the choice of the type of delivery in primigravid women requesting elective cesarean section

Protocol summary

Summary

The participants of the study will be couples applying for Caesarean section in private clinics in Zanjan city. With some arrangements with the research deputy and a number of gynecologists, we will seek their cooperation, thus private clinics will provide us a list of phone numbers belonging to pregnant women qualified for the study purposes. A number of female participants will be selected using convenient sampling, and consequently the researcher will contact them in order to convince them to participate in the study. All qualified women for the study who are willing to participate will be categorized with randomized blocked method into control and intervention groups. The intervention will be in the form of a problem-solving consultation with couples for 3 sessions, once a week. Instructional booklets, membership in telegram channels of child delivery guide, and relevant guidance text-messages will be used to attract more cooperation on the part of the couples. The study instrument will include of demographic information, awareness, attitude, delivery mode selection, delivery phobia as well as low child-delivery self-efficacy scale and Wijma delivery expectancy- experience questionnaire. In both intervention and control groups, all questionnaires will be given to the mothers and the fathers. They will be asked to complete the awareness and attitude questionnaires in a self-report manner once in the beginning and once after the one-month intervention. The delivery type will be checked after birth via a phone call. The results of the study will be compared between the two groups through both parametric and non-parametric tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060828352N1**

Registration date: **2016-08-22, 1395/06/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-22, 1395/06/01

Registrant information

Name

Roghieh Kharaghani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8144

Email address

r.kharaghani@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Chancellor for Research and Technology of Zanjan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of couples counseling based on problem solving approach on the childbirth fear, childbirth self-efficacy and the choice of the type of delivery in primigravid women requesting elective cesarean section

Public title

The effect of couples counseling based on problem solving approach on the childbirth fear, childbirth self-efficacy and the choice of the type of delivery in primigravid women requesting elective cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Being primigravida; No history of infertility based on mother's report; Singleton pregnancies; Being in 28 to 32 weeks of pregnancy based on the first day of the last menstrual period or sonographic assessment before 12 weeks of gestation; Lack of any obstetric complications in the current pregnancy according to mother's report (preeclampsia, gestational diabetes, placenta previa, etc.); Not participation in the counseling classes at the same time; No indication for cesarean delivery; Lack of a history of physical and mental diseases in couples based on mother's report (hypertension, diabetes, using psychiatric drugs, history of hospitalization for various reasons ...); Complete satisfaction for participation in the study. Exclusion criteria: any abnormal condition before the onset of labor which prevents the normal delivery such as bleeding and placental abruption (premature separation of the placenta from the uterine wall); Difficult or impossible access to participant because of changing the living place; Lack of consent to continue participation in the study.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 76

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

A randomized blocked design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

North Side Azadi Boulevard

City

Zanjan

Postal code

Approval date

2016-07-09, 1395/04/19

Ethics committee reference number

ZUMS.REC.1395.103

Health conditions studied

1

Description of health condition studied

Elective cesarean

ICD-10 code

082.0

ICD-10 code description

Delivery by elective caesarean section

2

Description of health condition studied

Single spontaneous delivery

ICD-10 code

080.0

ICD-10 code description

cases with minimal or no assistance, with or without episiotomy delivery in a completely normal case

Primary outcomes

1

Description

childbirth Self- efficacy

Timepoint

At baseline and one month after the intervention

Method of measurement

Lowe's childbirth self-efficacy scale

2

Description

childbirth Fear

Timepoint

At baseline and one month after the intervention

Method of measurement

Wijma delivery expectancy- experience questionnaire

3

Description

The choice of the type of delivery
Timepoint
At baseline and one month after the intervention
Method of measurement
The choice of the type of delivery scale

Secondary outcomes

1

Description
The type of delivery
Timepoint
Postpartum
Method of measurement
Question will be asked by phone

2

Description
Childbirth Awareness
Timepoint
At baseline and one month after the intervention
Method of measurement
Childbirth awareness scale

3

Description
Childbirth attitude
Timepoint
At baseline and one month after the intervention
Method of measurement
Childbirth attitude scal

Intervention groups

1

Description
Intervention group: Counseling based on problem solving with couples will be performed in 3 sessions once a week.
Category
Prevention

2

Description
control group: Control group will receive routine care.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan Bahman hospital
Full name of responsible person
Leila Ahmadi

Street address

poonak

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor for Research and Technology of Zanjan
University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

North Side Azadi Boulevard

City

Zanjan

Grant name

پایان نامه

Grant code / Reference number

A-11-980-3

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

Yes

Title of funding source

Chancellor for Research and Technology of Zanjan
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

Zanjan University of Medical Sciences

Full name of responsible person

Leila Ahmadi

Position

Graduate student midwifery

Other areas of specialty/work

Street address

N 85 Bahar2 Baharestan

City

Zanjan

Postal code

Phone

+98 24 3377 2279

Fax

Email

ahmadileila5@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Karmandan town

City

Zanjan

Postal code

4515789589

Phone

+98 24 3314 8319

Fax

+98 24 3314 8319

Email

r.kharaghani@zums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Roghieh Kharaghani

Position

Ph.D of Reproductive Health

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Karmandan town

City

Zanjan

Postal code

4515789589

Phone

+98 24 3314 8319

Fax

+98 24 3314 8319

Email

r.kharaghani@zums.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