Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 lowe 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 expectacy- 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
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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

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School of Nursing and Midwifery, Karmandan town

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Person responsible for updating data

Contact

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Full name of responsible person
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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