

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of motivational interviewing on attitude, self-efficacy and decision about type of delivery in primigravid women requesting elective cesarean section referring to comprehensive health services centers

Protocol summary

Study aim

determine the effect of motivational interview on attitude, self-efficacy and decision about type of delivery in primigravid women requesting elective cesarean section referring to comprehensive health services centers of Zahedan in 1397

Design

The samples are selected by multistage sampling method. First, health centers of Zahedan are divided into 5 groups (clusters), including north, south, east, west, and center. Then, from each of the mentioned five districts, two centers are randomly chosen according to the required sample size. Again in the second clusters, one center is chosen as the intervention and the other as the control group; subsequently, 120 subjects satisfying the inclusion criteria are chosen by drawing and assigned to the groups.

Settings and conduct

The place of study is the health centers of Zahedan. How to conduct a motivational interviewing group counseling session during four 90 minute sessions of two sessions.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- Normal pregnancy between 28-31 weeks 2- Do not receive education prior to entering the study Exit criteria: 1-history of acute or chronic cardiovascular diseases and systemic disease 2- have indication for emergency cesarean

Intervention groups

The intervention group will provide motivational interviewing group counseling sessions in four sessions of 90 minutes a week, two sessions at the clinic and at agreed time with women in groups of 5 to 10 people. The control group will only receive routine pregnancy training.

Main outcome variables

attitude in relation to type of delivery, childbirth self-efficacy, decision-making in relation to type of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150727023370N5**

Registration date: **2018-12-13, 1397/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-13, 1397/09/22**

Update count: **0**

Registration date

2018-12-13, 1397/09/22

Registrant information

Name

Maryam Navaee

Name of organization / entity

Nursing and Midwifery Faculty

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 4510

Email address

navaee.m@zamuc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-21, 1397/08/30

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	The effect of motivational interviewing on attitude, self-efficacy and decision about type of delivery in primigravid women requesting elective cesarean section referring to comprehensive health services centers
Public title	The effect of motivational interviewing on attitude, self-efficacy and decision about type of delivery in primigravid women requesting elective cesarean section
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: Normal pregnancy between 28-31weeks Ages 18 to 35 Normal fetus condition and amniotic fluid volume Singleton pregnancy Maternal body mass index in the normal range (25 >BMI >18.5) At least a fifth-grade of elementary education Do not receive education prior to entering the study Cephalic presentation Exclusion criteria: history of infertility history of acute or chronic cardiovascular diseases and systemic disease have indication for emergency cesarean
Age	From 18 years old to 35 years old
Gender	Female
Phase	3
Groups that have been masked	No information
Sample size	Target sample size: 120
Randomization (investigator's opinion)	Randomized
Randomization description	First, two centers located in each of the five districts of Zahedan are randomly selected. In the second clusters, one center is chosen as the intervention and the other as control group by drawing. The names of groups are designated as A (motivational interview) and B (control group) on two sheets, and the names of centers are written on two other sheets as A and B and put in another bag. Then, one sheet is chosen from each bag by drawing, and the first selected center is thus assigned to the first group and the remaining center in each cluster is assigned to the other group.
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 Ethic's committee of Zahedan University of Medical Sciences Street address Dr hesabi's Square, Zahedan University of Medical Sciences City Zahedan Province Sistan-va-Balouchestan Postal code 98167-43463 Approval date 2018-10-23, 1397/08/01 Ethics committee reference number ir.zaums.rec.1397.294
Health conditions studied	
1	Description of health condition studied attitude and self efficacy and decision-making ICD-10 code Z55.9 ICD-10 code description Problems related to education and literacy, unspecified
2	Description of health condition studied cesarean-section ICD-10 code P03.4 ICD-10 code description Newborn (suspected to be) affected by Cesarean delivery
Primary outcomes	
1	Description attitude in relation to type of delivery Timepoint before and one month after the intervention Method of measurement Childbirth Attitudes Questionnaire
2	Description childbirth self-efficacy Timepoint before and one month after the intervention Method of measurement Childbirth Self-Efficacy Questionnaire

3

Description

decision-making in relation to type of delivery

Timepoint

before and one month after the intervention

Method of measurement

using a researcher-made check list to investigate of decision-making in relation to type of delivery

Secondary outcomes

1

Description

Fear of childbirth

Timepoint

before and one month after the intervention

Method of measurement

Using a harmen childbirth attitude questionnaire

Intervention groups

1

Description

Intervention group: For the intervention group, motivational interviewing group sessions will be conducted in four sessions of 90 minutes, two sessions a week, at the clinic and at agreed time with women in groups of 4 to 9 people.

Category

Prevention

2

Description

Control group: The control group will only receive routine pregnancy training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hadi Health Center

Full name of responsible person

Maryam Liaghat

Street address

Moalem Street

City

Zahedan

Province

Sistan-va-Balouchestan

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3819845672

Phone

+98 54 3341 3934

Email

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2

Recruitment center

Name of recruitment center

kosar Health Center

Full name of responsible person

Malihe Bizhanpur

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3

Recruitment center

Name of recruitment center

Imam javadi Health Center

Full name of responsible person

Mahbube Gholami

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4

Recruitment center

Name of recruitment center

Musabne Jaafar Health Center

Full name of responsible person

هاجر عباسی

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Mirzaye Shirazi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Taheri

Street address

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Navaee

Position

Master degree, faculty member

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Master degree, faculty member

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

Master degree, faculty member

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information about study implications

When the data will become available and for how long

Starting the access period from 2019

To whom data/document is available

academic researchers

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

by email: helennavaee@gmail.com

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

10 days

Comments