

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The Effect of Shared Decision- Making on the Choice of Type of Delivery and its Cognitive Consequences in Pregnant Women with Previous Cesarean History

Protocol summary

Study aim

Determining the effect of shared decision- making on the choice of type of delivery and its cognitive consequences in pregnant women with previous cesarean history

Design

A randomized controlled clinical trial

Settings and conduct

This study will be conducted in Torbat Jam Community Health Centers. At the beginning of the study, the questionnaire of knowledge, conflict of decision, will be completed by the pregnant mother. The intervention group holds a counseling session for 90 minutes. The researcher also referred the pregnant mothers of the intervention group and their companions to the office of a gynecologist to obtain the information needed to complete the consultation . At 37-35 weeks of gestation, the knowledge questionnaire, decision conflict questionnaire in the intervention and control groups will be completed and they will be asked about their preferred delivery method. 4 weeks after delivery for mothers in both groups, a questionnaire of regret and decision satisfaction at community health centers will be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, history of a previous cesarean section, expecting delivery in 37 weeks or more. Exclusion criteria: Medical or midwifery contraindication for vaginal delivery, attending other counseling sessions other than routine counseling at the center, mental illness

Intervention groups

The intervention group holds a counseling session for 90 minutes. The researcher also referred the pregnant mothers of the intervention group and their companions to the office of a gynecologist to obtain the information needed to complete the consultation. The control group will not receive any intervention.

Main outcome variables

Choice of type of delivery, awareness of delivery options, conflict of decision, regret of decision, satisfaction of decision

General information

Reason for update

Acronym

VBAC

IRCT registration information

IRCT registration number: **IRCT20190506043499N1**

Registration date: **2019-08-10, 1398/05/19**

Registration timing: **prospective**

Last update: **2019-08-10, 1398/05/19**

Update count: **0**

Registration date

2019-08-10, 1398/05/19

Registrant information

Name

Faezeh Ghoryshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5253 8647

Email address

faezehghoryshi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Shared Decision- Making on the Choice of Type of Delivery and its Cognitive Consequences in Pregnant Women with Previous Cesarean History

Public title

The Effect of Shared Decision- Making on the Choice of Type of Delivery and its Cognitive Consequences in Pregnant Women with Previous Cesarean History

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women with a history of a previous cesarean section Waiting for delivery at 37 weeks of pregnancy or more Ability to Speak and Understand Persian

Exclusion criteria:

medical or obstetric contraception for vaginal delivery Participate in other counseling sessions other than the usual center consulting having mental illness

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **86****Randomization (investigator's opinion)**

Randomized

Randomization description

To randomly assign samples to each of the two intervention and control groups, four variable blocks are used. In this way, six of the possible blocks (BBAA, BABA, ABBA, BAAB AAB, ABAB) are first listed, and each one is assigned a number from one to six. Then, randomly, a number is selected from one to six, followed by individuals assigned to the test group (A) and control (B), based on the corresponding block. This will continue until the sample size is completed.

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**

Ethics committee of gonabad university of medical sciences

Street address

Asian Roadside Border, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-03-17, 1397/12/26

Ethics committee reference number

IR.GMU.REC.1397.132

Health conditions studied**1****Description of health condition studied**

Vaginal delivery after cesarean section

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Preferred delivery type

Timepoint

Before intervention, 35-37 weeks of gestation pregnancy

Method of measurement

Questionnaire

2**Description**

Awareness of delivery options

Timepoint

Before the intervention, 37-35 weeks of gestation

Method of measurement

knowledge of delivery options Questionnaire

3**Description**

Decisional Conflict

Timepoint

Before the intervention, 37-35 weeks of gestation

Method of measurement

Decisional Conflict Scale

4

Description

Decisional Regret

Timepoint

6 weeks after delivery

Method of measurement

Decisional Regret Scale

5

Description

Satisfaction with the decision

Timepoint

6 weeks after delivery

Method of measurement

Satisfaction with the decision Scale

Secondary outcomes

empty

Intervention groups

1

Description

In addition to the usual care in the two groups, the intervention group had a 90-minute consultation session based on 3-step shared decision making with the researcher, pregnant mother, spouse as well as other people whose pregnant mother or spouse tended to attend. After the first consultation session, additional meetings will be held if needed. The researcher also referred the pregnant mothers of the intervention group and their companions to the office of a gynecologist to obtain the information needed to complete the consultation (second session) and also answer their potential questions.

Category

Behavior

2

Description

Control group: There will be no intervention in control group.

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Community Health Centers of Torbate- Jam University of Medical Sciences

Full name of responsible person

Faezeh Ghorayshi

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Torbate-jam university of Medical Sciences, Shahid Beheshti Ave

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr Shahla Khosravan

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Email

khosravan@gmu.ac.ir

Web page 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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Fatemeh Hadizadeh- Talasaz

Position

Assistant Professor of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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

Participant information is confidential.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available