Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Shared Decision- Making on the Choice of Type of Delivery and its Cognitive Concequences 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)

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+98 51 5253 8647

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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 Concequences 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 Concequences 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 Underestand Persian
Exclusion criteria:
medical or obstetric contraception for vaginal delivery Participate in other counseling sessions other than the usual center consulting having mental illness
Age
From **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 AABB, 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 univercity 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
Street address
Asian Roadside , Gonabad University of Medical Sciences
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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 scientific inquiries

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Person responsible for updating data

Contact

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Web page address
http://www.gmu.ac.ir/

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