

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The impact of supportive counseling on decision self-efficacy and intention to Vaginal Birth after Caesarean in prior cesarean section mothers

Protocol summary

Study aim

Determine the impact of supportive counseling on decision self-efficacy and intention to Vaginal Birth after Caesarean in prior cesarean section mothers

Design

Clinical trials with control group and parallel groups without blindness ; and Randomized.

Settings and conduct

Initially, 2 comprehensive health centers are randomly selected from Mashhad comprehensive health centers (1,2,3,4, and 5). From each center, 2 covered base are selected. then, one centers and totally 4 bases with random allocation are assigned to each group. The method of random assignment would be to have the name of the bases and the names of the groups written on separate papers and put in two separate envelopes. Then the names of one centers and one group from one envelopes are selected simultaneously. Sampling will be done at each base in an accessible manner.

Participants/Inclusion and exclusion criteria

1-desire to participate in study 2-.Low birth fear score less than 85 from Vijima questionnaire version A, which indicates no clinical fear 3- Gestational age between 28 weeks and 30 weeks. 4- low-risk singleton pregnancies and is showing head. 5- Having a history of previous cesarean section. 6. Do not have a history of infertility. 7- Not having a medical cause for cesarean section . Non-entry terms: indication of cesarean section, medical or obstetric disease, non-transverse cesarean section, Failure to attend at least one counseling session, failure to take the test after research, Failure to receive channel content and pamphlets.

Intervention groups

'intervention group" receives two Individual of supportive counseling sessions for 45 minutes and receive the pamphlet and the link of the messenger channel .
Control group: receives routine counseling about vaginal

birth after cesarean by midwives at health centers.

Main outcome variables

Decision self-efficacy and intention to Vaginal birth after cesarean

General information

Reason for update

Acronym

VBAC

IRCT registration information

IRCT registration number: **IRCT20200614047768N1**

Registration date: **2020-06-21, 1399/04/01**

Registration timing: **prospective**

Last update: **2020-06-21, 1399/04/01**

Update count: **0**

Registration date

2020-06-21, 1399/04/01

Registrant information

Name

Roghayeh Pakdaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

pakdamanr971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of supportive counseling on decision self-efficacy and intention to Vaginal Birth after Caesarean in prior cesarean section mothers

Public title

The impact of counseling on decision self-efficacy and intention

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian and resident of Mashhad At least have the ability to read and write The interval between pregnancy and previous delivery is greater than 6 months Childbirth fear score less than 85 from Vijima questionnaire version A, which indicates no clinical fear and Single-pregnancy A live embryo and a cephalic display Amniotic fluid and placental placement are normal based on pregnancy ultra sonography in trimester 2 . The gestational age based on the LMP or the first trimester ultrasound is of 28-30 weeks BMI 19/8-29/9 History of once prior cesarean section Do not have a history of infertility Do not have a history of mental and medical illness No complication of midwifery(Preeclampsia, diabetes, etc) Not having a medical cause for cesarean section No history of any surgery on the uterus other than a transverse incision below the previous cesarean section

Exclusion criteria:

Not participating to attend at least one counseling session Not participating to take the test after research Indication of pregnancy termination before the end of the research period Failure to receive channel content and pamphlets Occurrence of medical disease and obstetric complication during research

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of groups will be such that the names of the databases that are randomly selected and the names of the groups are written on separate papers and placed in two separate envelopes. Then the name of a database and a group of direct envelopes are selected simultaneously. Thus, one base from the center will be allocated to the intervention group and one base from

each center will be allocated to the control group, and a total of two bases will be allocated to the control group and two bases to the intervention group. Then, sampling will be done inside each center.

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**

Mashhad University of Medical Sciences and Health Services

Street address

Khorasan Razavi - Mashhad-Ave. University- Facing Khayyayan University 18- Mashhad University of Medical Sciences- Vice-President of Research and Technology University

City

Mashhad

Province

Razavi Khorasan

Postal code

9188667656

Approval date

2020-06-15, 1399/03/26

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.018

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

vaginal birth after cesarean

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

The intent Vaginal birth after cesarean

Timepoint

At the beginning of the study and 4 week after the intervention.

Method of measurement

Intent selection choose the type of delivery checklist

2

Description

Decision self-efficacy

Timepoint

At the beginning of the study and 4 week after the intervention.

Method of measurement

Decision self-efficacy questionnaire

3

Description

Decision Conflict

Timepoint

At the beginning of the study and 4 week after the intervention.

Method of measurement

Decision Conflict Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention Group" Consulting package based on the supportive counseling approach includes: 1- Two individual supportive counseling sessions for each session of 45 minutes and in the middle of the week and in person and face to face 2- Pamphlet and link of the messenger channel. Content of counseling sessions based on supportive counseling steps includes the first session: explanation (right to choose the type of delivery, natural childbirth mechanism, recurrent cesarean complications), reassurance (benefits of natural childbirth for mother and baby, comparison of benefits and losses of natural childbirth after cesarean section, amount The success of natural childbirth after cesarean section), the content of the second session: guidance (methods of awakening in Libra, relaxation techniques in Liber, different positions in Libra and childbirth, mobile support, helping to remove barriers to selection from his point of view), encouragement (experience Her mothers have had a back-to-back presentation of her statistics, her success rate, and leave for emotional discharge (listening to clients talk about their feelings, beliefs, experiences, and expectations about childbirth). At the end of the first session, the delivery of the pamphlet and the link of the messenger channel will be provided (channel content includes: showing cesarean section and natural childbirth animation (taken from the educational contents of the Ministry of Health and uploading the audio file of the interview with mothers who have had a successful back)

Category

Behavior

2

Description

Control group: The "control group" receives routine counseling about vaginal birth after cesarean by midwives at health centers.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 3 of Mashhad

Full name of responsible person

Baratali Arab Nejad

Street address

Khayyam Blvd - Ershad Blvd. 8 - Message Street - Opposite Message 6

City

Mashhad

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 51 3763 4007

Email

presidentoffice@mums.ac.ir

2

Recruitment center

Name of recruitment center

Health Center No. 1 of Mashhad

Full name of responsible person

Naser Amini

Street address

Health center No 1. After Vakilabad 66, Vakilabad Blvd, Mashhad, Razavi Khorasan, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9179793945

Phone

+98 51 3501 8011

Fax

+98 51 3501 7420

Email

HC1.PR@ MUMS.AC.IR

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Darabi mahboob

Street address

Khorasan Razavi - Mashhad - University Street -
Gharishi Building Presidential Building of Razavi
Khorasan University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Phone

+98 51 3841 3007

Fax

+98 51 3841 3006

Email

Bahreynimh@mums.ac.ir

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mahboobeh Firoozi

Position

Teacher

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

No. 9, West Fajr, Baharan Ave., Faramarzabasi Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

0098 51 38591511-3

Email

Firoozim@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Roghayeh Pakdaman

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.40, Karimi 1, Sardaran st.17 Shahrivar North.

City

Bojnourd

Province

North Khorasan

Postal code

9415658969

Phone

+98 58 3226 2332

Email

pakdamanr971@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Roghayeh Pakdaman

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.40, Karimi 1, Sardaran st.17 Shahrivar North

City

Bojnourd

Province

North Khorasan

Postal code

9415658969

Phone

+98 58 3226 2332

Email

pakdamanr971@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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