

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of individual counseling through Fogg model on the intention to choose vaginal birth after cesarean in pregnant mothers

Protocol summary

Study aim

Determine the impact of individual counseling through Fogg model on the intention to choose Vaginal birth after cesarean in pregnant mothers in Mashhad Health Centers

Design

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

Settings and conduct

At first, five centers of health centers in Mashhad, Center No 3 and 1 were randomly selected. From each center, 4 bases with random numbers are selected. In order to prevent interaction and dissemination of information in two groups, From any center two bases and totally 4 bases will be allocated to each group randomly assigned. The method of random assignment is that the names of the bases and the names of the groups will be written on separate papers and placed in two separate envelopes. Then the names of two centers and a one group of two envelopes are selected simultaneously. Two bases from each center were assigned to the intervention group and two bases from each center to the control group. Sampling at each center is done in an accessible manner..

Participants/Inclusion and exclusion criteria

1-desire to participate in study 2- Age between 18 and 35 years. 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, such as a transverse position, previous uterine surgery, etc. Non-entry terms: indication of cesarean section, medical or obstetric disease, non-transverse cesarean section

Intervention groups

Intervention group: three Individual counseling sessions for 45-60 minutes based on the Fogg model structure.

Control group: Routine care of childbirth classes

Main outcome variables

intention to choose Vaginal birth after cesarean

General information

Reason for update

Acronym

VBAC

IRCT registration information

IRCT registration number: **IRCT20200105046014N1**

Registration date: **2020-02-22, 1398/12/03**

Registration timing: **prospective**

Last update: **2020-02-22, 1398/12/03**

Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Somayeh Attarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3606 7374

Email address

attarians971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-01, 1398/12/11

Expected recruitment end date

2020-07-01, 1399/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of individual counseling through Fogg model on the intention to choose vaginal birth after cesarean in pregnant mothers

Public title

The effect of individual counseling on the intention to choose

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian and resident of Mashhad At least have the ability to read and write Aged 18-35 years old Single-pregnancy, A live embryo and a cephalic display Amniotic fluid and placental placement are normal based on pregnancy ultra sonography The interval between pregnancy and previous delivery is greater than 6 months. The gestational age based on the LMP or the first trimester ultrasound is of 28-30 weeks. History of once prior cesarean section Do not have a history of infertility Not having a medical cause for cesarean section, such as a transverse position, previous uterine surgery, etc.

Exclusion criteria:

indication of cesarean section. Have a history of infertility. Embryo abnormalities are contraindicated in normal delivery. Have a medical or obstetric illness. Non-transverse cesarean section. Have a mental illness.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **68****Randomization (investigator's opinion)**

Randomized

Randomization description

Multi-stage sampling will be performed. The sampling frame is Mashhad comprehensive health centers. Initially, 2 comprehensive health centers are randomly selected from Mashhad comprehensive health centers (1,2,3,4, and 5). From each center, 4 covered base are selected according to the number of clients and appropriate locations for consultation. In order to prevent interaction and dissemination of information in two groups, two 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 two centers and one group from two envelopes are selected simultaneously. Sampling will be done at each base in an accessible manner.

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

2019-12-30, 1398/10/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.081

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

Vaginal birth after cesarean delivery

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

The intent to choose Vaginal birth after cesarean

Timepoint

At the beginning of the study and 2 and 4 week after the intervention.

Method of measurement

Intent selection choose the type of delivery checklist

2**Description**

Fogg Model Structures (Motivation, Ability, Stimulus)

Timepoint

At the beginning of the study and 2 and 4 week after the intervention.

Method of measurement

Fogg Model Structures (Motivation, Ability, Stimulus) the researcher-made questionnaire

3

Description

Fear of delivery

Timepoint

At the beginning of the study and 2 and 4 week after the intervention.

Method of measurement

Vijma's fear of delivery Questionnaire; Version A

4

Description

Self-efficacy of delivery

Timepoint

At the beginning of the study and 2 and 4 week after the intervention.

Method of measurement

Maternal self-efficacy questionnaire

5

Description

Decision self-efficacy

Timepoint

At the beginning of the study and 2 and 4 week after the intervention.

Method of measurement

Decision self-efficacy questionnaire

6

Description

Decision Conflict

Timepoint

At the beginning of the study and 2 and 4 week after the intervention.

Method of measurement

Decision Conflict Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: The 'intervention group' receives three Individual of Fogg model counseling sessions for 45-60 minutes and once every two weeks, based on a structure developed by the researcher and approved by a professor of psychology

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. 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

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Email

HC1.PR@ MUMS.AC.IR

2

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

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presidentoffice@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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahboobeh firoozi

Position

Teacher

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Attarian Somayeh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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