Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of effectiveness of midwifery counseling based on Solution-focused approaches and routine prenatal cares on preferred normal vaginal delivery in women with elective cesarean section based on Extended Parallel Process Model (EPPM)

Protocol summary

Summary

This study aims to investigate the effectiveness of midwifery counseling based on solution-focused approaches on preferred normal vaginal delivery based on Extended Parallel Process Model (EPPM). Design: A randomized multicenter non-blinded controlled trial. Setting and conduct: The overall aim and setting of the study are explained for eligible people. Samples will be allocated to intervention and control groups with the block size of 4 and informed consents are completed. The control group will receive routine cares. The intervention group will participate in solution-focused sessions as well as receiving routine cares. Sessions are held weekly. Inclusion criteria: nulliparous women, age of 18 to 35 years, gestational age of 22 to 30 weeks at the starting point of the study, healthy and normal fetus in first trimester ultrasound scans (no fetal anomalies, normal placental position, normal cervix length), no evident and diagnosed prohibition of vaginal delivery at the time of sampling, having at least primary education, singleton pregnancy, having normal body mass index, negative history of psychotherapy or mental disease, no cigarette, opioid, and alcohol addiction, having single partner , negative history of repetitive abortion and infertility, preferred cesarean delivery at the starting point of the study. Exclusion criteria: absence more than two sessions, moving home and no access to pregnant mothers and termination of pregnancy for any reason before completion of counseling sessions, any indication of cesarean delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042425480N1**

Registration date: **2016-05-28, 1395/03/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-28, 1395/03/08

Registrant information

Name

Masoumeh Sharifzadeh

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4466 6828

Email address

sharifzade@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research; Shahroud University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of midwifery counseling based on Solution-focused approaches and routine prenatal cares on preferred normal vaginal delivery in women with elective cesarean section based on Extended Parallel Process Model (EPPM)

Public title
The effectiveness of midwifery counseling on preferred normal vaginal delivery

Purpose
Prevention

Inclusion/Exclusion criteria
This study aims to investigate the effectiveness of midwifery counseling based on solution-focused approaches on preferred normal vaginal delivery based on Extended Parallel Process Model (EPPM). Design: A randomized multicenter non-blinded controlled trial. Setting and conduct: The overall aim and setting of the study are explained for eligible people. Samples will be allocated to intervention and control groups with the block size of 4 and informed consents are completed. The control group will receive routine cares. The intervention group will participate in solution-focused sessions as well as receiving routine cares. Sessions are held weekly. Inclusion criteria: nulliparous women, age of 18 to 35 years, gestational age of 22 to 30 weeks at the starting point of the study, healthy and normal fetus in first trimester ultrasound scans (no fetal anomalies, normal placental position, normal cervix length), no evident and diagnosed prohibition of vaginal delivery at the time of sampling, having at least primary education, singleton pregnancy, having normal body mass index, negative history of psychotherapy or mental disease, no cigarette, opioid, and alcohol addiction, having single partner , negative history of repetitive abortion and infertility, preferred cesarean delivery at the starting point of the study. Exclusion criteria: absence more than two sessions, moving home and no access to pregnant mothers and termination of pregnancy for any reason before completion of counseling sessions, any indication of cesarean delivery.

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Shahroud University of Medical Sciences

Street address
Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud. shahroud Semnan Iran, Islamic Republic Of 3614773955

City
Shahroud

Postal code
3614773955

Approval date
2016-02-25, 1394/12/06

Ethics committee reference number
IR.SHMU.REC.1394.193

Health conditions studied

1

Description of health condition studied
cesarean delivery without indication

ICD-10 code
082

ICD-10 code description
cesarean delivery without indication

Primary outcomes

1

Description
Self-efficacy for preferred delivery method

Timepoint
Before intervention and a week later

Method of measurement
Standard questionnaire of Extended Parallel Process Model (EPPM)

2

Description
Behavioral intention

Timepoint
Before intervention and a week later

Method of measurement
Standard questionnaire of Extended Parallel Process Model (EPPM)

Secondary outcomes

1

Description
Delivery Expectancy/Experience
Timepoint
Before intervention and a week later
Method of measurement
Standard questionnaire of Wijma Delivery Expectancy/Experience(W-DEQ)

Intervention groups

1

Description
The intervention group will participate in solution-focused sessions(6sessions,45-60 minutes) as well as receiving routine cares.
Category
Behavior

2

Description
The control group will receive routine prenatal cares.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Urban Health Center of Sabzevar University of Medical Sciences
Full name of responsible person
Masoumeh Sharifzadeh
Street address
Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud.
City
Shahroud

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research; Shahroud University of Medical Sciences
Full name of responsible person
Dr Mohammadhasan Emamian
Street address
Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud.
City
Shahroud
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research; Shahroud University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahroud university of medical sciences
Full name of responsible person
Masoumeh Sharifzadeh
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty