Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of implementation of birth plan and childbirth preparation classes maternal satisfaction and delivery outcomes: a randomized controlled clinical trial

Protocol summary

Study aim

The effect of the birth plan and childbirth preparation classes on delivery outcomes and maternal satisfaction

Design

Controlled randomized controlled clinical trial

Settings and conduct

This randomized controlled trial will be conducted at childbirth preparation classes of Tehran University of Medical Sciences and Omid, Ansari, and Baharloo hospitals. The topic of the birth plan will be merged into the scientific content of the childbirth preparation classes and will be taught to pregnant mothers. The subjects will be randomly using www.random.org assigned to a group with a birth plan and without a birth plan. Their delivery will be done according to their birth plan. The allocation sequence will be determined by the person not involved in sampling and data collection. In order to the allocation concealment, the type of intervention will be sequentially numbered sealed packages by a person not involved in sampling and analysis. After obtaining informed consent, the envelope and the type of intervention will be determined.

Participants/Inclusion and exclusion criteria

Singleton pregnancy,Low risk pregnancy without medical or medwifery history such as history of abortion, infertility and preterm labour Gestational age of 32–33 weeks , participation at least 5 session of the childbirth preparation classes,Willingness to undergo vaginal delivery Literacy (reading and writing in Persian), Previous cesarean section with Willingness to undergo vaginal delivery

Intervention groups

Pregnant mothers attending at least 5 sessions of childbirth preparation classes and having a birth plan

Main outcome variables

Delivery type, Perineal lacerations rate, Episiotomy rate, Induction of labor rate , Maternal satisfaction with childbirth, Apgar score at 1 and 5 minutes, Neonatal intensive care unit admission rates, Breastfeeding initiation within the first hour of life, Fulfilling mother's wishes rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043283N2**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**

Registration date

2020-12-07, 1399/09/17

Registrant information

Name

Zaynab Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8331

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mohaghegh.z@ajmus.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementation of birth plan and childbirth preparation classes maternal satisfaction and delivery outcomes: a randomized controlled clinical trial

Public title

The implementation of birth plan and childbirth preparation classes plan on maternal satisfaction and delivery outcomes

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Singleton pregnancy Low risk pregnancy without medical or medwifery history such as history of abortion, infertility and preterm labour Gestational age of 32–33 weeks participation in 5 session of the childbirth preparation classes Willingness to undergo vaginal delivery Literacy (reading and writing in Persian) Previous cesarean section with willingness to undergo vaginal delivery

Exclusion criteria:

Reluctance to continue attending the study Change of decision to C-section

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Pregnant mothers participating in childbirth preparation classes will be randomly assigned into one of with the birth plan or with not birth plan (routine) using www.random.org.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor will not know how the intervention and control groups are assigned and will review data on outcome variables without considering groups of individuals.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Research Committee Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Ave

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-10-19, 1399/07/28

Ethics committee reference number

1399.586.IR.AJUMS.REC.

Health conditions studied

1

Description of health condition studied

Vaginal delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Frequency of vaginal delivery

Timepoint

After delivery

Method of measurement

Maternal and neonatal outcomes checklist

2

Description

Duration of labor stages

Timepoint

At the beginning of the active phase until one hour after postpartum

Method of measurement

Recorded time(minute)

3

Description

Frequency of labor induction

Timepoint

During labor

Method of measurement

Maternal outcomes checklist

4

Description
Maternal satisfaction with childbirth
Timepoint
24 hours after postpartum
Method of measurement
McKay Questionnaire

5

Description
Initiation of breastfeeding within 30 minutes after birth
Timepoint
After postpartum
Method of measurement
Neonatal outcomes checklist

6

Description
Delivery fear scale
Timepoint
During labor
Method of measurement
Delivery fear scale

7

Description
Frequency of fulfilling mother's wishes
Timepoint
After postpartum
Method of measurement
Maternal outcomes checklist

8

Description
Frequency of perineal lacerations
Timepoint
After postpartum
Method of measurement
Maternal outcomes checklist

9

Description
Frequency of episiotomy
Timepoint
After postpartum
Method of measurement
Maternal outcomes checklist

10

Description
Frequency of hospitalization in the neonatal intensive care NICU
Timepoint
After postpartum
Method of measurement
Neonatal outcomes checklist

Secondary outcomes

empty

Intervention groups

1

Description
First, the topic of birth plan is integrated into the educational content of childbirth preparation classes.Then, the subjects participating in session 5 of the childbirth preparation classes write the birth plan and their childbirth will be scheduled base on their's birth plan.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Childbirth preparation Classes at Tehran University of Medical Sciences
Full name of responsible person
MojganJavadnoori
Street address
No 226, Hafez Avenue,Tehran, Iran.
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Postal code
1134845764
Phone
+98 21 6345 3117
Fax
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mojganjavadnoori@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghadam
Street address
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Email

ahmadi-m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mojgan Javadnoori

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mojgan Javadnoori

Position

Associate Professor

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The data of this study will be accessible upon the request form the corresponding author after publication, or we

may deposit our data in the “Figshare” for sharing with other researchers after the publication of the manuscript.

When the data will become available and for how long

The data will be accessible upon the request from the corresponding author or in the Figshare” after publication of the manuscript (we anticipate this time by the end of 2021)

To whom data/document is available

Our data will be accessible upon the request from faculty members who interested to use our data with the research purpose (with acknowledgement of authors in our study).

Under which criteria data/document could be used

Interested researchers can send an e-mail to the corresponding author and request our data. In case of if we deposited our data in the “Figshare” cite, they will be accessible from the cite

From where data/document is obtainable

Mojgan Javadnoori Ahvaz, Golestan Ave, Ahvaz Jundishapur University of Medical Sciences, Nursing & Midwifery School, Midwifery Department

What processes are involved for a request to access data/document

The requested information will be sent at the most up to one week after receiving the email.

Comments