Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the birth plan implementation on experiences childbirth and duration of the active phase of labor: a randomized controlled clinical trial

Protocol summary

Study aim
To determine the effect of birth plan implementation on childbirth experience and duration of active phase of labor

Design
Clinical trial, with control group, parallel groups, single blind, randomized

Settings and conduct
This randomized controlled clinical trial will be conducted on pregnant women with gestational age of 32-36 weeks in Taleghani hospital of Tabriz. Participants will be divided into two groups by randomized blocking method and an assignment ratio of 1:1. The participants in intervention group will complete the birth plan checklist and their labor and delivery will be managed according to completed checklist by researcher and the control group will receive routine care. The participants will be followed up until 4-6 weeks after childbirth and the childbirth experience questionnaire, post-traumatic stress scale and Edinburgh's postpartum depression scale will be completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women with at least 18 years old and with first and second delivery; Residence in Tabriz city; Having a desire to have a vaginal delivery; Gestational age 36-32 weeks; Having Depression score less than 13; Singleton pregnancy and having read and write literacy. Exclusion criteria: Non-cephalic presentation of the fetus; Indication of cesarean section; Obstetrics problems and high-risk pregnancies

Intervention groups
Intervention group (Birth plan requested by the mother and approved by a gynecologist). Control group (routine care during labor and delivery)

Main outcome variables
Childbirth experience score; Duration of active phase of labor

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N58**
Registration date: **2020-07-07, 1399/04/17**
Registration timing: **prospective**

Last update: **2020-07-07, 1399/04/17**
Update count: **0**

Registration date
2020-07-07, 1399/04/17

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 1479 6969

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mirghafourvandm@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-19, 1399/04/29

Expected recruitment end date
2020-12-19, 1399/09/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the birth plan implementation on experiences childbirth and duration of the active phase of labor: a randomized controlled clinical trial

Public title
Assessing the effect of the birth plan implementation on experiences childbirth and duration of the active phase of labor

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
At least 18 years old Residence in Tabriz city Having a desire to have a vaginal delivery Gestational age 32-36 weeks Having Depression score less than 13 Singleton pregnancy Having read and write literacy Planning for childbirth in Taleghani Hospital Women with first and second delivery

Exclusion criteria:
Non-cephalic presentation of the fetus An indication of the cesarean section including abnormal presentation, placental previa, etc. Obstetrics problems such as placental previa, vaginal delivery after cesarean section, placental abruption, preeclampsia High-risk pregnancies such as diabetes, heart disease, etc., and a dead or abnormal fetus

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned into three groups by block randomization method with block sizes of 4 and 6 and allocation ratio of 1:1 including intervention 1 (Having birth plan), and control (Routine care). The allocation sequence will be determined by the person who is'n involved in the sampling and data collection. For allocation concealment, the type of intervention will be written on piece of paper and placed inside the serial numbered envelopes. After obtaining informed consent, the relevant envelope will be opened and the intervention type will be determined.

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 Tabriz Univercity of Medical Sciences

Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City
Tabriz

Province
East Azarbaijan

Postal code
00984113357311

Approval date
2020-05-21, 1399/03/01

Ethics committee reference number
IR.TBZMED.REC.1399.278

Health conditions studied

1

Description of health condition studied
Delivery

ICD-10 code
080.0

ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
Childbirth Experience score

Timepoint
4 to 6 weeks after delivery

Method of measurement
Childbirth Experience Questionnaire

2

Description
Duration of active phase of delivery

Timepoint
From dilatation 4 cm until full dilatation of cervix

Method of measurement
Partograph chart (minute)

Secondary outcomes

1

Description
Duration of second stage of delivery
Timepoint
From full dilatation of cervix until birth of newborn
Method of measurement
Partograph chart (minute)

2

Description
Duration of Third stage of delivery
Timepoint
From birth of newborn until complete expulsion of placenta
Method of measurement
Partograph chart (minute)

3

Description
Fear of Childbirth Score
Timepoint
During labor
Method of measurement
Fear of Childbirth Scale

4

Description
Frequency of vaginal delivery
Timepoint
After childbirth
Method of measurement
Childbirth checklist

5

Description
Post-traumatic stress score
Timepoint
4 to 6 weeks after delivery
Method of measurement
Post Traumatic Stress Questionnaire

6

Description
The frequency of infant hospitalization in the NICU
Timepoint
Postpartum
Method of measurement
Neonatal checklist

7

Description
Postpartum depression score
Timepoint
4 to 6 weeks after delivery
Method of measurement
Edinburgh’s Postpartum Depression Scale

8

Description
Apgar score at one and five minutes
Timepoint
After childbirth
Method of measurement
Childbirth checklist

Intervention groups

1

Description
Intervention group: The participants in intervention group will receive interventions according to completed birth plan checklist by mother herself including the mother's wishes and preferences regarding labour and childbirth (such as delivery position, mother's movements in labour, pain relief, labour acceleration, fetal monitoring, etc) that are approved by the obstetrician.
Category
Treatment - Other

2

Description
The control group will receive hospital routine care.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Educational and Treatment Center of Tabriz
Full name of responsible person
Parivash Ahmadpour
Street address
Rah Ahan square, Tabriz
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East Azarbaijan
Postal code
5197615413
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Web page address
https://www.drsaina.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Samiei

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Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

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5138947977

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Email
Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mojgan Mirghafourvand

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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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
Yes - There is 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

Yes - There is 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 results of the clinical study will be published as articles.

When the data will become available and for how long

Immediately after publishing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to the article

From where data/document is obtainable

mirghafourvandm@tbzmed.ac.ir

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

Up to one week after communication by email

Comments