Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The effect of supportive interventions on birth experience: Randomized Controlled Trial

Protocol summary

Study aim
Effect of supportive interventions on birth experience
Design
Randomized controlled trial with two parallel arms
Settings and conduct
This study will be conducted at Taleghani Hospital in Tabriz city. So, the researcher will select eligible women in the hospital. Participants will be assigned to two groups of intervention and control. The intervention and control groups will receive supportive care and a routine maternity care during the labor phase, respectively.The birth experience of women will be measured four weeks postpartum.
Participants/Inclusion and exclusion criteria
Inclusion criteria includes age older than 18 years and gestational age of 37-42 weeks. Exclusion criteria includes having complications during pregnancy or childbirth such as preeclampsia, diabetes, placenta abruption; having a cesarean section indication such as history of cesarean section and having mental-psychological problems, according to mother's report.
Intervention groups
The intervention group will be received interventions during labor, delivery, and postpartum including the provision of latent and active labor definitions, management of labor, presence of doula, the possibility of telephone conversation with her family, not doing unnecessary interventions, woman's participation in decision-making, getting different positions such as upright position during labor, doing exercise during labour, encouraging the woman to follow their own urge to push, choosing the delivery position according to the woman choice, delayed umbilical cord clamping, controlled cord traction, skin to skin contact during the first hour after birth, and follow up and responding to postpartum maternity problems by telephone and, if necessary, attending in person will be provided. The control group will be received routine hospital care.
Main outcome variables
Birth experience

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120718010324N50**
Registration date: **2019-06-28, 1398/04/07**
Registration timing: **prospective**

Last update: **2019-06-28, 1398/04/07**
Update count: **0**
Registration date
2019-06-28, 1398/04/07

Registrant information
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Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-08-02, 1398/05/11
Expected recruitment end date
2019-09-16, 1398/06/25
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of supportive interventions on birth experience: Randomized Controlled Trial

Public title
The effect of supportive interventions on birth experience

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age older than 18 years Gestational age of 37 to 42 weeks

Exclusion criteria:
Having complications during pregnancy or childbirth such as preeclampsia, diabetes, placenta abruption Having a cesarean section indication such as history of cesarean section and ... Having mental-psychological problems, according to mother's report

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be conducted using the website www.random.org and through blocking with block sizes of four and six and an allocation ratio of 1: 1 to the two groups of intervention and control.

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 University 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
5166614766

Approval date
2017-12-03, 1396/09/12

Ethics committee reference number
IR.TBZMED.REC.1396.786

Health conditions studied

1

Description of health condition studied
Birth experience

ICD-10 code
Z39.0

ICD-10 code description
Encounter for care and examination of mother immediately after delivery

Primary outcomes

1

Description
Birth experience

Timepoint
Four weeks postpartum

Method of measurement
Childbirth Experience Questionnaire version 2.0

Secondary outcomes

1

Description
Duration of childbirth stages

Timepoint
During the labor and childbirth stages

Method of measurement
Partograph

2

Description
Frequency of oxytocin use

Timepoint
After childbirth

Method of measurement
Postpartum checklist

3

Description
Frequency of Cesarean childbirth

Timepoint

After childbirth

Method of measurement

Postpartum checklist

4

Description

Apgar score

Timepoint

5 minutes and 10 minutes after baby's birth

Method of measurement

Postpartum checklist

Intervention groups

1

Description

Intervention group: The intervention group will receive interventions during labor, delivery, and postpartum. Interventions during labor and delivery include the provision of latent and active labor definitions, duration of labor, answering questions from women, respectful care, caring with empathy, management of labor pain (use of pharmacological pain relief methods such as remifentanil or pethidine or non-pharmacological such as teaching visualization techniques, breathing techniques, progressive muscle relaxation, massage or use a warm bag according to the woman's preference), providing a hygienic room, private, presence of doula, the possibility of telephone conversation with her family, woman's participation in decision-making, not doing unnecessary interventions such as connecting the bladder catheter, frequent vaginal examinations, pushing during delivery, women's inactivity, lack of nutrition, continuous heartbeat auscultation and recording cardiotocography, use of early onset of oxytocin, perineal/pubic shaving, privacy and confidentiality (using a separate room, no vaginal examination in the presence of women or other providers, the absence of a male student, access to a suitable cover for keeping hijab during transfer to other parts of the hospital), getting different positions such as upright position during labor, doing exercise during labour, encouraging the woman to follow their own urge to push, no routine use of episiotomy, choosing the delivery position according to the woman choice, delayed umbilical cord clamping, controlled cord traction, no nasal or oral suction baby in case of clear amniotic fluid, and during postpartum included use of uterotonics for the prevention of postpartum haemorrhage, sufficient analgesia during episiotomy repair, skin to skin contact during the first hour after birth, breastfeeding during the first hour after birth, uterine tonus assessment, regular assessment of vaginal bleeding, uterine contraction, fundal height, temperature and heart rate during the first 24 hours starting from the first hour after birth, no antibiotics prophylaxis for uncomplicated vaginal birth and follow up and responding to postpartum maternity problems by telephone and, if necessary, attending in person will be provided.

Category

Behavior

2

Description

The control group will receive routine maternity care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Solmaz Ghanbari Homayi

Street address

Nursing & Midwifery Faculty, South Shariati Stree

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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

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

Solmaz Ghanbari Homayi

Position

PhD in Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

Mojgan Mirghafourvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

Associate Professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants' data is confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available