Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Effect of implementing the WHO maternity care model on the childbirth experience, fear of childbirth, and quality of intrapartum care: a randomized controlled clinical trial

Protocol summary

Study aim
To determine the effect of the WHO Maternity Care Model on childbirth experience, fear of childbirth and quality of intrapartum care

Design
Single-blind randomized controlled clinical trial with two parallel groups on 108 women at the beginning of the active phase of labor

Settings and conduct
The present study will be performed in the delivery ward of Al-Zahra and Taleghani hospitals in Tabriz. Participants will be allocated into two groups by randomized blocking method and an assignment ratio of 1:1. The fear of childbirth questionnaire will be completed before the start of the active phase to record the basic fear of childbirth and again in 7-8 cm dilatation. For women in the intervention group, components of the intrapartum care model and for women in the control group, routine hospital care will be applied. Participants in both groups will be followed up to 6 weeks postpartum and the Childbirth Experience Questionnaire and Pregnancy and Childbirth Questionnaire will be completed by the research assistant.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being at the beginning of the active phase; First or second delivery. Exclusion criteria: Having indications for cesarean delivery; Obstetric problems; Underlying maternal diseases; Mental illness; and death of a close relative during the past three months

Intervention groups
Intervention group: Those who will receive care based on the WHO maternity care model Control group: Those who will receive routine care of the hospital

Main outcome variables
childbirth experience; fear of childbirth; quality of intrapartum care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N69**
Registration date: **2022-05-01, 1401/02/11**
Registration timing: **prospective**

Last update: **2022-05-01, 1401/02/11**
Update count: **0**

Registration date
2022-05-01, 1401/02/11

Registrant information

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Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-19, 1401/02/29

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of implementing the WHO maternity care model on the childbirth experience, fear of childbirth, and quality of intrapartum care: a randomized controlled clinical trial

Public title
Comparison of the effect of implementing the WHO maternity care model with routine hospital care on the childbirth experience of women

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Being at the beginning of the active phase of labor First or second pregnancy

Exclusion criteria:
Multiple pregnancy Non-cephalic presentation Having indication for cesarean delivery including abnormal presentation, placenta previa and etc. Midwifery problems such as placenta previa, vaginal delivery after cesarean section, placenta abruption, preeclampsia Mothers with underlying problems such as cardiovascular disease, diabetes and etc. Having a mental disability and other psychological problems Death of one of close relatives during the last three months

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
If women accept to participate in the study, they will be assigned to study groups at the beginning of the active phase of labor. In order to allocate the participants to the study groups, the stratified random blocking method (nulliparous and the second delivery) with the block sizes of 4 and 6 and a 1:1 allocation ratio will be used. For Allocation Concealment, the type of intervention will be written on paper and will be placed inside sequential numbered opaque envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the intervention, it is not possible to blind the researcher and the participants. In order to blind the outcome assessor, questionnaires related to the postpartum stage will be completed by the research assistant.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences Ethics Committee

Street address
Tabriz-Golgasht street-Tabriz University of Medical Sciences-Building 2 - Floor 3

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Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2022-04-20, 1401/01/31

Ethics committee reference number
IR.TBZMED.REC.1401.093

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

Timepoint
4-6 weeks after childbirth

Method of measurement
Childbirth Experience Questionnaire

2

Description
Fear of childbirth

Timepoint
At the beginning of the active phase and in dilatation 7-8 cm

Method of measurement
Delivery Fear Scale

3

Description
Quality of intrapartum care
Timepoint
4-6 weeks after childbirth
Method of measurement
Pregnancy and Childbirth Questionnaire

Secondary outcomes

1

Description
Postpartum depression
Timepoint
4-6 weeks after childbirth
Method of measurement
Edinburgh's Postpartum Depression

2

Description
Postpartum stress
Timepoint
4-6 weeks after childbirth
Method of measurement
PTSD Symptom Scale 1

3

Description
Duration of active phase of delivery
Timepoint
From dilatation 4 cm until full dilatation of cervix
Method of measurement
Partograph chart (minute)

4

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

5

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

6

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

7

Description
Tendency to childbearing
Timepoint
4-6 weeks after childbirth
Method of measurement
Tendency for childbearing checklist

Intervention groups

1

Description
Intervention group: Intrapartum care in the intervention group will be based on the constructs of the care model of the World Health Organization. The nine dimensions of this model are as follows: 1) Respectful labor and childbirth care; All considerations of confidentiality and privacy, no physical harm or abuse, dignity and respect, lack of care, right to necessary information, informed consent, and choices/preferences during labor, delivery and postpartum. 2) Emotional support from a companion of choice; Suggested activities for the companion of choice include support for women (stay with her, calm her down, massage her, show her affection, and encourage and stimulate her), behave correctly when the woman faces fatigue, anxiety and worry, cries or screams or feels helpless, observe the regulations (wear standard clothes, avoid eating, smoking, or touching the equipment and devices), and inform the staff whenever it is necessary to leave the hospital). 3) Effective communication by the staff; Effective communication with the participants will include listening and being polite to them, quickly relieving their pain, behaving in a jovial fashion and being kind and close to them as well as involving the mother in decisions related to her in order to create a sense of control, independence, and security in them 4) Pain relief strategies; Non-pharmacological pain relief techniques, such as teaching diaphragmatic breathing with proper inhalation and exhalation, thermotherapy, position change, and massage, if the participant agrees. If necessary, pharmacological pain relief methods will be used at the discretion and under the supervision of a gynecologist involved in the project. 5) Regular monitoring of labor, documentation, auditing, and feedback; Documentation of labor and delivery events by partograms and delivery checklists, accurate and regular monitoring of delivery care during labor, childbirth, and the first two hours after delivery by the researcher. 6) Receiving oral fluids and food; Provision a list of foods or liquids that are easy to digest (drinking water, fruit juices, dates, biscuits, and cakes) to prepare. However, they will be free to consume whatever they want in small and frequent amounts.7) Maternal mobility and birth position of choice; Positions considered during the first stage of labor include sitting, walking, semi-sitting, four-legged, and lateral positions (both sides). The participants will be asked to begin with any position

that is easier for them, hold each position for 10 minutes, and take a 10-minute rest between two positions. They should also repeat these five positions at 4-cm, 7-cm, and 10-cm of cervical dilatation. For each woman in the intervention group, depending on her tolerance and the duration of labor for an average of one hour, it will be recommended to walk several times. 8) A pre-established referral plan; Since the research setting includes sub-specialty hospitals, there will be no need for referral for the participants to receive higher levels of care. Nevertheless, they will be regularly monitored during labor and in the early postpartum period in order to coordinate with the gynecologist as soon as possible if necessary and make prompt decisions. 9) Continuity of care; To observe the continuity of care in this study, the researcher will visit the mother one day after delivery in the midwifery ward, on the tenth day, and on the fortieth day after delivery.

Category
Behavior

2

Description
Control group: Care in the control group will be based on the routine hospital care

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Somaiyeh Abdolalipour

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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Somaiyeh Abdolalipour

Position
دانشجو

Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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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
Confidentiality of participants' information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The protocol and results of the clinical study will be published as an article
When the data will become available and for how long
Immediately after extraction the results
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific use with reference to the article
From where data/document is obtainable
Email: mirghafourvandm@tbzmed.ac.ir
What processes are involved for a request to access data/document
Up to one week after correspondence by email
Comments