

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of implementing the continuous care model by midwifery students during pregnancy, childbirth, and postpartum on childbirth experience, fear of childbirth, and postpartum depression

Protocol summary

Study aim

To determine the effect of implementing the continuous care model by midwifery students during pregnancy, childbirth, and postpartum on childbirth experience, fear of childbirth, and postpartum depression

Design

A randomized clinical controlled trial with two parallel arms, with no blinding, on 92 participants. The allocation sequence will be generated through individual stratified (based on 1st or 2nd-3rd birth order) block randomization with randomly varied block sizes of four and six, and an allocation ratio of 1:1 using a computer program. The central method will be used for the allocation concealment.

Settings and conduct

The continuous care will be at least two in-person visits and a required number of virtual consultations during pregnancy, attending labor and delivery, an in-person visit after delivery, and at least three postpartum virtual consultations provided by Tabriz sixth/seventh-semester midwifery students

Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age 26 to 29 weeks; single pregnancy; maximum history of two births; no underlying disease; no pregnancy complications; no high-risk pregnancy; a minimum of secondary education; willingness to give birth in one of Tabriz Government Hospitals. Exclusion criteria: history of cesarean section; willingness to elective cesarean section; lack of access to smartphones and the internet; major known abnormalities in the fetus; occurrence of stressful events in the last three months; simultaneous participation in another trial

Intervention groups

The intervention group will receive continuous care provided by midwifery students from pregnancy to six weeks after delivery, in addition to routine care. The

control group will receive only routine care during pregnancy, birth, and postpartum.

Main outcome variables

Scores of fear of childbirth; childbirth experience, and postpartum depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100414003706N41**

Registration date: **2022-04-30, 1401/02/10**

Registration timing: **prospective**

Last update: **2022-04-30, 1401/02/10**

Update count: **0**

Registration date

2022-04-30, 1401/02/10

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-25, 1401/04/04

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing the continuous care model by midwifery students during pregnancy, childbirth, and postpartum on childbirth experience, fear of childbirth, and postpartum depression

Public title

Effect of continuous care model from pregnancy to postpartum by midwifery students

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age 26 to 29 weeks based on LMP or under 12- week ultrasonography Single pregnancy Maximum history of two birth No known underlying disease before pregnancy No history of high-risk pregnancy Have a minimum of secondary education Willingness to give birth in hospitals affiliated with Tabriz University of Medical Sciences or Tabriz Social Security Hospital

Exclusion criteria:

History of cesarean section Willingness to elective cesarean section No access to smartphones and the internet Known major abnormalities in the fetus Occurrence of any stressful events (such as divorce, death of first-degree family members, and diagnosis of an incurable disease for a family member) in the last three months Simultaneous participation in another trial

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **92****Randomization (investigator's opinion)**

Randomized

Randomization description

Participating pregnant women will be randomized into two groups, receiving continuous care by midwifery students or control. The allocation sequence will be generated by a person not involved in the recruitment and data collection through stratified (based on 1st or 2nd-3rd birth order) block randomization with randomly varied block sizes of four and six, and an allocation ratio of 1:1 using a computer program. Central allocation (phone) will be used for the allocation concealment. Simple randomization will be used to determine the sequence of assigning the participating women to midwifery students. Two pregnant women will be assigned to each student (as primary caregivers) and each student will support another student who provides

care for two other women.

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

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-04-19, 1400/01/30

Ethics committee reference number

IR.TBZMED.REC.1401.094

Health conditions studied**1****Description of health condition studied**

Fear of childbirth

ICD-10 code

F40.232

ICD-10 code description

Fear of other medical care

2**Description of health condition studied**

Postpartum depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

3**Description of health condition studied**

Childbirth experience

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Childbirth experience score

Timepoint

40 to 50 days after delivery

Method of measurement

Childbirth Experiences Questionnaire v2.0 (CEQ2.0)

2

Description

Postpartum depression score

Timepoint

50-40 days after delivery

Method of measurement

Edinburgh Postnatal Depression Scale (EPDS)

3

Description

Fear of childbirth score

Timepoint

Baseline (before randomization), 35-36 weeks of pregnancy, 50-40 days after delivery

Method of measurement

The Wijma delivery expectancy/experience questionnaire (W-DEQ-A and B)

Secondary outcomes

1

Description

Fear of childbirth score (during pregnancy)

Timepoint

Baseline (before randomization), 35-36 weeks of pregnancy

Method of measurement

The Wijma delivery expectancy/experience questionnaire (W-DEQ-A)

2

Description

Pregnancy depression score

Timepoint

Baseline (before randomization), 35-36 weeks of pregnancy

Method of measurement

Edinburgh Postnatal Depression Scale (EPDS)

3

Description

Childbirth satisfaction score

Timepoint

12 to 24 hours after delivery

Method of measurement

Maternal satisfaction in normal and caesarean birth

(SMMS-normal birth and SMMS- caesarean birth)

4

Description

Score for receiving support and control

Timepoint

12 to 24 hours after delivery

Method of measurement

Support and Control in Birth (SCIB)

5

Description

Score of experiences of maternity care

Timepoint

40-50 days after delivery

Method of measurement

Women's experiences of maternity care (EMC)

6

Description

Breastfeeding self-efficacy score

Timepoint

40-50 days after delivery

Method of measurement

Breastfeeding Self-efficacy Scale (BSES)

7

Description

Type of delivery

Timepoint

After delivery

Method of measurement

Checklist (vaginal/cesarean)

8

Description

Duration of hospitalization until delivery

Timepoint

12-24 hours after delivery

Method of measurement

Mother's hospital record

9

Description

Infant's fifth-minute APGAR

Timepoint

12-24 hours after delivery

Method of measurement

Infant's hospital record

10

Description

Change in hematocrit between before and after delivery

Timepoint

At the time of admission of the mother in the hospital and 12-24 hours after delivery

Method of measurement

Measurement of blood hematocrit at laboratory of the hospital

Tabrizphc@tbzmed.ac.ir
Web page address
<https://tabriz-phc.tbzmed.ac.ir/>

Intervention groups

1

Description

Intervention group: Continuous care will include the following: 1. Receive at least twice face-to-face care (between 26-29 weeks and between 35-36 weeks of pregnancy), 2. Telephone or video consultations (at least four consultations with intervals of 7-10 days between two face-to-face care sessions and then weekly until delivery), 3. Attending a woman's bedside and providing care during labor and delivery up to 2 hours after delivery, 4. Face-to-face visit 24-12 hours after delivery in the hospital, 5. Giving at least three telephone or video consultations (3-5 days, 7-10 days and 20-30 days) after delivery, 6. Giving students' mobile numbers to women to answer possible non-emergency questions (from 8 am to 11 pm) and emergency questions and delivery information (24 hours a day, 7 days a week), 7. Additional face-to-face or online care will also be provided by the students during pregnancy or after delivery.

Category

Prevention

2

Description

Control group: Control group: will receive their usual pregnancy, childbirth, and postpartum care in health centers and hospitals. This group of mothers will also receive free online counseling from six weeks (end of follow-up on the impact of the intervention) to six months after delivery by the Ph.D. student in midwifery who owns the dissertation.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Selected health centers in Tabriz

Full name of responsible person

Ahmad Mardi

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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

Elham Jafari

Position

P.hD student in midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
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Ph.D.
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)

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

All deidentified IPD can be shared.

When the data will become available and for how long

Starting soon after the publication of the study results.

To whom data/document is available

Data will be available for researchers working in academic institutions, as well as to the chief editor and reviewers of the submitted manuscript.

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of the proposal to perform a meta-analysis using IPD. Also, in exceptional cases, data will be made available to the chief editor of the journals for checking.

From where data/document is obtainable

Refer to the email addresses (alizades@tbzmed.ac.ir)

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

The requests should be sent by email and data will be available within two weeks.

Comments