Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Implementation and evaluation of the effectiveness of the continuous midwifery care model in socially vulnerable women: a randomized controlled clinical trial

Protocol summary

Study aim

Implementation and Evaluation of the Effectiveness of the Continuous Midwifery Care Model in Pregnant Women with Social Vulnerability

Design

A randomized, controlled clinical trial with parallel groups on 92 pregnant women with vulnerable conditions (violence or poverty or unwanted pregnancy). A stratified random block design (primiparous and multiparous) with block sizes of 4 and 6 and an allocation ratio of 1:1 will be used for randomization.

Settings and conduct

This study is a randomized controlled trial that will be conducted in health centers and Shohada Hospital in Bonab. Women will be randomly assigned to intervention and control groups. The intervention group will receive the continuous midwifery care model and the control group will receive routine care.

Participants/Inclusion and exclusion criteria

Eligible pregnant women are 12–14 weeks gestation, literate (≥5th grade), have smartphone access, plan to deliver in Bonab, and meet criteria like vulnerability, prior vaginal birth or nulliparity, and ability to attend health center sessions.

Intervention groups

The intervention group will receive continuous midwifery care alongside routine maternity services, spanning antenatal, intrapartum, and postpartum phases. Antenatal care includes six sessions from 12 to 38 weeks gestation, covering education, counseling, and clinical assessments. Intrapartum and postpartum phases provide labor support and Giving birth and two postnatal sessions up to six weeks after delivery.

Main outcome variables

Pregnancy experience, childbirth experience, and depression during pregnancy and postpartum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N84**
Registration date: **2025-08-23, 1404/06/01**
Registration timing: **prospective**

Last update: **2025-08-23, 1404/06/01**
Update count: **0**

Registration date

2025-08-23, 1404/06/01

Registrant information

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Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-11, 1404/06/20

Expected recruitment end date

2026-03-11, 1404/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Implementation and evaluation of the effectiveness of the continuous midwifery care model in socially vulnerable women: a randomized controlled clinical trial

Public title

Investigating the impact of continuous midwifery care on socially vulnerable women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women with vulnerable conditions (violence or poverty or unplanned pregnancy). Gestational age 12-14 weeks Possibility of participants attending (depending on location) in antenatal and postnatal group sessions at health centers. Nulliparous women or with a history of vaginal delivery Possibility of access to a smartphone Literacy (at least fifth grade education) Willingness to give birth in Bonab city

Exclusion criteria:

Multiple pregnancy History of cesarean delivery Major fetal anomalies Medical comorbidities History of high-risk pregnancy (stillbirth, recurrent miscarriage, preeclampsia, etc.)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

A study will be conducted on 92 pregnant women identified as vulnerable (experiencing violence, living in poverty, or having an unplanned pregnancy), with 46 participants in each group, beginning from gestational weeks 12 to 14. Eligible participants will be selected for inclusion in the present study. Sampling will be performed using a simple random method based on a random number table. Comprehensive information regarding the research, its objectives, and implementation procedures will be provided to the women. Those who express willingness to participate will complete the following questionnaires: the World Health Organization's Domestic Violence Questionnaire, the Socio-Economic Status (SES) assessment, and forms collecting individual, social, and obstetric information. Subsequently, participants who, based on the aforementioned questionnaires, have experienced physical or sexual violence, fall within the poor or poorest categories according to the wealth index, or report an unplanned pregnancy, will be asked to provide written informed consent. These individuals will then be randomly assigned to the study groups. For the allocation of participants into intervention and control groups, a simple block randomization method will be employed, using block sizes of 4 and 6 and an allocation ratio of 1:1. Stratification will be based on parity status (primiparous vs. multiparous). To ensure allocation concealment, the type of intervention will be written on paper and placed inside opaque, consecutively numbered envelopes. These envelopes will be opened in the order of participants' entry into the study, thereby determining their group assignment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of this study, blinding of participants or the intervention provider is not feasible. However, the outcome assessor and data analyst will remain blinded. Outcome evaluation will be conducted by a research assistant. Regarding data analysis, participants will be coded in such a way that the analyst will not have access to information indicating group allocation. This approach ensures that data analysis and interpretation remain unbiased.

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

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

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East Azarbaijan

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Approval date

2025-07-30, 1404/05/08

Ethics committee reference number

IR.TBZMED.REC.1404.345

Health conditions studied

1

Description of health condition studied

Maternal care and high-risk pregnancies

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mean score of pregnancy experience

Timepoint
At 34–36 weeks of gestation

Method of measurement
Pregnancy Experience Scale (PES)

2

Description
Mean score of childbirth experience

Timepoint
At 4–6 weeks postpartum

Method of measurement
Childbirth experience questionnaire version 2.0 (CEQ2.0):

3

Description
Depression scores at both time points, while controlling for baseline levels

Timepoint
At 34-36 weeks of pregnancy and 4-6 weeks after delivery

Method of measurement
Edinburgh postnatal depression scale (EPDS)

Secondary outcomes

1

Description
Frequency of type of delivery (cesarean section and vaginal delivery)

Timepoint
After birth

Method of measurement
Maternal and neonatal outcome checklist

2

Description
Average length of labor stages (active, second, and third phases)

Timepoint
In labour

Method of measurement
Maternal and neonatal outcome checklist

3

Description
Average length of hospitalization until delivery

Timepoint
From hospitalization to delivery

Method of measurement
Maternal and neonatal outcome checklist

4

Description
Average score of satisfaction with care

Timepoint
After completing the intervention in 36-39 weeks of pregnancy

Method of measurement
Visual Analogue Scale

5

Description
Average lactation performance score

Timepoint
At 4-6 weeks postpartum

Method of measurement
Breastfeeding performance questionnaire

6

Description
Average score of fear of childbirth

Timepoint
After birth

Method of measurement
(W-DEQ= The Wijma Delivery Experience Questionnaire version B)

7

Description
Average specific anxiety score

Timepoint
At 4-6 weeks postpartum

Method of measurement
Postpartum specific anxiety scale

8

Description
Frequency of desire to have more children

Timepoint
At 4-6 weeks postpartum

Method of measurement
Maternal and neonatal outcome checklist

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive continuous midwifery care from the 14th week of pregnancy until 6 weeks after delivery by a permanent midwife (researcher). In addition to routine prenatal and postpartum services, this care will include continuous and individualized care in three stages:

antenatal (pregnancy), labor, and postpartum. In the prenatal stage, obstetric care will include continuous visits, group education, assessment of the mother's clinical condition, and continuous response to women's physical and psychological needs. For this purpose, six group sessions will be held during pregnancy at intervals of (14-16 weeks, 18-20 weeks, 22-24 weeks, 26-30 weeks, 32-34 weeks, and 36-38 weeks) in health centers in Bonab city. In the postpartum phase, two counseling and education sessions will be held in the health centers of Bonab city within 3 to 5 days and 4 to 6 weeks after delivery. Each group session will be held for 2 hours with the presence of 2 to 10 women and will be facilitated by a researcher (midwifery doctoral student). The content of each session will be based on the educational curriculum of the World Health Organization (WHO), the International Confederation of Midwives (ICM), the national guide to providing midwifery and childbirth services, and the content of the Midwifery continuous care model. The opinions of experts (perinatologists, reproductive health specialists, and midwives) will be used to confirm the content of the sessions. The duration of training in each session will be 60 minutes on predetermined topics focused on the patient's needs and related to the content, and 30 minutes will be allocated to measuring vital signs, listening to the fetal heartbeat, checking the height of the uterus and the weight of the pregnant mother, and the remaining 30 minutes of each session will be allocated to group discussion on possible questions and problems of the mothers. Also, a group will be formed on the social network that the mothers have the most convenient and most access to (such as ETA or WhatsApp, etc.), and the meeting materials will be uploaded there in a completely simple and understandable language, as well as additional materials, and the group members will also have the opportunity to ask questions and answer questions, and the research midwife will be available to the mothers at any time. The control group will receive standard care according to national guidelines. Participants in the intervention group will be encouraged not to visit the hospital before the onset of real pain (even before the start of the active phase of labor, if possible) to minimize unnecessary intervention, and participants will also be emphasized to inform the researcher when they visit and are hospitalized for delivery. For participants in the intervention group, the researcher will be present at their bedside in the labor ward and will support and encourage them throughout all stages of labor (this support includes providing a calm and stress-free environment, psychological and emotional support, and the active presence of the midwife to guide the mother by teaching breathing and relaxation techniques, encouraging the mother to focus on her abilities, reducing anxiety and boosting self-confidence, and helping to do appropriate exercises such as waist movements, kicking mud, and climbing stairs). The mother will be delivered by the researcher's midwife. She will also accompany the mothers in starting breastfeeding for the first 2 hours after delivery to support this stage. If mothers are hospitalized prematurely, the researcher will meet with the mothers in person at least once a day to check on their condition. Participants in both groups will be followed up for up to 6 weeks postpartum, and the final two counseling and education sessions will be held 3-5 days and 4-6 weeks postpartum.

Category

Treatment - Other

2

Description

Control group: The control group will receive standard care according to national guidelines.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Bonab city

Full name of responsible person

Fatemeh Ahadi- yulghunlu

Street address

Health Center, Esteghlal Ave, 1st Street, Bonab City

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2

Recruitment center

Name of recruitment center

Bonab shohada hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
Fatemeh Ahadi- yulghunlu

Position
Student

Latest degree
Master

Other areas of specialty/work
Midwifery

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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
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