Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of educational intervention based on trauma-informed care approach on fear of childbirth and childbirth self-efficacy in pregnant women with a history of traumatic childbirth

Protocol summary

Study aim

Determining the effect of an educational intervention based on a trauma-informed care approach on fear of childbirth and childbirth self-efficacy in pregnant women with a history of traumatic childbirth.

Design

A randomized, double-blind, controlled, parallel-group Phase 2 clinical trial involving 80 patients.
Randomization is performed using a block randomization method with an equal allocation ratio (1:1); the allocation sequence is concealed using opaque, sealed envelopes and administered by an individual independent of the researcher.

Settings and conduct

The setting for this study was the prenatal care clinics at hospitals affiliated with Qom University of Medical Sciences. The blinding method employed was double-blinding, involving both the participants and the data analyst.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Provision of informed consent to participate in the study; 2. Age range of 18 to 40 years; 3. Gestational age between 24 and 28 weeks; 4. Ultrasound-confirmed singleton pregnancy; 5. History of at least one traumatic childbirth in previous pregnancies, based on two items from Criterion A of the City BiTS scale; 6. Ability to read, write, and comprehend Persian.
Exclusion criteria: 1. Documented history of severe/major psychiatric disorders and substance or alcohol abuse; 2. Presence of serious obstetric complications or high-risk pregnancy requiring hospitalization or intensive care.

Intervention groups

The educational intervention group will receive a trauma-informed program delivered in four weekly, 90-minute sessions. The control group will receive a peer-attention training program consisting of four weekly, 90-minute sessions; a trauma-informed counseling intervention will not be administered to the control group participants during the study.

Main outcome variables

Fear of childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260906070939N1**
Registration date: **2026-09-17, 1405/06/26**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **0**

Registration date

2026-09-17, 1405/06/26

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-18, 1405/06/27

Expected recruitment end date

2026-12-19, 1405/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention based on trauma-informed care approach on fear of childbirth and childbirth self-efficacy in pregnant women with a history of traumatic childbirth

Public title

The effect of educational intervention based on trauma-informed care approach on fear of childbirth and childbirth self-efficacy in pregnant women with a history of traumatic childbirth

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Giving written and informed consent to participate in the research. Falling within the 18–40 age range. Gestational age between 24 and 28 weeks. Confirmation of singleton pregnancy via ultrasound. A history of at least one traumatic birth in previous pregnancies, based on the perception of the prior birth as a traumatic experience and an affirmative response to at least one of the two Criterion A items of the City BiTS scale—specifically, the individual's belief during labor, delivery, or immediately thereafter regarding the likelihood of serious physical injury or death for themselves or the infant. Ability to read, write, and comprehend Persian in order to communicate with the researcher and accurately complete the questionnaires.

Exclusion criteria:

Documented history of severe or major psychiatric disorders (such as psychosis, schizophrenia, bipolar disorder, or major depression with suicidal ideation) Substance or alcohol abuse Occurrence of serious obstetric complications and high-risk pregnancies (such as preeclampsia, placenta previa, uncontrolled gestational diabetes, or the Detection of fetal anomalies via ultrasound) requiring hospitalization or specialized care

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Following the selection of participants, the study objectives will be explained to eligible individuals, and written informed consent will be obtained from them. After initial registration and completion of the pre-test questionnaires, participants will enter the randomization phase. To prevent selection bias and ensure a balanced and homogeneous distribution of participants between the intervention and control groups, block randomization with an equal allocation ratio (1:1) will be used. The randomization sequence of the blocks will be generated by a statistician who will have no role in participant recruitment or intervention implementation, using R software version 4.5.1. To prevent the allocation sequence from being predictable to the researcher, variable block sizes (blocks of 4 and 6) will be used. To conceal the allocation sequence from the researcher and participants until the participant's final enrollment in the study, the standard method of sequentially numbered, opaque, sealed envelopes will be used. Accordingly, the allocation codes (A for the intervention group and B for the control group) will be placed inside opaque envelopes and sealed by an independent individual who is not involved in the sampling process. Only one sequential numerical code will be recorded on the outside of each envelope. After the final registration of each participant and completion of the pre-test, the envelope corresponding to the participant's number will be opened in sequence, and the participant's group assignment will be determined. To minimize detection bias and analysis bias, the statistician conducting the data analysis will be fully blinded to the participants' group assignments. Specifically, the data will be entered and analyzed in the statistical software using only numerical codes (Group 1 and Group 2), and the group codes will be unblinded only after completion of the final analysis. To reduce assessor bias, distribution and collection of the questionnaires at the post-test and follow-up stages will be conducted by an independent individual who is unaware of the mothers' group assignments. Since the control group will also receive a structurally equivalent educational program in terms of the number, duration, and method of session delivery (peer-attention education), participants will remain unaware of their group assignment throughout the study. Thus, in addition to controlling for attention bias, participant blinding to the study hypothesis will be maximized.

Blinding (investigator's opinion)

Double blinded

Blinding description

Efforts are made to minimize detection bias through the blinding of the statistical analyst and the use of self-report questionnaires. A peer-attention program is provided for the control group—matching the intervention group in the number and duration of sessions—which controls for the attention effect while also facilitating partial blinding of the participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qom University of Medical Sciences

Street address
Qom University of Medical Sciences and Health Services, Shahid Lavasani Street (Saheli)

City
Ghoum

Province
Ghoum

Postal code
3713649373

Approval date
2026-09-16, 1405/06/25

Ethics committee reference number
IR.MUQ.REC.1405.223

Health conditions studied

1

Description of health condition studied
Childbirth

ICD-10 code
XV

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Fear of childbirth

Timepoint
Stage 1 (Pre-test): Prior to the assignment of participants to research groups. Stage 2 (Post-test): Immediately following the conclusion of each group's final training session (for the intervention group: the fourth intervention session; for the control group: the fourth session of the peer-attention training program). Stage 3 (36-week follow-up): To assess the sustainability of the intervention's effects during the peak period of prenatal anxiety.

Method of measurement
Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ-A)

Secondary outcomes

1

Description
Childbirth Self-Efficacy

Timepoint
Stage 1 (Pre-test): Prior to the assignment of participants to research groups. Stage 2 (Post-test): Immediately following the conclusion of each group's final training session (for the intervention group: the fourth intervention session; for the control group: the fourth session of the peer-attention training program). Stage 3 (36-week follow-up): To assess the sustainability of the intervention's effects during the peak period of prenatal anxiety.Childbirth.

Method of measurement
Childbirth Self-Efficacy Inventory (CBSEI)

Intervention groups

1

Description
Intervention group: The intervention designed for this study is group counseling based on the Trauma-Informed Care (TIC) approach. This structured package was developed by integrating the four fundamental principles of the TIC approach (realization, recognition, response, and resisting re-traumatization) with the four sources of self-efficacy from Bandura’s theory (mastery experiences, vicarious experiences, verbal persuasion, and management of physiological states). The implementation protocol is as follows: the intervention will take place in a dedicated, well-lit, and air-conditioned room within the research setting, featuring a circular seating arrangement (aligning with the principles of collaboration and participation, and the elimination of therapeutic hierarchies in TIC) and ensuring complete privacy (consistent with the TIC principle of physical and psychological safety); it will consist of four 90-minute sessions held once a week. The first session will commence between the 24th and 32nd weeks of pregnancy.

Category
Behavior

2

Description
Control group: The attention-matched training program for the control group is implemented as follows: in addition to routine prenatal care, this group will attend four weekly, 90-minute sessions (matching the frequency, duration, and delivery format of the intervention group) in groups of six to eight participants. These sessions will cover general maternal health topics—such as prenatal nutrition, safe physical activity, sleep hygiene, and medication safety—deliberately designed to be unrelated to the mechanisms of the primary intervention (fear of childbirth and childbirth self-efficacy). The content holds no specific therapeutic effect and is intended solely to equate the level of attention and contact time with the provider (controlling for attention bias). The trauma-informed counseling

intervention will not be administered to the control group participants during the study.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Prenatal care clinics at hospitals affiliated with Qom University of Medical Sciences

Full name of responsible person
Zohreh Momeni Movahed

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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
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
Elham Mohammadian

Position
Master's student

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
I haven't decided yet—the release schedule is not yet clear.

When the data will become available and for how long
I haven't decided yet—the release schedule is not yet clear.

To whom data/document is available
Individuals employed in scientific and research institutions

Under which criteria data/document could be used
In a situation where all group members agree.

From where data/document is obtainable
Zohreh Momeni Movahed

What processes are involved for a request to access data/document
The applicant should send an email to Dr. Momeni Movahed. It will be sent if approved.

Comments