Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The effect of psychoeducational counseling on post-traumatic stress disorder and fear of childbirth in pregnant women with experience of childbirth trauma: a randomized controlled trial

Protocol summary

Study aim

Determining the effect of psychoeducational counseling on post-traumatic stress disorder and fear of childbirth in pregnant women with a history of traumatic childbirth

Design

The randomized controlled clinical trial, with a 1:1 parallel design will be conducted on 70 pregnant women with a history of previous traumatic childbirth. Blocked randomization will be done using web-based software

Settings and conduct

Pregnant women if they meet the inclusion criteria are assigned to the intervention or control group based on the predetermined allocation sequence. Holding 8 counseling sessions of psychological education in groups of 5 in Psychoeducational counseling sessions are held one week apart in comprehensive health centers in Hamedan. The duration of the sessions will be 45-60 minutes. Mothers in the control group received only routine care. To comply with ethical considerations, after the end of the study, a group meeting will be held for the mothers of the control group. At the 36th week of pregnancy, mothers of both groups are invited to complete the PSS-SR and CAQ questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: score 12 and above based on PSS-SR questionnaire; having a history of pregnancy and childbirth; previous vaginal delivery. Exclusion criteria: not attending two counseling sessions; hospitalization or early termination of pregnancy.

Intervention groups

Intervention group: in addition to routine care, holding 8 counseling sessions of psychological education in groups of 5 in weeks 24 to 32; Control group: routine care.

Main outcome variables

Post-traumatic stress disorder and fear of childbirth

General information

Reason for update

The educational content needed to be completed: teaching the birth process, sharing experiences, and relaxation techniques were added. These were included in the proposal but were not recorded in detail in this system.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201102049233N2**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **prospective**

Last update: **2026-05-08, 1405/02/18**
Update count: **1**

Registration date

2023-02-01, 1401/11/12

Registrant information

Name

Farideh Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3838 0150

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f.kazemi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-07-06, 1402/04/15

Actual recruitment start date

2023-03-06, 1401/12/15

Actual recruitment end date

2023-08-12, 1402/05/21

Trial completion date

2024-02-10, 1402/11/21

Scientific title

The effect of psychoeducational counseling on post-traumatic stress disorder and fear of childbirth in pregnant women with experience of childbirth trauma: a randomized controlled trial

Public title

Post-traumatic stress disorder and fear of childbirth in pregnant women with experience of childbirth

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Score 12 and above based on PSS-SR questionnaire Having a history of pregnancy and childbirth Previous vaginal delivery Gestational age 28-30 weeks at the time of entering the study Singleton pregnancy in the current pregnancy Being literate in reading and writing Ability to speak Persian Not suffering from mental illnesses diagnosed based on the records available in comprehensive health centers Not suffering from medical diseases such as diabetes, hypertension, thyroid, liver, heart diseases, etc. according to the file Not suffering from pregnancy complications such as gestational diabetes, pre-eclampsia, placenta previa and IUGR, etc. according to the file The absence of an unfortunate incident in the last month

Exclusion criteria:

Not attending two counseling sessions Hospitalization or early termination of pregnancy due to pregnancy-related complications during the intervention period The occurrence of an unfortunate accident for the participant Suffering from mental disorders or taking psychiatric drugs based on the person's own statements

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to assign mothers to the intervention and control groups, a 4 and 6 random blocking method is used. To do this, the allocation sequence is first determined using AABB blocks before the start of the study. Then, the type of intervention is written in opaque closed envelopes based on the specified sequence and is numbered in sequence. Participants will complete a demographic and midwifery information questionnaire and receive an envelope before entering the study. People are then placed in one of the control or intervention groups based on the contents of the envelope.

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 Hamadan University of Medical Sciences

Street address

In front of Mardom's Park, Research Square

City

Hamedan

Province

Hamadan

Postal code

6517838687

Approval date

2022-12-03, 1401/09/12

Ethics committee reference number

IR.UMSHA.REC.1401.732

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

O99.3

ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Post-traumatic stress disorder and fear of childbirth scores

Timepoint

Before the intervention and 4 weeks after the end of the counseling sessions

Method of measurement

Posttraumatic Stress Disorder Self-Report Scale (PSS-SR) and Childbirth Attitude Questionnaire(CAQ)

Secondary outcomes

empty

Intervention groups

1

Description
In addition to routine care, the people in the intervention group will participate in 8 counseling sessions of 5-person group psychological education from week 24 to 32. Meetings will be held at an interval of one week and the venue of the meetings will be in Hamedan Comprehensive Health Centers. The time of the mother's presence is determined by their prior arrangement and by phone. The duration of the sessions will be 45-60 minutes. In the present study, women are primarily informed about the issues they are afraid of. In addition, women are educated about the pregnancy process, hormones, the birth process, pharmacological and non-pharmacological methods of pain relief. Knowledge gaps are addressed by correcting misinformation about childbirth and obstetric interventions at birth, and experiences are shared. In addition, women are informed about the type of delivery and the impact of the type of delivery on themselves, the fetus, and the postpartum period. Women practice relaxation techniques such as breathing techniques, distraction, and muscle relaxation in all sessions.

Category
Other

2

Description
Control group: Routine prenatal care

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Health Centers of Hamedan city

Full name of responsible person
Farideh Kazemi

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Hamedan University of Medical Sciences (UMSHA), Pazhouhesh Crossroad., Hamadan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Reza Shokoohi, Deputy of research and technology of Hamadan University of Medical Sciences

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Hamedan University of Medical Sciences (UMSHA), Pazhouhesh Crossroad., Hamadan, Iran.

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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Farideh Kazemi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data will be accessible if necessary
When the data will become available and for how long
After the results are published
To whom data/document is available
The data will be provided to academic and scientific institutions if necessary
Under which criteria data/document could be used
If a meta-analysis is required, the data will be made available to the corresponding author
From where data/document is obtainable
Correspondence with the responsible person by email
What processes are involved for a request to access data/document
If you agree to the request, the data will be sent by email.
Comments