Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

The effect of psychodrama-based group therapy counseling on postpartum anxiety in women with traumatic childbirth experience: A randomized controlled clinical trial

Protocol summary

Study aim

The effect of psychodrama-based group therapy counseling on postpartum anxiety in women with traumatic childbirth experience

Design

A controlled clinical trial with two intervention groups and one control group, non-blinded; coded questionnaires; allocation by an independent person using sequentially numbered sealed envelopes opened in order of entry; outcomes assessed by an independent evaluator; randomization via RAS software using stratified blocks of sizes 4 and 6 with a 1:1 ratio; total sample size: 62.

Settings and conduct

70 women will be selected by convenience sampling from Tabriz centers. The researcher will obtain a list and phone numbers of all mothers 1–6 months postpartum, contact them, briefly explain the study objectives, and, if willing, assess eligibility and complete the Childbirth Experience, the PSS_I Posttraumatic Stress Scale, and Edinburgh Postnatal Depression questionnaires via interview. If eligible, an in-person meeting will be arranged to provide full study details and obtain written informed consent. The required questionnaires will then be completed again in person.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Term delivery; singleton delivery; experience of traumatic vaginal delivery and an average score lower than 2.5; anxiety score higher than 28 based on the questionnaire. Exclusion criteria: having post-traumatic stress syndrome; history of depression or postpartum depression; use of antidepressants based on medical record review.

Intervention groups

After random allocation to intervention and control groups, the intervention group will attend six weekly in-person group counseling sessions (45–60 min) using the psychodrama approach at a health center/hospital (4–5 participants each). The control group will receive routine postpartum care and counseling.

Main outcome variables

Postpartum anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220926056046N5**
Registration date: **2025-10-28, 1404/08/06**
Registration timing: **prospective**

Last update: **2025-10-28, 1404/08/06**
Update count: **0**

Registration date

2025-10-28, 1404/08/06

Registrant information

Name

Solmaz Ghanbari Homaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3524 5181

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-19, 1404/08/28

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of psychodrama-based group therapy counseling on postpartum anxiety in women with traumatic childbirth experience: A randomized controlled clinical trial

Public title
The effect of psychodrama on postpartum anxiety in women with traumatic birth experiences.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Term delivery Singleton birth Living in Tabriz city or its suburbs Having experienced traumatic vaginal birth based on the Childbirth Experiences Questionnaire version 2.0 (CEQ 2.0) and a mean score lower than 2.5 Obtaining an anxiety score higher than 28 based on a specific postpartum anxiety questionnaire Having a smart phone Internet access Education level: Elementary school completion and above
Exclusion criteria:
Having post-traumatic stress syndrome (PTSD) based on the Post-Traumatic Stress Symptom Scale (PSS_1) questionnaire History of depression or postpartum depression based on maternal self-report or medical record review or score of 13 or higher on the Edinburgh Depression Questionnaire or mental illness based on self-report or medical record review Participating in two studies simultaneously Use of antidepressants based on medical record review The occurrence of a stressful life event, such as divorce, death of a close family member, and diagnosis of a terminal or incurable disease for a family member within three months prior to data collection.
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done by convenience sampling and according to the inclusion and exclusion criteria. Participants will be randomly assigned to the intervention and control groups using RAS (Random Allocation Software) with stratified blocks (based on being prime and multiparous) with block sizes of 4 and 6 and with a ratio of 1:1. The allocation of women will be done by a person not involved in the sampling. To conceal the allocation, the type of allocation will be written on paper and placed in consecutively numbered opaque envelopes (Allocation Concealment). The envelopes will be opened in the order of the participants' names in the study and by a person not involved in the study.
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
Central Building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, Iran.
City
Tabriz
Province
East Azarbaijan
Postal code
5155668474
Approval date
2025-10-06, 1404/07/14
Ethics committee reference number
IR.TBZMED.REC.1404.502

Health conditions studied

1

Description of health condition studied
Postpartum depression
ICD-10 code
F53
ICD-10 code description
Puerperal psychosis

2

Description of health condition studied
Postpartum anxiety
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

Primary outcomes

1

Description
Postpartum anxiety
Timepoint
Before the start of the intervention, 4 weeks after the end of the intervention
Method of measurement
Postpartum Specific Anxiety Scale-Research Short-Form (PSAS-RSF)

Secondary outcomes

1

Description
Postpartum depression
Timepoint
Before the intervention, 4 weeks after the end of the intervention, controlling for the effect of the baseline score
Method of measurement
Edinburgh Postpartum Depression Scale (EPDS)

2

Description
Maternal function
Timepoint
Before the intervention, 4 weeks after the end of the intervention, controlling for the effect of the baseline score
Method of measurement
Barkin Index of Maternal Functioning (BIMF)

Intervention groups

1

Description
Intervention group: For the intervention group, 6 sessions (once a week) of psychodrama-based intervention will be held in groups of 4-5 people for 45-60 minutes in a group and in person at the health center/hospital. The implementation of psychodrama will be carried out by a trained student under the supervision of an expert psychologist (consulting professor). In the intervention group, homework will be given to the individuals at the end of each session, and a review of the previous session will be conducted at the beginning of each session. A text message will be sent to the individuals each week to remind them of the assignments and sessions. Participants will receive free internet incentives to motivate them to do their homework each week. The researcher's contact number and email will be provided to the intervention group so that they can express their questions and talk confidentially if needed. The content of the sessions includes: Session 1: General session: Getting to know each other, building trust and group cohesion; Session objectives: Explaining the concept of psychodrama and the goals of group therapy and the effect of group activity on solving problems by the therapist; Introducing members and talking about their current discomfort and experiences related to traumatic childbirth; creating a sense of psychological safety; Session techniques: Warm-up games such as introducing yourself with a positive characteristic; Sociometry technique; free discussion about shared feelings after childbirth; explaining the framework of the sessions and group rules. Session 2: Session overview: Recognizing feelings and experiences of childbirth; Session objectives: Expressing the personal experience of childbirth; Identifying repressed feelings such as sadness, fear, anger, loneliness, worry, etc. and expressing them through physical exercises and alternating expressions on the face and body; Session techniques: Drawing a picture of the childbirth experience; Using the monologue technique (each person talks about their experience); playing a short role of a difficult childbirth scene; group reflection and empathy. Session 3: Session overview: Role-playing a traumatic scene; Session objectives: Reconstructing and discharging emotions related to traumatic childbirth after physical and expressive exercises and warming up, using stage props, music, and other clients in the form of defined roles; Reducing anxiety related to the memory of childbirth; Accurately simulating traumatic situations for each client; Session techniques: Choosing a protagonist (one of the members); Performing a complete psychodrama with the help of egos (auxiliary characters); Working with feelings of fear, anger, and helplessness; Technique of “changing the ending of the scene” in a healthier way. Session 4: Session overview: Working with the maternal role and female identity; Session objectives: Identifying negative beliefs about motherhood after warming up exercises; Reconstructing the maternal role in the individual’s mind; Performing unpleasant experiences and dysfunctional feelings and thoughts of the protagonist by the egos and watching their own experiences from the perspective of the protagonist. Spectator; Session techniques: Double technique: reflection of the individual's hidden feelings by the therapist or another member; role-playing in the form of a conversation with the "critical self"; conversation with the "ideal mother self"; reconstruction of the positive maternal role; continued accurate simulation of the life situations of each client. Session five: General session: strengthening internal resources and social support; Session objectives: activating internal and external support resources; increasing the sense of maternal adequacy; consciously repeating the bitter and unpleasant experiences of the clients and forming a pleasant and controllable experience; continued accurate simulation of the life situations of each client; Session techniques: working with an empty chair (conversation with a source of support such as mother or spouse or God); visualizing a capable self and a successful mother; writing a supportive message to the future self; practicing relaxation and self-care. Session six: General session: summary, farewell and evaluation; Session objectives: reviewing previous sessions and the path

taken; evaluating constructive individual changes in the members' relationships; increasing awareness, empathy and confrontation in social interactions; Discovering new patterns and reducing conflicts; clarifying roles, interpersonal relationships, values, and revealing new desirable feelings, thoughts, and behaviors that are fruitful through group solidarity; preparing for the end of sessions; session techniques: reviewing initial feelings and current changes; drawing a chart of personal change; writing a letter to the pre-treatment self; group farewell ritual and transferring support outside the group.

Category
Behavior

2

Description
Control group: The control group will be provided with routine postpartum education, care, and counseling. After the intervention, if the results are significant and the psychodrama has a positive effect on the main outcome of the study, a virtual group counseling session will be held for the control group upon their request and willingness.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Solmaz Ghanbari Homaie
Street address
School of Nursing and Midwifery, shariati street
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Phone
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Email
homayisolmaz@gmail.com
Web page address
https://taleghanihosp.tbzmed.ac.ir/

2

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Solmaz Ghanbari Homaie
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School of Nursing and Midwifery, Shariati street
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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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Central Building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, Iran.
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info@tbzmed.ac.ir
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
Solmaz Ghanbari Homaie
Position
Assistant Professor
Latest degree
Ph.D.

Other areas of specialty/work
Midwifery
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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
Participant data is confidential.
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
Undecided - It is not yet known if there will be 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