# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the Effects of Supportive Counseling With and Without Auriculotherapy on Postpartum Stress and Anxiety

### Protocol summary


**Study aim**
Determining and comparing the effect of supportive counseling With and Without Auriculotherapy on Postpartum Stress and Anxiety

**Design**
A randomized clinical trial with three parallel arms will be conducted on 78 postpartum women. Participants will be allocated using block randomization based on the number and type of delivery, with blocks of 3 and 6, in a 1:1:1 ratio to two intervention groups and one control group

**Settings and conduct**
Sampling will be conducted on women visiting the Al-Zahra and Taleghani educational and therapeutic centers in Tabriz, as well as other health centers in Tabriz, who have given birth 10 to 15 days prior. The scales for postpartum stress, anxiety, and depression, as well as the weight of the newborn, will be measured before the intervention and one and two months after delivery. The frequency of exclusive breastfeeding will also be recorded one and two months after delivery for all three groups. Only the evaluator of the results will be masked.

**Participants/Inclusion and exclusion criteria**
Women with singleton newborns weighing 2500-4000 grams, no contraindications to breastfeeding, living in Tabriz, with stress scores of 14-26, moderate anxiety scores of 32-50, and Edinburgh depression scores below 13.

**Intervention groups**
In the intervention group, three sessions of supportive counseling and Auriculotherapy will occur on days 10-15, 20-22, and 30 post-delivery, focusing on self-care, stress assessment, and coping skills. The control group will receive standard postpartum care. Auriculotherapy will use Vaccaria patches on specific ear points: Shen Men, Anxiety, Mammary Gland 1 and 2 (left ear), and Thalamic, Master Shoulder, Cerebral, and Lung 1 and 2 (right ear).

**Main outcome variables**
stress; anxiety


### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250907067159N1**
Registration date: **2025-12-07, 1404/09/16**
Registration timing: **prospective**

Last update: **2025-12-07, 1404/09/16**
Update count: **0**

**Registration date**
2025-12-07, 1404/09/16

**Registrant information**


**Name**
Roghaiyeh Nourizadeh

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-12-22, 1404/10/01

**Expected recruitment end date**
2026-06-21, 1405/03/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
Comparison of the Effects of Supportive Counseling With and Without Auriculotherapy on Postpartum Stress and Anxiety

**Public title**
Effect of Supportive Counseling With and Without Auriculotherapy on Postpartum Stress and Anxiety

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Women aged 18–49 years Willingness to breastfeed their infants Residence in Tabriz Singleton delivery Mothers with term neonates weighing 2,500–4,000 grams Mothers with a stress score higher than 14–26 and a moderate anxiety score of 32–50 (above the mean score according to the Angoff method)

**Exclusion criteria:**
Mothers with hospitalized neonates Presence of systemic or chronic diseases or conditions exacerbated during pregnancy or postpartum, including gestational or overt diabetes, hypertensive disorders, cardiac diseases, or inability to care for the newborn Experience of major adverse life events during the past three months, such as death of first-degree relatives or divorce History of psychiatric disorders or use of antidepressant or antipsychotic medications, based on the mother's self-report Unplanned pregnancies, fetal abnormalities, hypothyroidism, or neonatal death Mothers with breast anomalies, history of breast surgery, or contraindications to breastfeeding, including: • Women under chemotherapy. • Women with HIV infection or untreated active tuberculosis. • Women using radioactive drugs, antimetabolites, or contraindicated medications during lactation, such as methotrexate, mercaptopurine, hydroxyurea, tamoxifen, bromocriptine, lithium, phenindione, phencyclidine, cyclophosphamide, and doxorubicin, as well as illicit drug use The Edinburgs Depression Score of 13 or higher

**Age**
From **18 years** old to **49 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **78**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomization will be performed using a stratified block randomization method. The unit of randomization is the individual mother. Stratification will be based on type of delivery (vaginal/cesarean) and parity (primiparous/multiparous) to ensure balanced baseline characteristics. The random allocation sequence will be generated using variable block sizes of 3 and 6 by an independent person through Random Allocation Software. For allocation concealment, the group codes will be placed in opaque, sealed, and sequentially numbered envelopes, opened in order by a person not involved in the study. Participants will be randomly assigned to one of three groups: supportive counseling, supportive counseling with auricular acupressure, or routine postpartum care.

**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**
Freedom Street, Golgasht Street, Tabriz University of Medical Sciences, Central Building No. 2, Third Floor, Research Vice-Chancellor's Office.

**City**
Tabriz

**Province**
East Azarbaijan

**Postal code**
51665118

**Approval date**
2025-12-03, 1404/09/12

**Ethics committee reference number**
IR.TBZMED.REC.1404.659

## Health conditions studied

### 1

**Description of health condition studied**
Postpartum Anxiety

**ICD-10 code**
F41

**ICD-10 code description**
Other anxiety disorders

## Primary outcomes

### 1

**Description**
Postpartum stress

**Timepoint**

one and two month after delivery by controlling the effect of baseline score

**Method of measurement**

Perceived Stress Scale

**2**

**Description**

Specific postpartum anxiety

**Timepoint**

one and two month after delivery by controlling the effect of baseline score

**Method of measurement**

PSAS-RSF(Postpartum Specific Anxiety Scale Research short-form)

## Secondary outcomes

**1**

**Description**

Postpartum Depression

**Timepoint**

one and two month after delivery by controlling the effect of baseline score

**Method of measurement**

Edinburgs Postpartum Depression Scale

**2**

**Description**

Frequency of exclusive breastfeeding

**Timepoint**

one and two month after delivery

**Method of measurement**

A checklist designed to record breastfeeding status

**3**

**Description**

Comparison of the frequency of newborn visits by doctors

**Timepoint**

one and two month after delivery

**Method of measurement**

Checklist designed to record the number of baby visits by the doctor

## Intervention groups

**1**

**Description**

Intervention group: In one of the intervention groups, supportive counseling will be conducted in person over three sessions on days 10–15, 15–22, and 30 postpartum, each lasting 30–45 minutes. The content of the counseling sessions, based on the supportive counseling protocol, is as follows:Session 1 (10–15 days postpartum):This session includes an introduction, taking a medical and psychological history, discussing the rules, conditions, and goals of the counseling process, and encouraging the mother to express any questions and concerns that cause stress and anxiety during the postpartum period. The session also focuses on exploring the mother's emotional and psychological reactions to her new situation. The counselor looks for signs of functional disruption, stress symptoms, and maladaptive coping strategies in order to identify the mother's adaptive strengths and weaknesses. This allows the counselor to explain appropriate coping methods (such as relaxation techniques, seeking and mobilizing social support, and improving communication skills—particularly with the spouse).Additionally, the session provides education on adequate breast milk supply, reasons for infant crying and refusal to breastfeed, neonatal danger signs, vomiting and aspiration, neonatal jaundice, maternal nutrition during breastfeeding and strategies to increase milk production, breast problems, constipation, postpartum bleeding, back pain, episiotomy wound care, pain management, and umbilical cord care.Session 2 (15–22 days postpartum):In this session, the mother's physical and psychological experiences are reviewed, and signs of stress and anxiety are assessed. Relaxation techniques and coping skills are revisited, with an emphasis on the role of social support. Practical, individualized strategies for managing stress and anxiety are also provided.Session 3 (30 days postpartum):At this stage, the mother's progress in using psychological coping skills is evaluated. Questions are addressed, and additional recommendations are offered.

**Category**

Behavior

**2**

**Description**

Intervention group: In the other intervention group, supportive counseling combined with auriculotherapy will be conducted in person over three sessions on days 10–15, 15–22, and 30 postpartum, each lasting 30–45 minutes. The content of the counseling sessions is identical to that of the first intervention group.Session 1:Alongside supportive counseling, Vaccaria seeds will be applied to specific points on the auricle. The selected points include Shen Men, Anxiety, and Mammary Gland 1 & 2 on the left ear, and Thalamic, Master Shoulder, Cerebral, and Lung 1 & 2 on the right ear. The mother will be instructed on how to stimulate these points: she should gently apply pressure to each point for one minute, 5–6 times a day.Session 2:In addition to supportive counseling, the auriculotherapy seeds will be replaced, and the same points will be stimulated again.Session 3:During this session, the auriculotherapy seeds will once again be replaced and the same points stimulated. The counselor will also assess whether the mother has been correctly stimulating the ear points and evaluate the extent of their effectiveness.

**Category**

Treatment - Devices

**3**

**Description**

Control group: In this study, the control group will receive only the usual care after delivery.

**Category**
Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Al-Zahra Hospital

**Full name of responsible person**
Zahra Omranian Esfahani

**Street address**
Al-Zahra Educational-Therapeutic Center, South Army St., Tabriz

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### 2

**Recruitment center**

**Name of recruitment center**
Taleghani Hospital

**Full name of responsible person**
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### 3

**Recruitment center**

**Name of recruitment center**
All health centers in Tabriz city

**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**
Zahra Omranian Esfahani

**Position**
Master student of counseling in midwifery

**Latest degree**
Bachelor

**Other areas of specialty/work**
Midwifery

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## Person responsible for scientific inquiries

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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**
It is confidential.
**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**
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
**Title and more details about the data/document**
The method of conducting the work will be published in the form of a protocol paper in scientific journals.
**When the data will become available and for how long**
6 months after registering in IRCT
**To whom data/document is available**
The protocol article does not contain data or findings; it will only report the methodology.
**Under which criteria data/document could be used**
The data will be made available to researchers upon request.
**From where data/document is obtainable**
It can be obtained through the corresponding author.
**What processes are involved for a request to access data/document**
It will be sent via email within a week after receiving the request, if there is a valid reason.
**Comments**