

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 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

Country

Iran (Islamic Republic of)

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Email address

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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	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.
Scientific title Comparison of the Effects of Supportive Counseling With and Without Auriculotherapy on Postpartum Stress and Anxiety	Blinding (investigator's opinion) Not blinded
Public title Effect of Supportive Counseling With and Without Auriculotherapy on Postpartum Stress and Anxiety	Blinding description
Purpose Supportive	Placebo Not used
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 Edinburghs Depression Score of 13 or higher	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
Age From 18 years old to 49 years old	Health conditions studied 1 Description of health condition studied Postpartum Anxiety ICD-10 code F41 ICD-10 code description Other anxiety disorders
Gender Female	Primary outcomes 1 Description Postpartum stress Timepoint
Phase N/A	
Groups that have been masked <i>No information</i>	
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	

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

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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

Name of organization / entity

Tabriz University of Medical Sciences

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

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