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
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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

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East Azarbaijan

Postal code
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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

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

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2

Recruitment center

Name of recruitment center
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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

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
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
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Other areas of specialty/work
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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