

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of auriculotherapy on postpartum depression

Protocol summary

Study aim

Determining the effect of Auriculotherapy on postpartum depression

Design

A randomized clinical trial, a blind side

Settings and conduct

This study is a single-blind clinical trial that is performed in health centers in Behbahan. The samples include women with postpartum depression, the sample size is 134 people and the duration of the intervention is 10 days. The Edinburgh Maternity and Postpartum Depression Inventory is completed by individuals. Eligible samples are randomly divided into intervention and control groups. In the intervention group, granular labels are placed on the relevant points, it is recommended to apply pressure on the labels for 4 minutes every 4 hours. In the control group, the seedless labels, which appear to be similar to the intervention group in shape and color, are affixed by the researcher in non-depressive areas without any pressure, and they are asked to apply these labels to the ears of people without No compressive actions remain.

Participants/Inclusion and exclusion criteria

Admission requirements: Iranian and resident of Behbahan city, at least 6 weeks of childbirth, no physical illness, no acute mental illness and literacy in the level of reading and writing and in the post-delivery depression questionnaire Edinburgh 13 and Earned higher (EPDS $\geq$ 13). Conditions for not entering: Criteria for leaving the study include: severe depression, manic episodes with irritable bowel syndrome, adjustment disorder with depressed mood, sadness, ADHD; Mothers who have the potential to commit suicide in the current period and need immediate treatment. Mothers who, for whatever reason, are reluctant to continue their treatment.

Intervention groups

Intervention group: Auriculotherapy Control group: Seedless and unrelated labels

Main outcome variables

Postpartum Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047466N1**

Registration date: **2021-08-23, 1400/06/01**

Registration timing: **prospective**

Last update: **2021-08-23, 1400/06/01**

Update count: **0**

Registration date

2021-08-23, 1400/06/01

Registrant information

Name

Mahbubeh Jamei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5283 0225

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-02, 1400/06/11

Expected recruitment end date

2021-10-03, 1400/07/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of auriculotherapy on postpartum depression

Public title

The effect of Auriculotherapy on Postpartum depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian resident of Behbahan city at least 6 weeks of childbirth lack of physical illness acute mental illness and illiteracy in reading and writing Score 10 or higher on the Edinburgh Questionnaire

Exclusion criteria:

Severe depression manic episodes with irritable bowel syndrome compatibility disorder with depressed mood, sadness Mothers who have the potential to commit suicide in the current period and need immediate treatment Mothers who, for whatever reason, are reluctant to continue their treatment

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 65

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals will be randomly assigned to one of the intervention or control groups. Each person is assigned a code and then randomly assigned by pairing and individualizing the codes.

Blinding (investigator's opinion)

Single blinded

Blinding description

To perform the intervention in the auriculotherapy group, the researcher pasted the Vaccaria granular labels on the 6 points related to depression after applying the ear massage and applied them on the pressure points for 2 minutes and taught them to label them every 2 hours for 2 minutes. Press the granules on each point with your finger, and they are also asked to repeat the procedure for 10 days. The shape and color are pasted by the researcher in areas not related to depression without any pressure and they are asked to keep the labels on the ear without any pressure until the end of the study. A description of the treatment will be given.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Golestan St., Ahvaz University of Medical Sciences

City

ahwaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2020-04-03, 1399/01/15

Ethics committee reference number

IR.AJUMS.REC.1399.058

Health conditions studied

1

Description of health condition studied

Postpartum Depression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Postpartum Depression

Timepoint

Before the intervention, after the intervention

Method of measurement

Postpartum depression questionnaire Edinburgh

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Auriculotherapy / every 4 hours 2 minutes / 10 days

Category

Treatment - Other

2

Description

Control group: Seedless labels that appear to be similar in shape and color to the intervention group and are affixed to non-depressive areas without any pressure and are asked to apply these labels to the ears of people

without No compressive actions remain.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Behbahan health centers
Full name of responsible person
Mahbubeh Jamei
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Ahvaz 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
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mahbubeh jamei
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Masters student
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data will be sent to the responsible author upon publication upon request.

When the data will become available and for how long

Information after the publication of the article will be available upon request from the responsible author.

To whom data/document is available

The data will be available to researchers after obtaining permission.

Under which criteria data/document could be used

Researchers can send an e-mail to the author requesting information.

From where data/document is obtainable

Ahvaz, Golestan St., Ahvaz University of Medical Sciences, Faculty of Nursing and Midwifery, Mojgan Javad Nouri

What processes are involved for a request to access data/document

The requested information will be sent after receiving the email.

Comments