Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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≥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
mahbubeh.jamei6244@gmail.com

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

Street address

Behbahan School of Medical Sciences

City

Behbahan

Province

Khouzestan

Postal code

6361913719

Phone

+98 61 3733 8358

Email

mahbubeh.jamei6244@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badvi

Street address

Golestan Boulevard،Ahwaz University of Medical Sciences

City

ahwaz

Province

Khouzestan

Postal code

6315733653

Phone

+98 61 3733 3838

Fax

Email

badvi-m@ajums.ac.ir

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

Ahvaz University of Medical Sciences

Full name of responsible person

mahbubeh jamei

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Golestan, Ahwaz University of Medical Sciences, School of Midwifery Nursing

City

ahwaz

Province

Khouzestan

Postal code

6195893774

Phone

+98 61 3373 8331

Email

mahbubeh.jamei6244@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mojgan Javadnori

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Ahwaz University of Medical Sciences, School of Nursing and Midwifery

City

ahwaz

Province

Khouzestan

Postal code

6195893774

Phone

0098 61 3738331

Email

javadnoori-m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mahboubeh Jamei

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Ahwaz University of Medical Sciences, School of Nursing and Midwifery

City
Ahwaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3733 1338

Email
mahbubeh.jamei6244@gmail.com

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
Ahwaz, Golestan St., Ahwaz 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