

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Investigating the effect of ear acupressure on postpartum blues: A randomized sham controlled trial

#### Protocol summary

##### Study aim

Comparison of postpartum blues intensity in the study groups after intervention

##### Design

Clinical trial with sham control group, in parallel groups, triple blind, randomized, phase 3 on 74 patients. Randomization will be done using online random generator software.

##### Settings and conduct

This study is a randomized Sham controlled clinical trial, which will be performed on primiparous mothers at Kowsar Hospital in Qazvin. First external earlobes will be cleaned with 75% alcohol and then special non-latex adhesives with vaccaria seeds will be adhered with on 5 points of the left ear, including the endocrine master, my sand, Zero, Gonadotroin, Master cerbal and 2 points of right side includes the thalamic and antidepressant points. The number of interventions is 2 times with an interval of 5 days. Participants are taught to keep the seeds in their ears for five days, during this time, they must press each point three times a day for twenty seconds. In the control group, a similar visit is made and non-latex adhesives without vaccaria seeds will be placed on their ear. Therefore, the participant, clinical caregiver, and outcome assessor and data analyzer will not be aware of the type of intervention.

##### Participants/Inclusion and exclusion criteria

In this study, primiparous women with term pregnancy and a singleton baby with a healthy earlobe will be invited to study.

##### Intervention groups

1- Intervention group of auriculotherapy 2- Sham control group

##### Main outcome variables

Intensity of postpartum blues

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180218038789N2**

Registration date: **2020-06-19, 1399/03/30**

Registration timing: **prospective**

Last update: **2020-06-19, 1399/03/30**

Update count: **0**

##### Registration date

2020-06-19, 1399/03/30

##### Registrant information

##### Name

Zainab Alimoradi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 6003

##### Email address

z.alimoradi@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-05, 1399/04/15

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of ear acupressure on postpartum blues: A randomized sham controlled trial

## Public title

Investigating the effect of ear acupressure on postpartum blues

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

The desire to participate in the study Being primiparous Born a full term, singleton baby Having a healthy earlobe with no lesions, sores and pain in the earlobe Being Iranian Being literate at least with ability in reading and writing Availability during the study period (residence in Qazvin city)

### Exclusion criteria:

Complications in pregnancy and postpartum (e.g. preterm delivery, preeclampsia, gestational diabetes, infant in need of special care, etc.) History of chronic mental and physical illness (self-report and review of the individual's file) Drug abuse in the individual or his spouse History of acupressure in the last three months History of stressful events in the last three months (such as the loss of loved ones)

## Age

No age limit

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **74**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random allocation will be done using balanced block randomization methods with each block size of 4. The allocation sequence will be generated using online software. After preparing the allocation sequence, the sequence will be written down on paper in order and placed inside the closed sealed envelopes. Envelopes are numbered sequentially. Questionnaires are coded in the same way. Accordingly, each person will be assigned to one of the intervention or control groups.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

In this study, the control group will receive the same intervention as the main group ( sham control). Therefore, participants will not know what group they are in. Since the clinical caregiver and the outcome assessor and data analyst are not aware of this, blindness of the second and third levels will also be implemented.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

##### Street address

Shahid Bahonar Boulevard

##### City

Qazvin

##### Province

Qazvin

##### Postal code

34199-15315

#### Approval date

2020-05-20, 1399/02/31

#### Ethics committee reference number

IR.QUMS.REC.1399.050

## Health conditions studied

### 1

#### Description of health condition studied

Postpartum blues

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Intensity of postpartum blues

#### Timepoint

pre-intervention, 5 , 10 , 15 days after intervention

#### Method of measurement

Maternity Blues Questionnaire

## Secondary outcomes

### 1

#### Description

Intensity of postpartum tiredness

#### Timepoint

pre- intervention, 5, 10, 15 , 21 days after intervention

#### Method of measurement

Iowa tiredness scale

### 2

#### Description

Maternal attachment

### Timepoint

pre- intervention, 5, 10, 15 , 21 days after intervention

### Method of measurement

Muller Maternal Attachment Index

### 3

#### Description

Intensity of postpartum depression

#### Timepoint

21 days after intervention

#### Method of measurement

Edinburgh Postnatal Depression scale

## Intervention groups

### 1

#### Description

Intervention group: Auriculotherapy

#### Category

Prevention

### 2

#### Description

Control group: Sham control

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kowsar Hospital, Qazvin

##### Full name of responsible person

Zainab Alimoradi

##### Street address

Vali-Asar Avenue

##### City

Qazvin

##### Province

Qazvin

##### Postal code

34156-13176

##### Phone

+98 28 3323 6374

##### Email

zainabalimoradi.sbmu.ac.ir@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Dr EmamJomeh

##### Street address

Shahid Bahonar Boulevard- Qazvin University of  
Medical Sciences- School of Nursing & Midwifery

##### City

Qazvin

##### Province

Qazvin

##### Postal code

3419759811

##### Phone

+98 28 3333 8034

##### Email

zainabalimoradi.sbmu.ac.ir@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

##### Full name of responsible person

Zainab Alimoradi

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Health

##### Street address

Bahonar Blouvard, Qazvin University of Medical  
Sciences, School of Nursing and Midwifery

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##### Email

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Zainab Alimoradi

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Assistant Professor

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The data related to the study will be published as an anonymous and unrecognizable file at the same time as the publication of the results as an appendix.

**When the data will become available and for how long**

After the publication of the article, the results of the data design will be available

**To whom data/document is available**

All people can access the data by referring to the appendix of published article

**Under which criteria data/document could be used**

All people with no limitation can access data

**From where data/document is obtainable**

Appendix of published article

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

Email to corresponding author

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Zainab Alimoradi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

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