

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of auriculotherapy on sleep disorders among mothers in the postpartum period

Protocol summary

Study aim

Determining the effect of auriculotherapy on the sleep disorder of mothers in the postpartum period.

Design

A clinical trial with a randomized, parallel, one-sided control group on 52 primiparous women, where randomization is done in a block way.

Settings and conduct

The study is carried out in the health centers of Qom city. In the intervention group, four points in both ears (relaxation, sleep, etc.) are stimulated with a manual Pointer, and then grainy labels (seeds) are stuck on those points, and mothers are taught to touch each point for one minute in four shifts. Press for 5 days. In the control group, stimulation of the points is done exactly like the intervention group, with the only difference being that the non-grain stickers (which are similar in color and appearance to the grainy stickers) are placed on four points unrelated to the purpose of the study (throat, neck, etc.) is placed on both ears. Before and after the study, the sleep quality of the participants is measured through the Petersburg Sleep Quality Questionnaire.

Participants/Inclusion and exclusion criteria

The entry criteria must be 18-40 years old, have written consent, be a virgin, and have at least literacy. Exclusion criteria from the study: Pittsburgh Questionnaire score less than five, drug addiction, wound or any kind of lesions on the target ear points, mother's medical disorders

Intervention groups

The auriculotherapy intervention group by stimulating the main points and the control group stick simple labels on irrelevant points.

Main outcome variables

sleep disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220815055712N1**

Registration date: **2023-01-14, 1401/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-14, 1401/10/24**

Update count: **0**

Registration date

2023-01-14, 1401/10/24

Registrant information

Name

Leila Arbil

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of auriculotherapy on sleep disorders among mothers in the postpartum period

Public title
The effect of auriculotherapy on sleep disorders among mothers in the postpartum period

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
A written consent have to participate in the study Having an age range of 18 to 45 years Vaginal delivery of a healthy term singleton baby At least be literate in reading and writing
Exclusion criteria:
The Pittsburgh Questionnaire score is lesser than five Have a history of using auriculotherapy. Presence of wound, infection, pain, or injury at the ear Taking anti-anxiety and sedative drugs Addicted to alcohol, tranquilizers and drugs The presence of medical disorders in the mother, such as heart, respiratory, liver or nerve diseases

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
The random assignment of participants in two control and intervention groups is done by random block method with a ratio of 1:1 and using blocks of 4. For this purpose, blocks of 4 are made with different combinations of two members A and B, and according to the sample size, a suitable number (13) of blocks are randomly selected and placed sequentially. The sequence obtained from the letters A and B will determine the entry of the participants into two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants are aware of the general introduction of the study groups and blinding is done with the aim that the participants are not aware of being in the intervention or control group. There are no differences in appearance between the work done for the intervention and control groups, and auriculotherapy is performed for both groups, with the only difference that, in the control group, the stickers without grains (which are similar in color and appearance to the adhesives with grains) It is placed on points unrelated to the purpose of the study, and only the researcher knows the difference between the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of Medical Sciences

Street address

West Aast No 2., Moallem Blvd., Qom City

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Province

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Postal code

3715835155

Approval date

2021-03-13, 1399/12/23

Ethics committee reference number

IR.MUQ.REC.1399.270

Health conditions studied

1

Description of health condition studied

sleep disorder

ICD-10 code

G47

ICD-10 code description

Sleep disorders

2

Description of health condition studied

Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The sleep quality score in the Pittsburgh Sleep Quality Questionnaire.

Timepoint

The beginning of the study (before the intervention), 5 and 10 days after auriculotherapy.

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description

Anxiety

Timepoint

The beginning of the study (before the start of the intervention), 5 and 10 days after auriculotherapy.

Method of measurement

Spielberger anxiety questionnaire.

Intervention groups

1

Description

Intervention group: In the intervention group, first, four points in both ears (Shen Man, Relaxation, etc.) are stimulated with a manual Pointer and then the seeds are glued. In such a way that if the vital signs are normal, the researcher sticks the tags containing Vacaria seed after disinfecting the ear with 70% alcohol in the mentioned points and teaches the research units to touch each point for one minute in four shifts (morning, noon, in the evening and at night) and press for 5 days (it is emphasized that the amount of pressure should be at a level that causes numbness, warmth or pain and burning sensation at that point). It is emphasized to the research units that after the completion of 5 days (8-10 days after delivery) they should return to the health center, again The new one is glued by the researcher and the second intervention is carried out for 5 days like the first intervention.

Category

Treatment - Devices

2

Description

Control group: In the placebo group, simple labels (without vacaria seeds) that are similar in color and appearance are pasted in unrelated places, and all follow-ups and completion of questionnaires are the same as in the intervention group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom health and treatment centers.

Full name of responsible person

Fateme Sadat Mousavi

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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

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Fateme Sadat Mousavi

Position

Teacher

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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