Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
City
Qom
Province
Ghoum
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
فhe 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
Fatame Sadat Mousavi
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Sponsors / Funding sources

1

Sponsor
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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
Midwifery
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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