Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Auriculotherapy on sexual function and sexual quality of life in primiparus lactating women

Protocol summary

Study aim
The effect of Auriculotherapy on the function and quality of life on lactating primipara women
Design
A single-blind parallel-controlled clinical trial with two groups of control and intervention
Settings and conduct
Centers and Comprehensive Health Service Centers of Qom. In the intervention group are accomplishedAuriculotherapy. In the control group, all stages are arranged artificially and the Shem method is used for the blindness.
Participants/Inclusion and exclusion criteria
Inclusion criteria: lactating primipara women aged 18 to 45 years old in the period of 6 weeks to 6 months after childbirth Exclusion criteria: pregnancy, dead of the infant during the study and being away from the spouse
Intervention groups
In the intervention group: using an Excel 2 device on the special points of the right ear including, Shen men points, zero points, thalamic points, vertebral and ovary points, endocrine point, external genitalia or libido, and Relax points), electrical stimulation with frequency 5 Hertz and every 15 seconds. Then three points are selected and cached. The sessions are 3 days a total of 5 weeks and 10 sessions. In the control group, we turn off the device and do not press it on the points. We seize the Vaccaria on non-specific points.
Main outcome variables
Sexual function of women, Quality of women's sexual life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180110038302N5**
Registration date: **2019-06-08, 1398/03/18**
Registration timing: **registered_while_recruiting**
Last update: **2019-06-08, 1398/03/18**
Update count: **0**
Registration date
2019-06-08, 1398/03/18

Registrant information
Name
Mansoureh Yazdkhasti
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-14, 1398/01/25
Expected recruitment end date
2019-06-15, 1398/03/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Auriculotherapy on sexual function and sexual quality of life in primiparus lactating women

Public title
The effect of Auriculotherapy on sexual function
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

single - term delivery Pass 6 weeks to 6 months of delivery The number of Edinburgh questionnaires (postpartum depression) is less than 13 18 to 45 years old Having a healthy eardrum for Auriculotherapy Exclusively breastfeeding

Exclusion criteria:

Pregnancy during study Loss of infant during study Being away from the spouse Hearing problems (tinnitus, ear infections, or otitis media). Having underlying physical illnesses (blood pressure, diabetes, and seizures in the participant or her spouse's)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Balance Randomization 4th is accomplished with software. In this method size of the whole Blocks are equal. In this study with 60 sample size, a number of blocks are 15 and the size of each block is 4 and there are 6 modes. The number of people in the control and intervention group is the same(30 people in each group).

Blinding (investigator's opinion)

Single blinded

Blinding description

In the control group, all stages are arranged and the Shem method is used for blindness. In this way, we turn off the device and do not put pressure on the points. And Seyyed Vakaria is tied to non-specific points. It should be noted that in order to avoid interference of the samples, in pairs for the clients in the group of monitors Auriculotherapy will be performed on the days of the person assigned to the patients in the control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Alborz University of Medical Sciences

Street address

Plaque 142,Boali street, Nabovat blvd, Karaj city , Iran

City

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Alborz

Postal code

3149779453

Approval date

2019-01-12, 1397/10/22

Ethics committee reference number

IR.ABZUMS.REC.1397.181

Health conditions studied

1

Description of health condition studied

Sexual function - Quality of sexual life

ICD-10 code

F66

ICD-10 code description

Other sexual dysfunction

Primary outcomes

1

Description

Female sexual function

Timepoint

Before intervention, after intervention, one month after intervention

Method of measurement

MSISQ-19

2

Description

Women's sexual Quality of Life

Timepoint

Before intervention, after intervention, one month after intervention

Method of measurement

Women's Quality of Life Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Auriculotherapy for Lactating primipara women eligible for study, for 10 sessions a week, 2 times for 5 weeks

Category

Treatment - Other

2

Description
Control group: Auriculotherapy for lactating primipara women who are eligible to participate in the study, which is done for 5 weeks, twice a week for 10 sessions with a silent work machine.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Centers in Qom city
Full name of responsible person
Mansoureh Yazdkhshati
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Plaque 16, ,Beheshti st, Health center, Qom city , Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Sciences
Full name of responsible person
Mansoureh Yazdkhshati
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Plaque 130, Taleqani Blvd, Taleqani Square, Karaj city, Iran
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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
Alborz 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
Karaj University of Medical Sciences
Full name of responsible person
Dr. Mansoureh Yazdkhshati
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Masoumeh Rashidi Ahmadabadi

Position

Midwife

Latest degree

Bachelor

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable