

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 accomplished Auriculotherapy. 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

Name of organization / entity

Alborz University medical science

Country

Iran (Islamic Republic of)

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+98 21 4401 8856

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m.yazdkhasti@abzums.ac.ir

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

Karaj

Province

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

Street address

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

Street address

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

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborz University of medical sciences

Full name of responsible person

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

Alborz University Medical Sciences

Full name of responsible person

Masoumeh Rashidi Ahmadabadi

Position

Midwife

Latest degree

Bachelor

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

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