Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Acupressure and Auriculotherapy on the Sexual Performance of Lactating Primiparous Women

Protocol summary

Study aim
Determining the effect of acupressure and auriculotherapy on the sexual performance of lactating primiparous women

Design
This research is a randomized clinical trial with a parallel group, a phase study, and no blinding. The estimated sample size is 64 people, and these people will be allocated to two groups of acupressure and auriculotherapy methods using a block method of 4.

Settings and conduct
This study aims to determine the effect of acupressure and auriculotherapy on the sexual performance of lactating primiparous women referred to selected comprehensive health centers in Isfahan City. The study is not blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: lactating primiparous women with singleton pregnancy, being between 6 months and one year after giving birth, having at least literacy, not having surgical scars or fat mass in the place of pressure points, being married. Exclusion criteria: being away from the spouse for more than one month, taking drugs that affect sexual function in primiparous lactating women and their husbands, ear sensitivity to Sidha glue, not attending or not participating in intervention groups for more than two sessions in a row.

Intervention groups
Acupressure intervention group: First, 7 acupressure points will be taught to mothers, and the points will be marked by the researcher, and it will be recommended to press the points three times a day, for at least two to four minutes each time. Auriculotherapy intervention group: Both external ear lobes will be cleaned with 74% alcohol, then Vacaria plant seeds will be glued on 10 points of the ear, endocrine point, ovary, pelvis, behind the ear, posterior pituitary, oxytocin and lactation.

Main outcome variables
Sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240618062166N1**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**
Update count: **0**

Registration date
2024-06-22, 1403/04/02

Registrant information
Name
Zahra Allahvand
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 7537
Email address
zahraallahvand403@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-22, 1403/05/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the Effectiveness of Acupressure and Auriculotherapy on the Sexual Performance of Lactating Primiparous Women

Public title
Comparison of the Effectiveness of Acupressure and Auriculotherapy on the Sexual Performance of Lactating Primiparous Women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Lactating primiparous women with singleton pregnancy Being between 6 months and a year after giving birth Having at least reading and writing literacy Not having surgical scars or fat mass in the place of pressure points Being married
Exclusion criteria:
Staying away from your wife for more than a month Taking drugs affecting sexual function in primiparous lactating women and their husbands Ear sensitivity to Sidha glue Non-attendance or non-participation in intervention groups for more than two sessions in a row.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the randomization method will be a randomized block design with a block size of 4. The block randomization method is designed to randomize participants into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. In this clinical trial with control and treatment groups, a randomized block procedure would be as follows: (1) a block size of 4 will be chosen, (2) possible balanced combinations with 2 A (intervention) and 2 B (control) subjects will be calculated as 6 (BBAA, BABA, BAAB, ABBA, ABAB, AABB) and (3) blocks will be randomly chosen to determine the assignment of all participants.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Hezarjarib, Isfahan University Of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
Approval date
2024-04-06, 1403/01/18
Ethics committee reference number
IR.MUI.NUREMA.REC.1403.003

Health conditions studied

1

Description of health condition studied
Sexual dysfunction
ICD-10 code
F52
ICD-10 code description
Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description
Sexual function
Timepoint
before the start of the intervention, immediately, 1 and 3 months after the start of the intervention.
Method of measurement
Women's Sexual Performance Index Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Acupressure intervention group: First, 7 acupressure points will be taught to mothers, and the points will be marked by the researcher. Pressing the points three times a day for at least two to four minutes each time is recommended.
Category
Treatment - Other

2

Description
Control group: Auriculotherapy intervention group: Both external ear lobes will be cleaned with 74% alcohol, then Vacaria plant seeds will be glued on 10 points of the ear, endocrine point, ovary, pelvis, behind the ear, posterior pituitary, oxytocin and lactation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Midwifery and Nursing Faculty of Medical Sciences
Full name of responsible person
Mahboobe Valiani
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 5149
Email
valiani@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Amir Mansour Alavi
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4 - Vice-Chancellor for Research and Technology of the University
City
Isfahan
Province
Isfehan
Postal code
Phone
+98 31 3668 5149
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mahboobeh Valiani
Position
Asistand Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Nursing and Midwifery College
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7537
Email
valiani@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mahboobeh Valiani
Position
Asistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Nursing and Midwifery College
City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 7537

Email

valiani@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Allahvand

Position

Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Nursing and Midwifery College

City

Esfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 7537

Email

zahraallahvand403@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The main implications of the study will be shared.

When the data will become available and for how long

Data access starts 6 months after results are published.

To whom data/document is available

Academic researchers.

Under which criteria data/document could be used

For the knowledge and use of other researchers in their similar studies.

From where data/document is obtainable

Email: valiani@nm.mui.ac.ir

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

The researcher must send a request to send information with a valid organizational email or university email.

Comments