

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Auricular Acupressure on Lactating Women's Sexual Function

Protocol summary

Study aim

Determining the effect of ear acupressure on the sexual function of lactating women referring to Qazvin comprehensive health centers in 1398

Design

A randomized controlled clinical trial.

Settings and conduct

1- Obtaining the permission of the Ethics Committee and the clinical trial code after the approval of the proposal, Obtaining the necessary letters for attending the centers (Qazvin Health Centers).2-After obtaining written consent and obtaining permission, samples will be registered for inclusion in the study.3-a simple random blocking method with 4 blocks will be used to randomize the sample. Research participants will be randomly divided into two groups of intervention (Acupressure) and control group (without intervention).4-The demographic-midwifery and female sexual function index (FSFI) questionnaire will be completed before the intervention by the participants and in the presence of the researcher.5-The intervention (Acupressure) will be performed.6-Sexual Function Evaluation in both intervention and control groups using the FSFI questionnaire will be performed immediately one and two months after the end of the intervention.A call will be made to remind the completion of the questionnaires.7-Analysis: After the end of the data gathering, the analysis of the findings will be done.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Being Primiparous, Having Lactation, Having a Baby from Term and Single Delivery, Being in the First Year after Childbirth Exclusion Criteria: The presence of complications in pregnancy and postpartum, substance abuse in a person or her husband, history of diseases and the use of drugs that affect sexual function

Intervention groups

1-Ear Acupressure 2-Control with routine care

Main outcome variables

Sexual Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190626044028N1**

Registration date: **2019-08-16, 1398/05/25**

Registration timing: **prospective**

Last update: **2019-08-16, 1398/05/25**

Update count: **0**

Registration date

2019-08-16, 1398/05/25

Registrant information

Name

Sanaz Barghamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7713 4704

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s.barghamadi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Blinding (investigator's opinion) Not blinded
Scientific title The Effect of Auricular Acupressure on Lactating Women's Sexual Function	Blinding description Placebo Not used
Public title The Effect of Auricular Acupressure on Lactating Women's Sexual Function	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: The Desire to Participate in the Study Being Primipara Having Lactation Having term and singleton Baby Being in the First Year after Childbirth Having a Natural Auricle Without Lesion, Wounds and Pain on the Auricle Being Iranian Ability to read and write Availability During the Study Period Exclusion criteria: Being Away from the Spouse Polygamous Husband Complications in Pregnancy and Postpartum The History of Mental and Physical Illness (Self-Declaration and Examination of a Person's Health Record) Postpartum Depression detected by the Edinburgh Postnatal Depression Scale Substance Abuse in the Person or her Husband A History of Using Acupressure in the Last Three Months A History of Diseases Affecting the Sexual Function of a Woman or her Husband such as Premature Ejaculation, Cardiovascular, Psychiatric, Thyroid Disease and All Types of Cancers and Genital Trauma Use of Drugs That Affect Sexual Function Such as Psychoactive, Cardiovascular, Nervous and Hormonal Drugs	Secondary Ids empty
Age From 18 years old	Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Qazvin University of Medical Sciences Street address Qazvin university of medical science, Bahonar Blvd., Qazvin Town City Qazvin Province Qazvin Postal code 34199-15315
Gender Female	Approval date 2019-06-26, 1398/04/05 Ethics committee reference number IR.QUMS.REC.1398.056
Phase N/A	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
Groups that have been masked <i>No information</i>	Primary outcomes 1 Description Sexual Function Timepoint Sexual Function Measurement at the beginning of the study (before intervention) ,immediate, 1 and 2 months after intervention Method of measurement Sexual Function Score in Female Sexual Function Index
Sample size Target sample size: 76	
Randomization (investigator's opinion) Randomized	
Randomization description participants will be randomized into two groups by the Simple Random Blocking method with 4 blocks. In the block randomization method, the assigning sequence will be written before the commencement of the research. Given that two groups will be studied, four blocks will be used and one letter will be assigned to one group (A: EMDR group; B: control group). All possible modes of the 4 blocks will be written and numbered. So, in each block, two participants will be assigned to the intervention group and two will be assigned to the control group. Then, using a simple random method and the table of random numbers, a number of blocks will be selected from the blocks of numbers. By writing the contents of the blocks for those numbers (as long as the sample size is determined), the sequence of random allocation is determined.	

Secondary outcomes

1

Description

sexual quality of life

Timepoint

before, 1 and 2 month after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: acupressure group: The trained researcher first cleaned both auricle with 75% alcohol and then sticks the vaccaria seeds with non-latex adhesives tape on the 5th point of the ear (genital points (two points), Pelvic point, Master Shoulder and posterior hypophysis) that affects the sexual function of the person. A total of 10 sessions are held at intervals of four days per person. During these sessions, the seeds are stuck on the points and the subject is trained to hold the seeds for three days on her ear and during this time she should press each of the points three times a day for twenty Seconds. The pressure technique should be such that the person performs a moderate instillation by pressing firmly and a little tighter, until she feels a tingling and mild discomfort. After three days, the person can remove the seeds from her ear and rest one day. The number of pressing will be reminded to the subject via SMS daily. she will also be reminded by phone call that the fifth day will be referred to the center for resticking the new vaccaria seeds. This procedure takes place in ten sessions for each subject. It should be noted that if the subject experienced any problem during the use of the method for any reason (the movement of seeds, removing them, etc.) could separate the previous seeds and request the researcher to restick the new seeds again.

Category

Treatment - Devices

2

Description

Control group: Receive Counseling and routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Health center

Full name of responsible person

Sanaz Barghamadi

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Bahonar blevard, Qazvin university of Medical Science, School of Nursing & Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Amir Peymani

Street address

Qazvin university of medical science, Bahonar Blvd.,
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Email

info@qums.ac.ir

Web page address

<http://qums.ac.ir/Portal/Home/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Sanaz Barghamadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the original outcome is shared

When the data will become available and for how long

Start of the 6 month period after the publication of the study results

To whom data/document is available

All researchers in the field of health sciences and medicine can apply for data.

Under which criteria data/document could be used

A new analysis of data can be done only by explaining the reasons for the request for such an analysis and with the knowledge of the researcher

From where data/document is obtainable

To receive the data, you can contact the person responsible for this clinical practice (Sanaz Borgamadi) by e-mail s.barghamadi@qums.ac.ir.

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

fter receiving the application for having a data file and obtaining permission from the university Research Deputy, the data file is shared.

Comments