Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Scientific title
The Effect of Auricular Acupressure on Lactating Women’s Sexual Function

Public title
The Effect of Auricular Acupressure on Lactating Women’s Sexual Function

Purpose
Treatment

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

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

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.

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 Qazvin University of Medical Sciences

Street address
Qazvin university of medical science, Bahonar Blvd., Qazvin Town

City
Qazvin

Province
Qazvin

Postal code
34199-15315

Approval date
2019-06-26, 1398/04/05

Ethics committee reference number
IR.QUMS.REC.1398.056

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
Sexual Function Measurement at the beginning of the study (before intervention) ,immidiate, 1 and 2 months after intervention

Method of measurement
Sexual Function Score in Female Sexual Function Index

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 Soulder 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., Qazvin Town
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Phone
+98 28 3333 6003
Fax
+98 28 3335 5162
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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Person responsible for updating data

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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