Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of foot reflexology on sexual function in lactating mothers

Protocol summary

Study aim
Determining the effect of foot reflexology on sexual function of lactating women referred to selected health centers in Isfahan in 2021

Design
A clinical trial with a control group, with parallel, randomized groups, on 76 subjects (38 in the intervention group and 38 in the experimental group). Two types of cards are used for randomization

Settings and conduct
The researcher referred to the selected health centers and invited the women who meet the inclusion criteria. After explaining the goals to them and obtaining their agreement to participate in the study, informed consent is taken from them. Then they completing a questionnaire on female sexual function index (FSFI) and receiving a pamphlet about sexual function after birth. After that they were randomly allocated to the intervention and control groups. In the intervention group, 10 sessions of foot reflexology are performed for each person and then 4 weeks later, and in the control group 9 weeks later FSFI questionnaire is completed

Participants/Inclusion and exclusion criteria
1. Lactating Women within 40 days to 5 months after delivery 2. Be literate 3. Having Iranian citizenship 4. Obtaining a score higher than zero from the Female sexual function index questionnaire 5. Absence of sexual problems and other known and effective diseases on sexual function in women or their husbands. 6. Do not use drugs that affect sexual function in research units and their spouses 7. No addiction to alcohol, cigarettes, and drugs in participants or their spouses 8. No deformity and problems in the foot

Intervention groups
In the intervention group, foot reflexology is performed in 10 sessions for 50 minutes twice a week, with an interval of 2 to 3 days (for 5 weeks) Educational pamphlets are given to people in both groups. The control group receives routine care from health centers.

Main outcome variables
Sexual function of lactating women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210814052180N1**
Registration date: **2021-10-07, 1400/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-07, 1400/07/15**
Update count: **0**

Registration date
2021-10-07, 1400/07/15

Registrant information

Name
Zahra Ghanbari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot reflexology on sexual function in lactating mothers

Public title
The effect of foot reflexology on sexual function in lactating mothers

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
lactating Women within 40 days to 5 months after delivery Be literate Having Iranian citizenship Obtaining a score higher than zero from the Female sexual function index questionnaire

Exclusion criteria:
Existence of known sexual problems which affecting sexual function in women or their husbands, such as premature ejaculation and impotence in the husband, or vaginismus and dyspepsia in women (determined by asking participants and reviewing their file) Having known chronic diseases in these women or their husbands that affect sexual function such as mental illness (schizophrenia), mood disorders (depression), ulcerative colitis, vasculitis, thyroid, and adrenal cortex diseases, diabetes, Blood pressure, heart, lung, liver, kidney diseases, central nervous system disorders, infectious and sexually transmitted infections (determined by asking participants and reviewing their file) Use of drugs affecting sexual function in women or their spouses, including psychotropic drugs, cardiac and anti-hypertensive drugs, thiazide diuretics, anticonvulsant drugs, H2 receptor blockers, opioids, anticholinergics, antihistamines, Antidepressants, and sleeping pills Alcohol, cigarette and drug addiction in women or their husbands use of other types of complementary and alternative medicine methods affecting sexual function such as acupuncture, auricular therapy, and massage therapy Presence of deformity, calluses, fissures or ulcers of the foot, active thrombosis or phlebitis, varicose veins, history of recent ankle trauma, sprains and fractures, infection or inflammation of the soles of the feet

Age
No age limit

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 are divided into control and intervention groups based on a simple random allocation method. To randomize, the researcher has two types of cards in a large envelope, one of which has the word “control” written on it and the other the word “intervention”, then Participants are asked to take out one of them without looking at the cards in the envelope, and thus will be placed in the intervention or control group based on the selected card.

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 Isfahan University of medical Sciences

Street address
Building No. 4 - Vice Chancellor for Research and Technology, Hezar Jerib St., Isfahan University of Medical Sciences and Health Services., Isfahan Town

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Isfahan

Province
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8174673461

Approval date
2021-06-26, 1400/04/05

Ethics committee reference number
IR.MUI.NUREMA.REC.1400.083

Health conditions studied

1

Description of health condition studied
sexual function in lactating mothers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sexual function score of lactating women in Women's Sexual function Index (FSFI) questionnaire

Timepoint
Evaluation of sexual function score before the intervention and then four weeks after the intervention

Method of measurement
Female Sexual function Index Questionnaire (FSFI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, an educational pamphlet about sexual function after birth is presented and a female sexual function index questionnaire is completed, then 10 sessions of foot reflexology are performed for each person in this group. Each intervention session takes 50 minutes, with 25 minutes for each foot (20 minutes of general reflexology and 5 minutes of specific reflexology). The intervention is performed twice a week with an interval of 2 to 3 days and a total of 10 sessions and then 4 weeks later the female sexual function index questionnaire is completed.

Category
Treatment - Other

2

Description
Control group: First, an educational pamphlet about sexual function after birth is presented and the female sexual function index questionnaire is completed, then the people receive routine care at health centers and after 9 weeks, the female sexual function index questionnaire is completed again.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Hamzeh Health Center
Full name of responsible person
Zahra Ghanbari
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2

Recruitment center
Name of recruitment center
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3

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Recruitment center
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5

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available