Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of ear acupressure on sexual function in women with diabetes mellitus

Protocol summary

Study aim
Determining the effect of ear acupressure on sexual function in women with diabetes mellitus, Kashan, 1404

Design
The study was a randomized, double-blind, controlled clinical trial on 60 patients, for block randomization using the Sealed Envelope Ltd. 2017 software available at www.sealedenvelope.com, with a total of 12 blocks, 6 blocks of 6 and 6 blocks of 4.

Settings and conduct
At the beginning of the study, after the end of the 4-week auriculotherapy course and 4 weeks after the end of the intervention on eligible clients (randomized intervention and control groups) under the auspices of the Kashan Diabetes and Metabolic Diseases Subspecialty Clinic, the FSFI and SQOL-F questionnaires will be completed by the participants.

Participants/Inclusion and exclusion criteria
The main inclusion criteria included; obtaining a score of 28 or less on the FSFI tool, at least one year after the diagnosis of diabetes mellitus, living with a spouse, and at least one year after a permanent marriage. The main exclusion criteria included; having serious acute or chronic complications of diabetes, having either partner suffer from physical or mental illnesses affecting sexual function, receiving any treatment for sexual problems by either partner during the past 6 months, using acupuncture or acupressure within the past 3 months, being pregnant or breastfeeding, and being menopausal, skin sensitivity to alcohol and adhesives, using drugs, alcohol, and smoking in the couple.

Intervention groups
In the auriculotherapy intervention group, Vaccaria seeds were glued to 5 points affecting sexual function and pressed by the patient for 4 weeks, 5 days a week, 4 times a day, 20 seconds each time. In the comparison group, only seedless stickers were glued to the points and no pressure was applied to the points.

Main outcome variables
Sexual performance score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100211003329N12**
Registration date: **2025-05-19, 1404/02/29**
Registration timing: **prospective**

Last update: **2025-05-19, 1404/02/29**
Update count: **0**

Registration date
2025-05-19, 1404/02/29

Registrant information

Name
Zahra Sooki

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-21, 1404/03/31

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of ear acupressure on sexual function in women with diabetes mellitus

Public title
The effect of ear acupressure on sexual function in women with diabetes mellitus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Obtaining a score of 28 or less on the FSFI tool At least one year has passed since the diagnosis of diabetes mellitus Consent to participate in the study living with a spouse, at least one year has passed since permanent marriage wife monogamy At least 6 months have passed since the birth or abortion Muslim couple Iranian citizenship and resident in Kashan Organ health in the earlobe area

Exclusion criteria:
Pregnancy, breastfeeding and menopause Suffering from serious acute or chronic complications of diabetes (such as eye, kidney, wound, infection) Suffering from physical or mental illnesses or conditions that affect sexual function (such as heart, kidney, malignant diseases, etc.) Simultaneous use of other therapeutic methods Taking medication that affects sexual function Use of acupuncture or acupressure within the past 3 months Being away from spouse for more than two weeks Allergy to glue (sensitivity, redness, etc.) Drug or alcohol abuse in couples Exposure to serious stress during the past 6 months in either partner Drug, alcohol, or cigarette abuse

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible samples will be listed in order of screening and then randomly assigned to each of the two intervention and sham groups in blocks of 4 and 6. Using Sealed Envelope Ltd. 2017 software available at www.sealedenvelope.com, 6 blocks of 6 and 6 blocks of 4 were defined, for a total of 12 blocks, and allocation to groups will be done in the order specified by the software.

Blinding (investigator's opinion)
Double blinded

Blinding description
The subject/participant is unaware of the nature of the seeds prescribed to her, and the person collecting the data is also unaware of the subject's group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medic

Street address
Kashan University of Medical Sciences, Pezeshk Blvd, Qutb Rawandi Blvd, Kashan

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Kashan

Province
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Postal code
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Approval date
2025-04-26, 1404/02/06

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1404.014

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Sexual performance score

Timepoint
At the beginning of the study, after the end of the intervention, and 4 weeks after the end of the intervention

Method of measurement
Rosen et al. Female Sexual Function Questionnaire (FSFI)

Secondary outcomes

1

Description
Sextual quality of life
Timepoint
At the beginning of the study, after the end of the intervention, and 4 weeks after the end of the intervention
Method of measurement
Women's Sexual Quality of Life Questionnaire (SQOL-F)

Intervention groups

1

Description
Intervention group: the researcher will attach ZHONG YANG brand Vaccaria seeds made in China to 5 points affecting sexual function, including: internal and external genitalia, shoulder, hip and posterior pituitary points, and the patient will be instructed to press each point using the thumb and index finger for four weeks, five days a week, four times a day, and each time for 20 seconds. It should be noted that during the 4-week intervention, Vaccaria seeds in the intervention group will be attached alternately to both ears every week by the researcher, after cleaning the skin with alcohol cotton. The seeds will be placed on the ear five days a week, and the patient will be asked to remove the adhesives at the end of the fifth day to prevent a possible allergic reaction. The patient will be instructed to contact the researcher if the adhesives come off during the five-day period so that the researcher can reattach the seeds at the agreed-upon location. During the intervention, the individual will also be provided with a weekly diary sheet in which they will record the duration of each pressure point, the occurrence of allergic reactions, and the start of new medication. The contents of the diary sheet are organized using visual symbols in a way that can be understood and completed by all subjects, both literate and illiterate, with simple training. During the intervention, all participants will be visited every week at the agreed-upon location and new seeds will be attached to them, and the diary sheet will be returned to them and another sheet will be given to them for the following week. If the average daily pressure on the testicles in the intervention group is less than 200 seconds during each week of the intervention, that person will be excluded from the study. The testicles will be taped for 4 weeks, and the samples will be followed up 4 weeks after the end of the intervention. The FSFI and SQOL-F questionnaires will be completed at the beginning of the study, after the end of the intervention, and 4 weeks after the end of the intervention for both groups through an interview with the individual by a collaborator who is not aware of the status of the allocation of the samples to the groups. At the time of sampling, the telephone number and home address of the samples will be recorded, and during the intervention period, at the end of each week, and also for the purpose of following up 4 weeks after the end of the intervention, coordination will be made with the patient by telephone regarding the time and place of the visit and, if necessary, transportation.
Category
Treatment - Drugs

2

Description
Control group: The patches will be applied to the internal and external genitalia, shoulder, hip, and posterior pituitary, but without seeds, and no pressure will be applied to them. During the 4-week intervention, the patches without seeds in the sham group will be applied alternately to both ears by the researcher every week, after cleaning the skin with alcohol swabs. The seeds will be on the ears for five days a week, and the patient will be asked to remove the patches at the end of the fifth day to prevent a possible allergic reaction. The patient will be instructed to contact the researcher if the patches are removed during the five-day period so that the patches can be reapplied by the researcher at an agreed location.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Center of Diabetes and Metabolic Disorders
Full name of responsible person
Ali Akbar Hashemzadeh
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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
Kashan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Not done yet.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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