Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of two methods of pelvic floor muscle training and pelvic floor biofeedback on sexual function and sexual satisfaction in women with urinary incontinence referred to Health and Medical Centers affiliated to Shahrekord University of Medical Sciences

Protocol summary

Study aim

To compare the effects of pelvic floor muscle training and biofeedback on sexual function and satisfaction in women with urinary incontinence attending healthcare centers affiliated with Shahrekord University of Medical Sciences.

Design

Randomized, three-arm parallel group trial in six health centers. Participants selected by simple random sampling. Block randomization with concealed allocation. Duration: 8 weeks. Outcome assessors blinded.

Settings and conduct

Trial conducted in six health centers. Participants randomly recruited and allocated by concealed block randomization. Intervention lasted 8 weeks. Outcome assessors blinded. Participants and providers not blinded. Adherence monitored by weekly calls and exercise logs.

Participants/Inclusion and exclusion criteria

Inclusion: Married women aged 20-51, sexually active, literate, no neurological or chronic diseases affecting sexual function, not using drugs affecting sexual function. Exclusion: Withdrawal, vaginal infection or bleeding, use of urinary incontinence medication, severe emotional stress, menopausal symptoms, recent surgery.

Intervention groups

Group 1 (Control): Home pelvic floor muscle training (PFMT) without biofeedback, 4 days/week for 8 weeks. Group 2: Weekly supervised biofeedback therapy using EMG vaginal probe for 8 weeks. Group 3: Combination of home PFMT and weekly biofeedback for 8 weeks.

Main outcome variables

Mean sexual function and satisfaction scores compared among three groups (home PFMT, biofeedback, combined), measured before and immediately after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180123038486N5**
Registration date: **2025-09-25, 1404/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-25, 1404/07/03**
Update count: **0**

Registration date

2025-09-25, 1404/07/03

Registrant information

Name

Ziba Raisi Dehkordi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

 A comparative study of two methods of pelvic floor muscle training and pelvic floor biofeedback on sexual function and sexual satisfaction in women with urinary incontinence referred to Health and Medical Centers affiliated to Shahrekord University of Medical Sciences

Public title

Effects of pelvic floor exercises and biofeedback on sexual health and satisfaction in women with urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women aged 20 to 51 years No permanent (divorce) or temporary separation from spouse At least 8 weeks since last delivery (if applicable) Sexually active No use of medications affecting sexual function in participants or spouses, including sedatives, addictive drugs (opioids, hallucinogens), cardiac and antihypertensive drugs, and anticonvulsants No addiction to drugs or alcohol in couples No abnormal uterine bleeding No severe uterine prolapse No history of surgery on back, pelvis, or abdomen within the last month No history of diseases affecting sexual function in participants or their spouses, including:Central nervous system diseases (multiple sclerosis, myasthenia gravis)Severe depression and bipolar disorderLimb paralysisVaginismusHeart diseaseDrug-dependent diabetesTumors, masses, and cancerThyroid disordersVasculitisAdrenal cortex diseases (Cushing's syndrome, adrenal insufficiency)HypertensionPulmonary and liver diseasesPeripheral neuropathies Obstetric history: previous vaginal delivery

Exclusion criteria:

Participant’s dissatisfaction or non-cooperation at any stage Presence of vaginal inflammation or infection during the study Presence of wounds, bleeding, or infection in vagina or urinary tract during the study Use of any medication or treatment for urinary incontinence during the study Emotional stress such as death of a first-degree relative within the past three months Presence of menopausal symptoms Regular gym exercise for more than one month

Age

From **20 years** old to **51 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the unit of randomization was the individual participant. After confirming eligibility based on inclusion and exclusion criteria and determining the type of urinary incontinence using the Bradley questionnaire, participants were randomly allocated to one of three intervention groups: (1) pelvic floor muscle training, (2) pelvic floor biofeedback, or (3) combined pelvic floor muscle training with biofeedback. The method of randomization was permuted block randomization, with a fixed block size of six. A total of eleven blocks were generated to cover the planned sample size. The random sequence was generated in advance by a statistician who was not involved in participant recruitment, using the Random Allocation Software. The random sequence assigned two participants to each group in each block, ensuring balanced group sizes throughout recruitment. Allocation concealment was maintained by keeping the randomization sequence confidential and inaccessible to the researcher responsible for enrollment, who only assigned participants to groups according to the pre-prepared list at the time of inclusion.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants and the data analyst were blinded to the group allocation. Participants were unaware of which intervention group they were assigned to, in order to minimize performance and response bias. The data analyst, who performed the statistical analysis, was also blinded to the group codes to prevent analysis bias. The principal investigator, care providers, and outcome assessors were not blinded due to the nature of the interventions, which required direct supervision and implementation by the research team.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

No. 1, Kashani Blvd., Shahrekord University of Medical Sciences, Shahrekord, Iran

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Chahar-Mahal-va-Bakhtiari

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Approval date
2025-02-18, 1403/11/30
Ethics committee reference number
IR.SKUMS.REC.1402.199

Health conditions studied

1

Description of health condition studied
Urinary incontinence in women
ICD-10 code
ICD-10 cod
ICD-10 code description
Stress incontinence (female) (Urinary)

Primary outcomes

1

Description
Determination and comparison of the mean female sexual function score in women with urinary incontinence in three groups: exercise therapy, pelvic floor biofeedback, and exercise therapy combined with biofeedback before and immediately after intervention.
Timepoint
Before intervention and immediately after intervention
Method of measurement
The primary outcome will be measured using the Female Sexual Function Index (FSFI), a validated 19-item questionnaire evaluating six domains of sexual function over the past four weeks. Additional demographic data including age, residence, education level, occupation, number of pregnancies, ethnicity, duration of urinary incontinence, and type of delivery will be collected via a demographic questionnaire.

2

Description
Determination and comparison of the mean female sexual satisfaction score in women with urinary incontinence in three groups: exercise therapy, pelvic floor biofeedback, and exercise therapy combined with biofeedback before and immediately after intervention.
Timepoint
Before intervention and immediately after intervention.
Method of measurement
The second outcome will be measured using the Larson Sexual Satisfaction Questionnaire (LSSQ) (1988). This questionnaire consists of 25 items covering four components: sexual desire, sexual attitude, quality of sexual life, and sexual compatibility. Responses are scored on a five-point Likert scale ranging from 1 to 5, where 1 = never, 2 = rarely, 3 = sometimes, 4 = often, and 5 = always. Thirteen items (numbers 4, 5, 6, 7, 8, 9, 11, 14, 15, 18, 20, 24, and 25) are reverse scored. Total scores range from 25 to 125, representing the level of sexual satisfaction.

3

Description
Determination and comparison of the type and severity of urinary incontinence in women with urinary incontinence in three groups: exercise therapy, pelvic floor biofeedback, and exercise therapy combined with biofeedback before and immediately after intervention.
Timepoint
Before intervention and immediately after intervention.
Method of measurement
The type and severity of urinary incontinence will be assessed using the Questionnaire for Urinary Incontinence Diagnosis (QUID) developed by Bradley et al. (2005). This self-reported questionnaire includes 6 items covering two subscales: stress incontinence (items 1–3) and urge incontinence (items 4–6). Each item is rated on a 6-point Likert scale ranging from 0 (“never”) to 5 (“always”). Scores for each subscale are summed to yield a total score. A score ≥4 on the stress subscale indicates stress incontinence, while a score ≥6 on the urge subscale indicates urge incontinence. The presence of both indicates mixed incontinence.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 2: Participants will receive weekly supervised biofeedback therapy using an EMG vaginal probe for 8 weeks.
Category
Treatment - Devices

2

Description
Intervention group: Intervention group 3: Participants will undergo a combination of home-based PFMT and weekly supervised biofeedback therapy for 8 weeks.
Category
Behavior

3

Description
Intervention group 1 (Control): Participants will perform home-based pelvic floor muscle training (PFMT) without biofeedback, 4 days per week for 8 weeks.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center

Shahrekord Health Care Center No. 1

Full name of responsible person
Maryam Afkhami

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Recruitment center

Name of recruitment center
Shahrekord Health Care Center No. 2

Full name of responsible person
Akbari Fariba

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Recruitment center

Name of recruitment center
Shahrekord Health Care Center No. 3

Full name of responsible person
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4

Recruitment center

Name of recruitment center
Shahrekord Health Care Center No. 4

Full name of responsible person
ziba malaki

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Recruitment center

Name of recruitment center
Shahrekord Health Care Center No. 5

Full name of responsible person
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Recruitment center

Name of recruitment center
Shahrekord Health Care Center No. 6

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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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

Not applicable

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

The anonymized individual participant data (including baseline characteristics, outcomes, and adverse events), as well as the final version of the study protocol, statistical analysis plan, and informed consent form, will be shared. Data will be made available to researchers who submit a methodologically sound proposal, for purposes of achieving the aims outlined in the approved proposal. Requests for data access should be sent to the corresponding author at [ziba758@gmail.com. Data will be shared after publication of the main results and will remain available for up to 3 years following publication. Access will be granted through secure data transfer upon approval of the request.

When the data will become available and for how long

Anonymized individual participant data and associated documents will be available starting from the date of publication of the main results and continuing for 3 years thereafter.

To whom data/document is available

The anonymized individual participant data and supporting documents will be available to qualified researchers affiliated with academic institutions or research organizations who submit a methodologically sound proposal. Requests from researchers working in other sectors (e.g., industry) will also be considered if their proposals align with the study objectives and ethical standards.

Under which criteria data/document could be used

Access to the deidentified individual participant data (IPD) and supporting documents will be granted only for research purposes that are consistent with the aims of the original study and comply with ethical and legal standards. Proposals must include a clear and methodologically sound analysis plan. All requests will be reviewed by the principal investigator and a data access committee to ensure scientific merit, feasibility, and adherence to data protection and confidentiality policies. Data will be shared through a secure data transfer mechanism after approval.

From where data/document is obtainable

The anonymized individual participant data and supporting documents can be requested by contacting the corresponding author via email at [ziba758@gmail.com]. Requests should include a detailed research proposal and intended use of the data. Additional communication can be made via phone at +98 38 32240556. Upon approval, data will be shared through a secure transfer system. For postal correspondence, please contact:

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

Applicants interested in accessing the anonymized individual participant data and supporting documents must submit a formal request via email to the corresponding author at ziba758@gmail.com]. The request should include a detailed research proposal outlining the objectives, methodology, and planned analyses. Upon receiving the request, the research team will review the proposal for scientific merit, feasibility, and ethical compliance. This review process typically takes up to 4 weeks. If the request is approved, the applicant will be asked to sign a data use agreement to ensure confidentiality and proper use of the data.

Comments

All data sharing will comply with ethical guidelines and privacy regulations to ensure participant confidentiality. Any requests for additional information or clarifications can be directed to the corresponding author via the provided contact details