Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of pelvic floor muscle training exercises along with radiofrequency or biofeedback compared to pelvic floor muscle training exercises alone on urinary incontinence and sexual dysfunction in women with urinary incontinence.

Protocol summary

Study aim

our purpose is to investigate the effectiveness of pelvic floor muscle strengthening exercises with the help of biofeedback or radio frequency compared to pelvic floor muscle exercises alone in the treatment of stress urinary incontinence and sexual disorders in women.

Design

A clinical trial with a control group, with two parallel groups, a blind strain, randomized on 45 patients. Block randomization is used for randomization.

Settings and conduct

Women living in the city of Noorabad, Mamsani, Fars who are eligible to enter the study are invited to participate. After obtaining informed consent and performing clinical examinations, the outcome variables are measured and based on the grouping, the patients in each group receive the desired treatment during the sessions. After the end of the last treatment session and one month after, the outcome variables will be measured.

Participants/Inclusion and exclusion criteria

Women aged 35 to 55 years with stress urinary incontinence and also sexual disorders. Absence of chronic diseases, urinary infections, copper IUD, pregnancy and heart pacemaker and not receiving other incontinence treatments..

Intervention groups

The RF+ PFMT group receives five sessions of radiofrequency therapy and 15 sessions of pelvic floor muscle strengthening exercises (5 weeks). - The Biofeedback+PFMT group receives 15 therapeutic sessions of pelvic floor muscle strengthening exercises with biofeedback during 5 weeks. - The PFMT group receives fifteen therapeutic sessions of pelvic floor muscle strengthening exercises during 5 weeks.

Main outcome variables

the performance (strength and endurance) of the pelvic floor muscles using perineometer urine lost using the one-hour test pad incontinence symptoms and sexual function using ICIQ-SF, ICIQ-VS, FSFI questionnaires treatment satisfaction using Likert scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241014063359N1**
Registration date: **2024-10-31, 1403/08/10**
Registration timing: **prospective**

Last update: **2024-10-31, 1403/08/10**
Update count: **0**

Registration date

2024-10-31, 1403/08/10

Registrant information

Name

Zahra Ardekani

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

2024-11-18, 1403/08/28

Expected recruitment end date

2025-02-16, 1403/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of pelvic floor muscle training exercises along with radiofrequency or biofeedback compared to pelvic floor muscle training exercises alone on urinary incontinence and sexual dysfunction in women with urinary incontinence.

Public title

Investigating the effect of radiofrequency and biofeedback in urinary incontinence and impotence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Women aged 35 to 55 with urinary incontinence as the main clinical complaint, whose urine loss of more than 1 gram per hour can be confirmed by the test pad, and who have sexual disorders and impotence at the same time.

Exclusion criteria:

Patients with chronic degenerative diseases that affect muscle and nerve tissues. Presence of any degree of pelvic organ prolapse Active or frequent urinary tract infections Vulvovaginitis Atrophic vaginitis Absence of a copper IUD in the uterus Patients who are pregnant or have given birth less than 6 months ago. Type 1 and 2 diabetes neurological disease Mental illness taking drugs that affect urination History of surgical or drug treatment for urinary incontinence Chronic debilitating diseases such as kidney failure Those who have a pacemaker. If the patient does not want to continue to cooperate at any stage of the study, does not complete the treatment sessions, and the patient's condition changes in such a way that they lose any of the entry criteria, the participants will be excluded from the study.

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The grouping method is also a type of random grouping in the block method where people are placed in three groups. In the current clinical trial study (two intervention groups and one control group), it will include 45 samples, which will be done with the block randomization method according to the following process. The size of the used block is 3, and therefore, the combination of these modes for the control group and the patient groups, which are displayed with the letters C, T1 and T2 respectively, will include 6 modes. which will include (T2T1C, T1T2C, T1CT2, CT2T1, and CT1T2, T2CT1,). Blocks will be selected randomly and with the help of Excel software, so that 10 blocks are randomly selected, and therefore 45 samples can be included in the study in a random sequence, which can be included in each control and treatment group. The number of blocks and how they are executed are done by hiding them inside the envelope. In this method, the blocks are numbered based on a random sequence and placed inside the envelopes, and the researcher assigns them to the intervention and treatment groups based on the order of arrival of the patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient receives the type of intervention or control group in sealed envelopes that are coded. Coding is done by one of the colleagues of the project. The evaluator and the person analyzing the data are blind to the grouping of the participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Rehabilitation Sciences and Social Health

Street address

University of Rehabilitation Sciences and Social Health, kodakyar Dead End, Daneshjoo boulevard, Velenjak

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Tehran

Province

Tehran

Postal code

1985713871

Approval date

2024-07-02, 1403/04/12

Ethics committee reference number

IR.USWR.REC.1403.113

Health conditions studied

1

Description of health condition studied
Urinary incontinence
ICD-10 code
R32
ICD-10 code description
Unspecified urinary incontinence

Primary outcomes

1

Description
Performance (strength and tolerance) of the pelvic floor muscles
Timepoint
Before the start of the intervention, the end of the last session of the intervention, one month later
Method of measurement
using perineometer device

2

Description
The quantitive amount of urine lost
Timepoint
Before the start of the intervention, the end of the last session of the intervention, one month later
Method of measurement
using one hour pad test

3

Description
Incontinence symptoms and sexual function
Timepoint
Before the start of the intervention, the end of the last session of the intervention, one month later
Method of measurement
Using the valid Persian version of ICIQ-SF, ICIQ-VS, FSFI questionnaires

4

Description
Satisfaction with treatment
Timepoint
Before the start of the intervention, the end of the last session of the intervention, one month later
Method of measurement
using Likert scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The RF+ PFMT group receives five radiofrequency therapy sessions as weekly sessions, with the settings that will be mentioned below, and 15 sessions of pelvic floor muscle strengthening exercises during 5 weeks. At first, patients will perform 3 exercises to strengthen the pelvic floor muscles. In radiofrequency treatment, using a standard technique in which the tip of the intravaginal probe of the device is moved back and forth on the mucosal surface of the vagina and the entire front wall of the vagina using a special probe slowly with wide movements in the treated area, and radiofrequency energy and will remain in direct contact with the tissue for 10 minutes at a temperature of 43°C (between 41 and 45°C based on patient tolerance). Bipolar radiofrequency with a frequency of one megahertz, maximum power of 65 watts will be applied to patients. The radio frequency power will be adjusted to maintain the required temperature.
Category
Rehabilitation

2

Description
Intervention group: The Biofeedback+PFMT group receives fifteen therapeutic sessions of pelvic floor muscle strengthening exercises with biofeedback during 5 weeks.At the beginning of the pelvic floor muscle strengthening exercises, patients are given the necessary anatomical information with the help of biofeedback, and the exercises are taught one-on-one by the therapist. Patients are asked to empty their bladder before the procedure. They lie on their backs with their knees slightly bent and their heads slightly raised. Surface EMG probes are placed on the perineum at the three and nine o'clock positions, an additional neutral probe is placed on the patella, and patients are observed. Patients are asked to contract only their pelvic floor muscles, not their abdominal muscles. They are also asked to track the contraction and relaxation of their pelvic floor muscles on a monitor to make sure they are contracting the correct muscle group. Therefore, it enables active participation in the educational program. In this way, patients are taught how to identify their pelvic floor muscles and how to use their pelvic floor muscles selectively without using their abdominal muscles. After training the correct contraction, the patients are asked to do three pelvic floor muscle strengthening exercises.
Category
Rehabilitation

3

Description
The PFMT group receives fifteen therapeutic sessions of pelvic floor muscle strengthening exercises during 5 weeks.Patients are asked to perform the following three exercises based on the exercise program table.Faucet exercise: repeatedly contract and release your pelvic floor (such as closing and opening the faucet)- Elevator exercise: slowly contract the pelvic floor for 5 counts - hold for 5 counts - release for 5 counts (such as going up in the elevator for 5 counts - holding for 5 counts at the

top floor - coming down with a count of 5) - Coughing or sneezing

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Taskin physiotherapy clinic

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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Nahid Rahmani

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Total potential data after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For use in systematic review studies and meta-analysis
From where data/document is obtainable
Zahraardekanipt@gmail.com
What processes are involved for a request to access data/document
Please send your written request and a full description of the reason for the data request to the email address provided. After reviewing your request, your email will be answered within ten working days.
Comments