Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Therapeutic Effect of Pelvic Floor Muscles Training alone with Pelvic Floor Muscles Training and Biofeedback in patients with Stress Urinary Incontinence

Protocol summary

Study aim
Comparison of the therapeutic effect of pelvic floor muscle training alone with pelvic floor muscle training and biofeedback in patients with stress urinary incontinence

Design
Clinical trial with control group, Not blind, Non-random

Settings and conduct
The IQOL questionnaire was given to two groups of 25 people before and after the exercise, including women who did Kegel exercises alone and women who did Kegel exercises with biofeedback

Participants/Inclusion and exclusion criteria
Women with stress urinary incontinence aged 40 to 70 years; no pregnancy and lactation; balanced mood, no use of exercise to treat urinary incontinence, no urinary tract and genital infections; no contraindications to exercise therapy; no use of surgical treatments to treat incontinence in the past, no pelvic cancers are included in the study. In case of pregnancy, urinary and genital infections; 6 months or less after delivery; fecal incontinence and having physical diseases (cancer and physical disability) that prevent cooperation, are excluded from the study.

Intervention groups
Intervention group: women undergoing PFMT and biofeedback. Control group: women undergoing PFMT alone.

Main outcome variables
Quality of life improvement score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200912048692N1**
Registration date: **2020-09-18, 1399/06/28**
Registration timing: **retrospective**

Last update: **2020-09-18, 1399/06/28**
Update count: **0**

Registration date
2020-09-18, 1399/06/28

Registrant information

Name
Mahta Razavian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
2019-05-31, 1398/03/10

Actual recruitment end date
2019-12-19, 1398/09/28

Trial completion date
2019-12-19, 1398/09/28

Scientific title
Comparison of the Therapeutic Effect of Pelvic Floor Muscles Training alone with Pelvic Floor Muscles Training and Biofeedback in patients with Stress Urinary Incontinence

Public title
Evaluation of the Therapeutic Effect of Pelvic Floor Muscles Training with Biofeedback in Stress Urinary Incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No pregnancy and lactation Do not use exercise to treat Stress Urinary Incontinence Balanced mental state No urinary tract and genital infections No contraindications to exercise therapy No using surgical treatments to treat incontinence in the past No Pelvic Cancers Do not take drugs that affect the urine Women aged 40 to 70 years
Exclusion criteria:
6 months or less after delivery Have any surgery on the pelvic and genital areas Stool incontinence Having physical illnesses (Cancer and physical disability) that prevent clients from cooperating
Age
From **40 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
University Blvd., Faculty of Medical Sciences, Shahroud Azad University
City
Shahroud
Province
Semnan
Postal code
3616677856
Approval date
2019-07-04, 1398/04/13
Ethics committee reference number
IR.IAU.SHAHROOD.REC.1398.015

Health conditions studied

1

Description of health condition studied
Stress Urinary Incontinence
ICD-10 code
N39.3
ICD-10 code description
Stress incontinence (female)

Primary outcomes

1

Description
Comparison of the therapeutic effect of pelvic floor muscle training alone with pelvic floor muscle training and biofeedback in patients with stress urinary incontinence by age
Timepoint
At the beginning of the study (before the intervention) and 21 days after pelvic floor muscle exercises and biofeedback
Method of measurement
Incontinence Quality of Life questionnaire

2

Description
Comparison of the therapeutic effect of pelvic floor muscle training alone with pelvic floor muscle training and biofeedback in patients with stress urinary incontinence by weight
Timepoint
At the beginning of the study (before the intervention) and 21 days after pelvic floor muscle exercises and biofeedback
Method of measurement
Incontinence Quality of Life questionnaire

3

Description
Comparison of the therapeutic effect of pelvic floor muscle training alone with pelvic floor muscle training and biofeedback in patients with stress urinary incontinence by type of delivery
Timepoint
At the beginning of the study (before the intervention) and 21 days after pelvic floor muscle exercises and biofeedback
Method of measurement
Incontinence Quality of Life questionnaire

4

Description
Comparison of the therapeutic effect of pelvic floor muscle training alone with pelvic floor muscle training and biofeedback in patients with stress urinary incontinence according to body mass index
Timepoint
At the beginning of the study (before the intervention) and 21 days after pelvic floor muscle exercises and biofeedback
Method of measurement
Incontinence Quality of Life questionnaire

5

Description
Comparison of the therapeutic effect of pelvic floor muscle training alone with pelvic floor muscle training and biofeedback in patients with stress urinary incontinence according to the duration of incontinence
Timepoint
At the beginning of the study (before the intervention) and 21 days after pelvic floor muscle exercises and biofeedback
Method of measurement
Incontinence Quality of Life questionnaire

6

Description
Comparison of the therapeutic effect of pelvic floor muscle training alone with pelvic floor muscle training and biofeedback in patients with stress urinary incontinence by number of pregnancies
Timepoint
At the beginning of the study (before the intervention) and 21 days after pelvic floor muscle exercises and biofeedback
Method of measurement
Incontinence Quality of Life questionnaire

Secondary outcomes

1

Description
Quality of life score
Timepoint
At the beginning of the study (before the intervention) and 21 days after pelvic floor exercises and biofeedback
Method of measurement
Incontinence Quality of Life questionnaire

Intervention groups

1

Description
Intervention group: In the first session, the patient is given the necessary training about this method, the questionnaires are completed. The proposed program for these patients is 3 weeks of Kegel exercises 4 times a day for 15 minutes. Simultaneous biofeedback of ten sessions, each session is taught and each session It lasts for 15 minutes and is performed under the supervision of a researcher every other day for 3 weeks in a physiotherapy center. To reduce the patient's stress and create more relaxation, a large sheet is used as a patient cover. (EMG. Biofeedback MYTII, EB Neuro)The computer monitor, which is connected to the biofeedback device, is placed in front of the patient and then the probe of the device is impregnated with lubricant gel and placed in the patient's vagina so that the probe electrodes are placed on the pelvic floor muscles and the electrode is inactive. It is tied to the patient's hand or foot
Category
Rehabilitation

2

Description
Control group: In Kegel group, exercises include a series of contractions of the pelvic floor muscles for 6 to 8 seconds and a 5 second rest that is performed in different positions, including lying down, sitting, standing, and patients are advised to do four times in Do these exercises for 15 minutes each day for 3 consecutive weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Asa Physiotherapy Center
Full name of responsible person
Mahta Razavian
Street address
28 meters from Imam Street, not far from Pasargad clinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Behrooz Yahyaei
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University Blvd., Faculty of Medical Sciences, Shahroud Azad University

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Seyed Vahid Sadr Blourian

Position
Phd, Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Urology

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Medical Student

Latest degree
A Level or less

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General Practitioner

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available