

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 25 3293 0207

###### Email address

azin.rahimii94@gmail.com

##### 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

##### **City**

Shahroud

##### **Province**

Semnan

##### **Postal code**

3616677856

##### **Phone**

+98 23 3222 9931

##### **Email**

azin.rahimii94@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Behrooz Yahyaei

##### **Street address**

University Blvd., Faculty of Medical Sciences,  
Shahroud Azad University

**City**

Shahroud

**Province**

Semnan

**Postal code**

3616677856

**Phone**

+98 23 3239 0360

**Email**

behroozyahyaei@yahoo.com

**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

**Street address**

Khatam al Anbya Hospital, Daneshgah Blvd

**City**

Shahroud

**Province**

Semnan

**Postal code**

3616677856

**Phone**

+98 25 3293 0207

**Email**

azin.rahimii94@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Seyed Vahid Sadr Blourian

**Position**

Phd, Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

**Street address**

Khatam al Anbya Hospital, Dneshgah Blvd

**City**

Shahroud

**Province**

Semnan

**Postal code**

3616677856

**Phone**

+98 25 3293 0207

**Email**

azin.rahimii94@gmail.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mahta Razavian

**Position**

Medical Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Khatam al Anbya Hospital, Daneshgah Blvd

**City**

Shahroud

**Province**

Semnan

**Postal code**

3616677856

**Phone**

+98 25 3293 0207

**Email**

azin.rahimii94@gmail.com

## 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