

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Shahrood University of Medical Sciences

Street address

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

City

Shahrood

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

Shahrour

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