

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### The effects of adding biofeedback to the pelvic floor muscles strengthening exercises on the treatment of women with urinary incontinence, a single-blinded randomized clinical trial

#### Protocol summary

##### Study aim

Studying the effects of pelvic floor muscles strengthening exercises with and without biofeedback on surface EMG variables including maximum and mean pelvic floor muscles strength and on the incontinence severity.

##### Design

A single-blind randomized clinical trial, with a parallel control group, consisting of 40 patients, done between July 2019 and March 2020, followed for 1 month.

##### Settings and conduct

The study population included all patients who referred to the gynecology and obstetrics clinic of Shohada Tajrish Hospital with a confirmed diagnosis of urinary incontinence. They were randomly divided into control and treatment groups. Physicians and therapists were blind to the patient groups. There was no ability to blind patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: women aged 35 to 75 years with an approved diagnosis of urinary incontinence. Exclusion criteria: being single; history of diabetes mellitus, previous pelvic floor surgery, spinal cord injury, or pelvic trauma.

##### Intervention groups

Intervention group: Pelvic floor strengthening exercises plus biofeedback therapy. Control group: pelvic floor strengthening exercises only.

##### Main outcome variables

Mean & Maximum pelvic floor muscles strength, ICIQ-SF questionnaire findings

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201130049543N2**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **retrospective**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

##### Registration date

2021-06-19, 1400/03/29

##### Registrant information

###### Name

Fateme Hojjati

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2273 1112

###### Email address

fatemehojjati@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-23, 1398/05/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

2019-08-06, 1398/05/15

##### Actual recruitment end date

2020-04-18, 1399/01/30

##### Trial completion date

2020-08-20, 1399/05/30

##### Scientific title

The effects of adding biofeedback to the pelvic floor muscles strengthening exercises on the treatment of women with urinary incontinence, a single-blinded

randomized clinical trial

**Public title**  
Biofeedback and urinary incontinence

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Women Aged 35-75 years Confirmation of the diagnosis of urinary incontinence (stress, urgency, or mixed type) by a gynecologist  
**Exclusion criteria:**  
 history of diabetes previous pelvic floor surgery history of spinal cord injury history of pelvic trauma being single

**Age**  
From **35 years** old to **75 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
 Target sample size: **40**  
 Actual sample size reached: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
 In this study, simple randomization by lottery or sortition method was used. According to the number of patients (40 patients), the numbers were considered from 1 to 40. The numbers were written on the cards. After placing the cards in closed envelopes, each patient randomly selected one of the envelopes. The number of each patient was delivered in a sealed envelope and only the doctor and therapist in charge of laser treatment were aware of its contents. Patients with envelopes containing numbers 1 to 20 were allocated in the control group, numbers 21 to 40 were in the biofeedback group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
 This was a single-blinded study. A physical medicine and rehabilitation specialist (responsible for initial evaluation and re-evaluation after treatment and also teaching the patient how to do the exercises) was blind to each patient's treatment group. Another physical medicine and rehabilitation specialist was responsible for conducting biofeedback treatment sessions for patients in the second group (exercise + biofeedback). Due to the fact that providing biofeedback in the form of sham (placing the probe in the vagina but with the device turned off) can cause errors in the treatment process (feeling the probe in the vagina itself is a kind of feedback), sham-biofeedback was not done in the control group, so patients blinding could not be done.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Iran National Committee for Ethics in Biomedical Research

##### Street address

13th floor, Block A, Ministry of Health, Treatment and Medical Educatio, Iran TV Street, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۹۹۴۳۴۷۱

#### Approval date

2015-08-14, 1394/05/23

#### Ethics committee reference number

IR.SBMU.RAM.REC.1394.268

## Health conditions studied

### 1

#### Description of health condition studied

Urinari Incontinence

#### ICD-10 code

R39.81

#### ICD-10 code description

Functional urinary incontinence

## Primary outcomes

### 1

#### Description

Urinary incontinence severity

#### Timepoint

Before and 1 month after treatment

#### Method of measurement

ICIQ-SF questionnaire

## Secondary outcomes

### 1

#### Description

Mean strength of pelvic floor muscles

#### Timepoint

Before and 1 month after treatment

#### Method of measurement

2**Description**

Maximum strength of pelvic floor muscles

**Timepoint**

Before and 1 month after treatment

**Method of measurement**

Surface electromyography

**Intervention groups**1**Description**

Intervention group: Performing pelvic floor strengthening exercises along with treatment sessions using a biofeedback device. The duration of treatment was 4 weeks and 7 days a week, they performed pelvic floor strengthening exercises three times a day for 15 minutes. 2 sessions of 20 minutes per week, biofeedback treatment without electrical stimulation was also performed.

**Category**

Treatment - Devices

2**Description**

Control group: Doing pelvic floor strengthening exercises. The duration of treatment was 4 weeks and 7 days a week, they performed pelvic floor strengthening exercises three times a day for 15 minutes.

**Category**

Rehabilitation

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Shohadaye Tajrish Hospital

**Full name of responsible person**

Dr. Fateme Hojjati

**Street address**

Tajrish Square, Tehran, Iran

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Pr\_shohada@sbmu.ac.ir

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**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Alireza Zali

**Street address**

Shahid Arabi St, Yemen St, Shahid Chamran highway, Tehran, Iran.

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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**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Fateme Hojjati

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University of Medical Sciences  
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Dr Fateme Hojjati  
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Assistant Professor  
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## Person responsible for updating data

### Contact

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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

Yes - There is a plan to make this available

### Informed Consent Form

No - There is not 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 study will be published as an article without patient information containing the findings and questionnaires used.

### When the data will become available and for how long

Start accessing immediately after printing results

### To whom data/document is available

For all health and technology activists

### Under which criteria data/document could be used

Information can be used with respect to copyright.

### From where data/document is obtainable

Send the request to the email of the corresponding author. Fatemehojjati@yahoo.com

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

If you send an e-mail request and submit a form to confirm the identity of the applicant, the information will be sent within a week.

### Comments