

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of pelvic floor muscle training with and without biofeedback and electrical stimulation on urinary incontinence and quality of life in postmenopausal women: A clinical trial

#### Protocol summary

##### Study aim

Determining the effect of pelvic floor exercises with and without biofeedback and electrical stimulation on urinary incontinence and quality of life in postmenopausal women

##### Design

A controlled, parallel-group, non-randomized, not blinded clinical trial on 60 postmenopausal women.

##### Settings and conduct

This is an interventional study with two groups of 30 postmenopausal women aged 45 to 60 years who suffer from urinary incontinence. For the pelvic floor exercises group, the necessary training will be given in the first session and for the electrical stimulation and biofeedback group, in addition to pelvic floor exercises, 8 physiotherapy sessions will be conducted at one-week intervals. The outcome of interest is urinary incontinence and quality of life

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 45-60 years, one year since the last menstrual period after the onset of natural menopause, not taking urinary incontinence medications, residing in Tabriz city. Exclusion criteria: Mental and motor disability, history of any physical or mental illness that causes urinary incontinence.

##### Intervention groups

For the pelvic floor exercises group, the necessary training will be given in the first session in a private room, and the researcher will make phone calls to the participants of this group every week for 8 weeks to follow up and provide the necessary training. For the electrical stimulation and biofeedback group, in addition to pelvic floor exercises, 8 physiotherapy sessions will be conducted at one-week intervals, and before each session, the time of the intervention will be reminded.

##### Main outcome variables

Urinary Incontinence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111219008459N18**

Registration date: **2025-04-26, 1404/02/06**

Registration timing: **prospective**

Last update: **2025-04-26, 1404/02/06**

Update count: **0**

##### Registration date

2025-04-26, 1404/02/06

##### Registrant information

##### Name

Shirin Hasanpoor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

hasanpoorsh@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-09-23, 1404/07/01

##### Expected recruitment end date

2026-03-20, 1404/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of pelvic floor muscle training with and without biofeedback and electrical stimulation on urinary incontinence and quality of life in postmenopausal women: A clinical trial

### Public title

The effect of pelvic floor muscle training with and without of biofeedback and electrical stimulation on urinary incontinence and quality of life in postmenopausal women

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 45-60 years One year has passed since the last menstrual period after the onset of natural menopause. Not taking urinary incontinence medications Resident of Tabriz city

#### Exclusion criteria:

Mental and motor disability History of any physical or mental illness that causes urinary incontinence

### Age

From **45 years** old to **60 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic's committee of Tabriz University of Medical Sciences

##### Street address

Physical Medicine and Rehabilitation Research Center, Imam Reza Hospital, Golgasht Street, Tabriz

##### City

Tabriz

### Province

East Azarbaijan

### Postal code

5166614756

### Approval date

2025-04-16, 1404/01/27

### Ethics committee reference number

IR.TBZMED.REC.1404.020

## Health conditions studied

### 1

#### Description of health condition studied

Urinary incontinence and quality of life in postmenopausal women

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Urinary Incontinence

#### Timepoint

8 weeks after intervention

#### Method of measurement

Using of Incontinence Questionnaire-Urinary Incontinence Short Form: ICIQ-UISF

## Secondary outcomes

### 1

#### Description

Life Quality

#### Timepoint

8 weeks after intervention

#### Method of measurement

Using of Incontinence Quality of Life Questionnaire: I-QoL

## Intervention groups

### 1

#### Description

Intervention group: In addition to pelvic floor exercise training, women in this group (30 postmenopausal women with urinary incontinence) will receive biofeedback and electrical pelvic floor stimulation over 8 sessions, one week apart.

#### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Alzahra Hospital of Tabriz

**Full name of responsible person**

Shirin Hasanpour

**Street address**

Physical Medicine and Rehabilitation Research Center,  
Imam Reza Hospital, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3382 3660

**Email**

shirinhasanpoor@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Khosrow Adibkia

**Street address**

Research department, third floor, central construction  
number 2, Tabriz University of Medical Sciences,  
Golgasht Street, Azadi Avenue, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5168743953

**Phone**

+98 41 3335 7310

**Email**

research-vice@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Shirin Hasanpour

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Physical Medicine and Rehabilitation Research Center,  
Imam Reza Hospital, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3335 2081

**Email**

shirinhasanpoor@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Shirin Hasanpour

**Position**

Assistant Professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

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Tabriz University of Medical Sciences

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Assistant professor

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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