Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Khosrow Adibkia

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

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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

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Person responsible for updating data

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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