

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effects of pelvic floor muscle strengthening exercise, pelvic floor muscle strengthening exercise plus hip rotator muscle exercise, and pelvic floor muscle strengthening exercise plus electrical stimulation on the symptoms of women with stress and mixed urinary incontinence

#### Protocol summary

##### Study aim

Comparison of the effectiveness of functional intravaginal electrical stimulation and pelvic floor and pelvic external rotator muscle strengthening exercises on urinary incontinence

##### Design

Clinical trial with 3 groups , with parallel groups, single - blind, randomized, on 60 patients. Sealed envelopes will be used for randomization

##### Settings and conduct

This study will be conducted in Isfahan city, in two rehabilitation faculty centers and in the pelvic floor clinic. The study will be conducted in a single-blind manner and the participants(patients) will be blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women diagnosed with stress and mixed urinary incontinence by a urologist,Average age between 30-65 years,Absence of pregnancy and a one-year postpartum period, No receive medical or surgical treatment for urinary incontinence,Absence of any urinary-genital infection,Absence of neuromuscular diseases, Absence of severe pelvic prolapse Exclusion criteria: Any problem that may interfere with the continuation of the treatment, Patient's lack of consent to continue the treatment

##### Intervention groups

Group 1:In this group, patients will receive feedback from the performance of the muscles while performing pelvic floor exercises using the EMG biofeedback device. Group 2:In this group, in addition to the exercises of the first group, patients will perform pelvic rotator muscle exercises. Group 3:In addition to the treatment of first group, this group will receive electrical stimulation of the pelvic floor.

#### Main outcome variables

Quality of life questionnaire, The number of unwanted urinations ,Pelvic floor muscle strength ,Strength of external hip rotator muscles

#### General information

##### Reason for update

##### Acronym

EMG

##### IRCT registration information

IRCT registration number: **IRCT20090301001722N30**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

##### Registration date

2023-07-11, 1402/04/20

##### Registrant information

##### Name

Samira Karimpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7753 3939

##### Email address

hadianrs@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-30, 1402/06/08  
**Expected recruitment end date**  
2023-11-22, 1402/09/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effects of pelvic floor muscle strengthening exercise, pelvic floor muscle strengthening exercise plus hip rotator muscle exercise, and pelvic floor muscle strengthening exercise plus electrical stimulation on the symptoms of women with stress and mixed urinary incontinence

**Public title**  
Evaluation of the effects of pelvic floor muscle strengthening exercise plus hip rotator muscle exercise on the stress urinary incontinence

**Purpose**  
Health service research

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Women diagnosed with stress and mixed incontinence by a urologist Average age between 30-65 years Absence of pregnancy and a one-year postpartum period No receive medical or surgical treatment for incontinence Absence of genital area disease Absence of neuromuscular diseases Absence of severe pelvic prolapse  
**Exclusion criteria:**  
Any problem that may interfere with the continuation of the treatment The patient's lack of consent to continue the treatment

**Age**  
From **30 years** old to **65 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **60**

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

**Randomization description**  
Patients are randomly assigned to three groups. Patients are explained in advance about being placed in one of these three treatment groups and it is understood that you will be placed in one of these three groups. Then, to observe the random assignment of patients, envelopes will be prepared containing the methods of treatment groups, and the patient will choose one of them. Accordingly, the patient will enter his treatment group.

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

**Blinding description**

In this study, patients know that they will participate in one of the treatment groups. The therapist and the assessor are blind to the grouping. It will be planned so that participants in different treatment groups do not face each other and there will be no contact between them.

**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Faculty of Nursing and Midwifery and Faculty of Rehabilitation - Tehran University of Medical Science

##### Street address

Tehran University of Medical Sciences, Qods corner., Keshavarz Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2023-06-25, 1402/04/04

#### Ethics committee reference number

IR.TUMS.FNM.REC.1402.061

## Health conditions studied

### 1

#### Description of health condition studied

stress and mix urinary incontinence

#### ICD-10 code

N39.3

#### ICD-10 code description

Stress incontinence (female)

## Primary outcomes

### 1

#### Description

Unwanted leakage of urine in one day

#### Timepoint

At the beginning of the study, after 6 weeks in the last session

#### Method of measurement

questionnaire

## 2

### **Description**

Quality of life

### **Timepoint**

At the beginning of the study, after 6 weeks in the last session

### **Method of measurement**

questionnaire (I-QOL)

## **Secondary outcomes**

## 1

### **Description**

Pelvic floor muscle strength

### **Timepoint**

At the beginning of the study, after 6 weeks in the last session

### **Method of measurement**

Perineometer instrument ,Electromyography

## **Intervention groups**

## 1

### **Description**

Control group: the patients, three times a week, when performing pelvic floor exercises alongside an EMG biofeedback device, will receive feedback on the functioning of the muscles. Patients will be treated and controlled with biofeedback for 15 minutes

### **Category**

Rehabilitation

## 2

### **Description**

First intervention group: in this group, in addition to the exercises, they will perform the exercises of the pelvic external rotator muscles.

### **Category**

Rehabilitation

## 3

### **Description**

Second Intervention group: In addition to the exercises, this group will receive electrical stimulation of the pelvic floor. In this group of patients, they also be treated three times a week and along with pelvic floor exercises, intravaginal electrical stimulation is performed by a vaginal probe (50 Hz, 200 microseconds for 15 minutes).

### **Category**

Treatment - Devices

## **Recruitment centers**

## 1

### **Recruitment center**

**Name of recruitment center**

Isfahan University of Medical Sciences

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

Anahita Torkzadeh

### **Street address**

Faculty of Rehabilitation Sciences ,University of Medical Sciences,Hazar Jarib St

### **City**

Esfahan

### **Province**

Isfahan

### **Postal code**

81746-73461

### **Phone**

+98 913 409 9848

### **Email**

Anahitatkz@yahoo.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

Pelvic floor disorders rehabilitation center

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

Anahita Torkzadeh

#### **Street address**

No 14, Hafez building , Felestin Ave

#### **City**

Esfahan

#### **Province**

Isfahan

#### **Postal code**

8143995956

#### **Phone**

+98 913 409 9848

#### **Email**

Anahitatkz@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

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

Tehran University of Medical Sciences

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

Akbar Fotuhi

#### **Street address**

Tehran University of Medical Sciences, Qods corner., Keshavarz Blvd

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1417653761

#### **Phone**

+98 21 81631

#### **Email**

tumspr@tums.ac.ir

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor**

**organization/entity?**

No

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Anahita Torkzadeh

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Faculty of Rehabilitation, Pich Shamiran., Enghelab St

**City**

Faculty of Rehabilitation, Corner of Safi Alishah St.,  
Pich Shamiran., Enghelab St

**Province**

Tehran

**Postal code**

1148965111

**Phone**

+98 21 6649 2271

**Email**

Anahitatz@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadreza Hadian Rasanani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neurorehabilitation, clinical electroneurophysiology,  
Locomotion

**Street address**

School of Rehabilitation, corner of Safi Alishah St.,  
Pich Shamiran., Enghelab St

**City**

Tehran

**Province**

Tehran

**Postal code**

1148965111

**Phone**

+98 21 7753 3939

**Email**

hadianrasan@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Anahita Torkzadeh

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Faculty of Rehabilitation, corner of Safi Alishah St.,  
Pich Shamiran., Enghelab St

**City**

Tehran

**Province**

Tehran

**Postal code**

1148965111

**Phone**

+98 21 6649 2271

**Email**

anahitatz@yahoo.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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available