

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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Iran (Islamic Republic of)

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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 Sciences
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

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

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2

Recruitment center

Name of recruitment center

Pelvic floor disorders rehabilitation center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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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

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Latest degree

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Other areas of specialty/work

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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