Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 Scienc

Street address

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

City

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Province

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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
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Sponsors / Funding sources

1

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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
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Anahita Torkzadeh
Position
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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