Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effects of Pelvic floor muscle training, Foot Reflexology, and Their Combination on Stress Urinary Incontinence in Women: A Randomized Controlled Trial

Protocol summary

Study aim
Determining the comparison of the effects of pelvic floor muscle exercises, foot reflexology, and their combination on the improvement of stress urinary incontinence (SUI) symptoms

Design
A phase 3, single-blind, parallel-group clinical trial will be conducted on 84 patients. Randomization will be carried out using a random number table.

Settings and conduct
This study is a single-blind randomized controlled trial (RCT), in which the analyst will be unaware of participants' group assignments. The study will be conducted on 84 women who have medical records in educational and therapeutic centers in Tabriz and have been definitively diagnosed with stress urinary incontinence (SUI). Participants will be randomized using a random number table with block sizes of six and nine and an allocation ratio of 1:1:1 into three intervention groups: foot reflexology alone, PFMT alone, and a combination of foot reflexology and PFMT.

Participants/Inclusion and exclusion criteria
Inclusion Criteria Scoring 4 or higher on the first three questions of the QUID (Questionnaire for Urinary Incontinence Diagnosis) Exclusion Criteria Asthma or chronic cough (lasting more than three months) Scoring 13 or higher on the ICIQ-UI SF (International Consultation on Incontinence Questionnaire – Short Form) Women over 50 years of age

Intervention groups
Intervention Group 1 includes patients with stress urinary incontinence who will receive reflexology intervention alone. Intervention Group 2 includes patients with stress urinary incontinence who will receive pelvic floor muscle training (PFMT) intervention alone. Intervention Group 3 includes patients with stress urinary incontinence who will receive a combination of reflexology and pelvic floor muscle training interventions.

Main outcome variables
Stress Urinary Incontinence Score

General information

Reason for update

Acronym
PFMT

IRCT registration information
IRCT registration number: **IRCT20110606006709N28**
Registration date: **2025-10-20, 1404/07/28**
Registration timing: **prospective**

Last update: **2025-10-20, 1404/07/28**
Update count: **0**

Registration date
2025-10-20, 1404/07/28

Registrant information

Name
Mahnaz Shahnazi

Name of organization / entity
Tabriz University of Medical Science

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-06, 1404/08/15

Expected recruitment end date
2026-05-22, 1405/03/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Pelvic floor muscle training, Foot Reflexology, and Their Combination on Stress Urinary Incontinence in Women: A Randomized Controlled Trial

Public title
Comparison of the Effects of Pelvic floor muscle training, Foot Reflexology, and Their Combination on Stress Urinary Incontinence in Women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Literacy in reading and writing at the middle school level. Obtaining a score of 4 or higher from the first three questions of the QUID questionnaire for the diagnosis of urinary incontinence. Having a phone number for follow-up. Organ health in the legs, especially the soles of the feet.
Exclusion criteria:
Travel during the intervention period or change of residence. Acute or chronic diseases that may affect the study results (such as uncontrolled diabetes, renal failure, or severe motor disorders). Pregnant women or those who have delivered within the past 6 months (due to the effect of hormones and anatomical changes on urinary incontinence). Smoking or alcohol consumption. History of reconstructive surgeries in the genital and urinary system. Having urinary tract infection. Asthma and chronic cough (more than three months). History of abnormality in the genitourinary system. Use of other treatments such as traditional medicine or biofeedback for urinary incontinence. Obtaining a score of 13 or higher from the standard urinary incontinence short form questionnaire (ICIQ-UI SF). Women over 50 years of age.
Age
To **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to one of the three intervention groups (reflexology alone, PFMT alone, or a combination of reflexology and PFMT) using a random number table with block sizes of six and nine and an allocation ratio of 1:1:1. Block randomization will be performed by an individual not involved in the sampling process. To ensure allocation concealment, the researcher or individuals responsible for patient assignment will prepare a series of sealed envelopes numbered consecutively from 1 to 84 before the start of the study. Each envelope will contain a random number or code corresponding to one of the treatment groups (PFMT alone, reflexology alone, or the combination of reflexology and PFMT). After each participant is enrolled in the study, one of the sealed envelopes will be assigned to them, and group allocation will be carried out confidentially, without the researcher's knowledge. This method prevents allocation bias since the researcher remains unaware of the treatment group until after the participant has been assigned. Each intervention will be administered over a period of eight weeks.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blind randomized controlled trial in which the data analyst will be unaware of the participants' group allocation.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Reaserch department, third floor, central construction nute 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue
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Tabriz
Province
East Azarbaijan
Postal code
5138947977
Approval date
2025-09-24, 1404/07/02
Ethics committee reference number
IR.TBZMED.REC.1404.453

Health conditions studied

1

Description of health condition studied
tress Urinary Incontinence

ICD-10 code
N39.3
ICD-10 code description
Stress incontinence (female) (male)

Primary outcomes

1

Description
Stress Urinary Incontinence Score
Timepoint
At baseline (before the intervention), and at 4 and 8 weeks after the intervention
Method of measurement
The standardized ICIQ-UI SF questionnaire

Secondary outcomes

1

Description
"Pelvic Floor Muscle Strength Score"
Timepoint
At baseline (before the intervention), and at 4 and 8 weeks after the intervention
Method of measurement
Modified Oxford Scale

2

Description
"Stress Urinary Incontinence–Related Quality of Life Score"
Timepoint
At baseline (before the intervention), and at 4 and 8 weeks after the intervention
Method of measurement
Incontinence Quality of Life questionnaire (I-QoL)

3

Description
"Women's Satisfaction"
Timepoint
After completion of the intervention
Method of measurement
satisfaction checklist

Intervention groups

1

Description
Group 1 (PFMT): Participants assigned to the pelvic floor muscle training (PFMT) group will be instructed to perform the exercises as taught. Before starting the exercises, the bladder should be emptied. The exercises can be performed in different body positions—lying down with legs straight, sitting with the back upright, or standing with feet shoulder-width apart. To identify the muscles involved in urinary control, participants will be asked to try to stop the flow of urine once while urinating by contracting their pelvic floor muscles. This helps them recognize the correct muscles to use, and they will be advised not to repeat this maneuver more than once or twice to avoid the risk of urinary tract infections. During training, breathing should remain normal, and only the pelvic floor muscles should contract while the rest of the body stays relaxed. The PFMT program will be carried out for eight weeks. Each week, the exercises will be performed three times per day (morning, afternoon, and evening) on five to six days per week, allowing one rest day to accommodate individual lifestyles. In each session, three sets will be performed, with 10 to 15 repetitions per set, and each session will last approximately 15–20 minutes. The progression of exercises is structured as follows: during weeks 1 and 2, the focus will be on learning the correct technique, with each contraction held for 3 seconds followed by 3 seconds of rest between contractions, performed in the lying position. During weeks 3 and 4, the duration of contraction and relaxation will increase to 4 seconds each, with 12 repetitions per set, and the sitting position will be added. From weeks 5 to 8, each contraction and relaxation will last 5 seconds, with 15 repetitions per set, and exercises will be performed in three positions: lying, sitting, and standing. In addition to slow contractions, fast contractions will be introduced during the later weeks, in which participants will perform 10 quick contractions in each set, each consisting of a 1-second contraction followed by a 1-second relaxation.
Category
Treatment - Other

2

Description
Group 2 (Reflexology): Participants in this group will be taught reflexology techniques by the researcher, who has completed the required training sessions and obtained a reflexology training certificate from a physiotherapy specialist. The reflexology intervention will be performed by the researcher during the first session, during which the participant will be thoroughly instructed on the correct technique and reflex points. In the second session, participants will be asked to perform the technique themselves under the researcher’s supervision to ensure accuracy and proper execution. After completing these initial sessions, participants will continue the remaining reflexology sessions as self-administered practice at home. To help participants remember the correct techniques and reflex points, they will be asked to record a short video of the first session while the researcher demonstrates and explains the correct reflexology method. This video can later be used as a reference if participants forget any part of the procedure. Reflexology will be conducted in a quiet, private room with the participant lying on a couch or examination bed. The room temperature will be adjusted to ensure the participant feels comfortable, without experiencing cold or sweating. Each participant’s feet will first be cleaned with a warm, damp cotton towel. The reflexology protocol will begin with the right foot. Relaxation techniques such as ankle rotations and gentle

vibrations will be applied, followed by general massage of the entire sole of the foot for five minutes. Reflexology massage will then be performed by applying rhythmic, alternating pressure with the thumb on specific reflex points corresponding to the pituitary gland, kidneys, ureters, bladder, vagina, and pelvic region. Pressure will be applied for one minute on each point, strong enough to cause whitening of the nail bed but without causing pain. The session will conclude with compression of the solar plexus and relaxation maneuvers. The same procedure will then be performed on the left foot. Immediately after each reflexology session, participants will be advised to drink one glass (200 mL) of water to help eliminate metabolic waste products. Each reflexology session will last approximately 20 minutes (10 minutes per foot). Participants in the reflexology group will perform the foot reflexology sessions three times per week for eight week.

Category

Treatment - Other

3

Description

Combined Group: Participants in this group will perform PFMT according to the same protocol as the PFMT-only group and will receive reflexology every other day (once per day), immediately after completing the PFMT exercises, for a duration of eight weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Teaching Hospital

Full name of responsible person

Mahnaz Shahnazi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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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
Confidentiality of participant 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