

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of pelvic floor muscle training alone and combined with hypopressive exercises on urinary Incontinence in postpartum women.

Protocol summary

Study aim

investigation of value-added effect of hypopressive exercises on pelvic floor muscle training on the presence and severity of urinary incontinence in postpartum women.

Design

A randomized controlled trial with parallel groups , single blinded.

Settings and conduct

Women diagnosed with stress urinary incontinence will first undergo baseline assessments . those meeting the inclusion criteria and not presenting with any exclusion criteria will be enrolled as participants . instructions on how to perform the exercises will be provided at the physiotherapy clinic , after which participants will continue the sessions at home once they have mastered the techniques.Completion of questionnaires will be based on self-report.

Participants/Inclusion and exclusion criteria

inclusion criteria: -Age range of 25 to 45 y/o -History of stress urinary incontinence for a minimum duration of 2 months -Not having undergone pelvic floor physiotherapy -Having had healthy childbirth(s) - exclusion criteria: - Pregnancy -Presence of mental disorders that interfere with comprehension or participation in the interventions - Having undergone abdominal or pelvic surgery, except for cesarean section -Inability to perform the intervention exercises -Presence of any physical disorder that restricts the ability to perform exercises (e.g., cardiovascular disease, active cancer, hypertension, fibromyalgia, COPD, etc.)

Intervention groups

Control group: participants in this group will perform pelvic floor muscle training , 3 times per week for a duration of 4 weeks , each session lasting 30 minutes. Intervention group: participants in this group will engage in pelvic floor muscle training combined with

hypopressive exercises , 3 times per week for a duration of 4 weeks , with each session lasting 30 minutes.

Main outcome variables

severity of urinary incontinence.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250826067010N1**

Registration date: **2025-09-18, 1404/06/27**

Registration timing: **prospective**

Last update: **2025-09-18, 1404/06/27**

Update count: **0**

Registration date

2025-09-18, 1404/06/27

Registrant information

Name

Mahdis Zare

Name of organization / entity

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

2026-02-04, 1404/11/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of pelvic floor muscle training alone and combined with hypopressive exercises on urinary Incontinence in postpartum women.

Public title
Comparison of the effect of pelvic floor muscle training alone and combined with hypopressive exercises on urinary Incontinence in postpartum women.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age range of 25 to 45 y/o History of stress urinary incontinence for a minimum duration of 2 months Not having undergone pelvic floor physiotherapy Having at least one delivery Having had healthy childbirth(s)
Exclusion criteria:
 Pregnancy Presence of mental disorders that interfere with comprehension or participation in the interventions Having undergone abdominal or pelvic surgery, except for Cesarean section Inability to perform the intervention exercises Presence of any physical disorder that restricts the ability to perform exercises (e.g., cardiovascular disease, active cancer, hypertension, fibromyalgia, COPD, etc.)

Age
From **25 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
To allocate participants into study groups, a block randomization method is used. Participants are randomly assigned in blocks (13 blocks of 4) to two intervention groups (26 people) and control group (26 people). To implement concealment of random allocation, opaque sealed envelopes with a random sequence will be used so that the allocated group is not known before individual allocation. In this method, after generating the random sequence using block randomization, a number of opaque envelopes (to ensure the content of the envelopes is not visible) are prepared based on the specified sample size, and each of the created random sequences is recorded on a card. The cards are then placed in the envelopes in order. To maintain the random sequence, the envelopes are numbered on the outer surface in the same order. Finally, the envelope flaps are

sealed, and they are placed sequentially inside a box. At the time the registration of participants begins, one of the envelopes will be opened in order based on the sequence of eligible participants entering the study, revealing the assigned group for that participant.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants are not aware of which treatment group they are placed in. For this purpose, the participants in both groups are given the same general explanations and the familiarization sessions on how to perform the exercises are held separately for the participants in each group in a way that the participants in each group are not informed that parts of the exercises of the participants in the other group may be different. In terms of the timing of the sessions, each treatment session is considered similar for the participants in both groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of school of Rehabilitation Sciences, Shiraz Univeristy of Medical Sciences

Street address

Shahid Dowran Campus, Shiraz University of Medical Sciences, Sadra Town's Entry Road

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shiraz

Province

Fars

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7198754361

Approval date

2025-07-30, 1404/05/08

Ethics committee reference number

IR.SUMS.REHAB.REC.1404.013

Health conditions studied

1

Description of health condition studied

Urinary Incontinence

ICD-10 code

N39.498

ICD-10 code description

Other specified urinary incontinence

Primary outcomes

1

Description

severity of urinary incontinence

Timepoint

pre-intervention,post-intervention(1 month after initiation) and at 1-month follow-up

Method of measurement

International Consultation on Incontinence
Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF)

Secondary outcomes

1

Description

quality of life score

Timepoint

pre-intervention,post-intervention,at 1-month follow-up

Method of measurement

International Consultation on Incontinence(ICIQ)- Lower Urinary Tract Symptoms Quality of Life Questionnaire(LUTSQoL)

Intervention groups

1

Description

Intervention group: hypopressive exercises + pelvic floor muscle training ,for 4 weeks ,3 times per week,for 30 minutes each session.

Category

Rehabilitation

2

Description

Control group: pelvic floor muscle training , for four weeks ,three times per week , for 30 minutes each session.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Affiliated to SUMS

Full name of responsible person

Dr Amin Niakan

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Deputy Chancellor for Treatment, 5th floor, Central Building of SUMS, Zand Boulevard

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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

MSc Thesis Grant

Grant code / Reference number

32865

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mahdis Zare
Position
M.Sc. student
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study Protocol, Statistical Analysis Plan, Clinical Study Report

When the data will become available and for how long

starting immediately after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

For Academic Purposes by considering publication general rights

From where data/document is obtainable

Through sending email to Mahdis Zarei
mahdis.zare.z@gmail.com

What processes are involved for a request to access data/document

After receiving the request via email and ensuring compliance with copyright ethics, the requested information will be sent within a maximum period of 2 months.

Comments