Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 71 4223 8863

Email address

mahdis.zare.z@gmail.com

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

City

shiraz

Province

Fars

Postal code

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
Street address
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
Shiraz University of Medical Sciences
Full name of responsible person
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Web page address
https://sums.ac.ir
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
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
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