

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of adding hypopressive exercise to specific pelvic floor function in semiprofessional female athletes

#### Protocol summary

##### Study aim

Investigating the effect of adding low pressure exercises to specific pelvic floor exercises on pelvic floor performance in semi-professional female athletes

##### Design

The clinical trial has two parallel groups and one blind strain. Simple randomization was done based on randomized blocks on 60 patients.

##### Settings and conduct

People go to the rehabilitation clinic under the supervision of a physiotherapist to evaluate and receive the exercise brochure and training and perform the desired exercises, and then after receiving and training the exercises, they perform the exercises for 8 weeks. The evaluator in the blind study and the participant and The interventionist is not blind.

##### Participants/Inclusion and exclusion criteria

Women aged 18 to 60 years who have persistent symptoms of stress urinary incontinence during the past six months and one year after giving birth and who exercise at least three days a week for more than one year. These people should not be on hormone therapy, and six months They should not have been pregnant before pregnancy, and they should not have undergone physical therapy and not performed gynecological and urological surgery in the previous year. and do not have neurological disease, and do not have the inability to properly contract the pelvic floor muscles and maintain the probe, and do not have irregularity in sports performance, and are able to cooperate in the subsequent evaluations and complete the questionnaire, and do not have prohibitions to do exercises.

##### Intervention groups

One group performs specific pelvic floor exercises that include pelvic floor contractions and the other group performs the same exercises along with low pressure exercises.

##### Main outcome variables

Displacement of the base of the bladder, strength and

endurance of pelvic floor muscles, stress urinary incontinence, quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241007063276N1**

Registration date: **2024-11-11, 1403/08/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-11-11, 1403/08/21**

Update count: **0**

##### Registration date

2024-11-11, 1403/08/21

##### Registrant information

##### Name

Atefe Gashteh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3344 2051

##### Email address

atefeh.gashte@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-10-22, 1403/08/01

##### Expected recruitment end date

2025-04-20, 1404/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Investigating the effect of adding hypopressive exercise to specific pelvic floor function in semiprofessional female athletes

## Public title

Effect of Hypopressive exercises

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Female athletes aged 18 to 60 despite symptoms of pelvic floor disorders lasting six months More than a year has passed since giving birth Exercising at least three days a week for more than a year

### Exclusion criteria:

Pregnancy six months before entering the study Gynecological and urological surgeries Age less than 18 and more than 60 Pelvic floor physiotherapy in the previous year Neurological and psychiatric disease Any medical prohibition to exercise Inability to participate in subsequent evaluations Inability to participate in subsequent evaluations Undergoing hormone therapy Irregularity in sports performance Inability to properly contract the pelvic floor muscles Inability to insert and maintain vaginal probe due to pain and discomfort

## Age

From **18 years** old to **60 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The sampling method is accessible, i.e. among semi-professional female athletes with pelvic floor disorders who are referred to the neuromuscular rehabilitation clinic of Semnan Rehabilitation Faculty to receive pelvic floor physiotherapy with the aim of managing the symptoms of pelvic floor disorders, those who consent to participate in the study and meet the entry criteria, they will be included in the study. Allocation to two groups is random and this allocation will be done using the randomized block method. For this purpose, two interventions A and B is considered in six blocks of ten as follows. When each patient enters, the physiotherapist will ask for the type of treatment from the relevant methodology. The methodologist, holding the prepared list below, chooses a number between one and six by throwing a dice, and in the selected block, selects the specified intervention (A or B) to The person is allocated and announced to the physiotherapist. In the next stages, if the selected block is filled, the dice throw is

repeated, two other numbers are selected that the sequence of interventions has not yet been completed, and this work will continue until the end of all blocks and the completion of 60 cases.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The study is one-sided blind. The evaluator in this study does not know the type of exercises of each person and is blind, the participant and the interventionist are fully present during the exercises and are not blind.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

##### Street address

Basij Boulevard, Semnan Medical Sciences Headquarters

##### City

Semnan

##### Province

Semnan

##### Postal code

۳۵۱۹۸۶۶۷۷۵

#### Approval date

2024-10-20, 1403/07/29

#### Ethics committee reference number

IR.SEMUMS.REC.1403.136

## Health conditions studied

### 1

#### Description of health condition studied

Low pressure exercises in stress urinary incontinence

#### ICD-10 code

N39.3

#### ICD-10 code description

Stress incontinence (female) (male)

## Primary outcomes

### 1

#### Description

Endurance and strength of the pelvic floor muscles

#### Timepoint

At the beginning and after eight weeks of training

### **Method of measurement**

Endurance and strength of the pelvic floor muscles with prineometer

### **2**

#### **Description**

Displacement of the base of the bladder

#### **Timepoint**

At the beginning and after eight weeks of training

#### **Method of measurement**

Using ultrasound

### **3**

#### **Description**

Stress urinary incontinence

#### **Timepoint**

At the beginning and after eight weeks of training

#### **Method of measurement**

One hour pad test

### **4**

#### **Description**

quality of life

#### **Timepoint**

At the beginning and after eight weeks of training

#### **Method of measurement**

Quality of life questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

intervention group: This group performs specific pelvic floor exercises that include pelvic floor contractions in standing and sitting positions and crouching with different rest and contraction times for eight weeks with weekly supervision by a physiotherapist.

##### **Category**

Rehabilitation

#### **2**

##### **Description**

Intervention group: Intervention group: This group performs specific pelvic floor exercises like the first group, and in addition, low pressure exercises are also performed along with it. They are performed with different rest and contraction times for eight weeks with the weekly supervision of a physiotherapist.

##### **Category**

Rehabilitation

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Tabatabai Rehabilitation Clinic

###### **Full name of responsible person**

Rosita Hedayati

###### **Street address**

Third Yasman St. East

###### **City**

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###### **Postal code**

3519877993

###### **Phone**

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atefeh.gashte@yahoo.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Semnan University of Medical Sciences

###### **Full name of responsible person**

Abasali Vafayi

###### **Street address**

Basij Boulevard, Semnan Medical Sciences  
Headquarters

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###### **Province**

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+98 23 3105 2120

###### **Email**

Sem.ums.res@Gmail.com

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Semnan University of Medical Sciences

##### **Proportion provided by this source**

10

##### **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**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Rosita Hedayati  
**Position**  
Associate Professor  
**Latest degree**  
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**Other areas of specialty/work**  
Physiotherapy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Investigating the effect of adding low pressure exercises to specific pelvic floor exercises on pelvic floor performance in semi-professional female athletes

### When the data will become available and for how long

1404

### To whom data/document is available

All people

### Under which criteria data/document could be used

Research and treatment projects

### From where data/document is obtainable

Rosita hedayati

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

Statement of the subject of the research plan and occupational therapy

### Comments