Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

Sponsor
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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
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Rosita Hedayati
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Person responsible for updating data

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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