Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of Pelvic Floor Muscle Training in non-diabetic pregnant women with urinary incontinence

Protocol summary

Study aim
Investigating the effects of Pelvic Floor Muscle Training on Pelvic floor muscles' function and quality of life in non-diabetic pregnant women with urinary incontinence

Design
Non-diabetic pregnant women with urinary incontinence form the statistical population. Participants are randomly assigned. Web-based randomization method is used to generate random sequence. The formula will be used to determine the sample size in each group. The number of samples in each group was calculated to be 20 and 40 in total.

Settings and conduct
This study will be conducted in Shahid Sadoughi University of Yazd. 25-week pregnant mothers suffering from urinary incontinence are included in the study by referring to a gynecologist through a simple sampling method. All participants sign an informed consent form. Participants will be randomly divided into treatment (number = 20) and control (number = 20) groups. Participants are assessed before and after 10 weeks of intervention. The evaluator will not know about the grouping allocation of the participants. Only the participants and the physiotherapist involved in training the exercises will know about the assignment of the groups.

Participants/Inclusion and exclusion criteria
safe pregnancy presence of urinary incontinence first pregnancy 20-30 years old

Intervention groups
Non diabetic treatment: The protocol includes PFM strengthening exercises that include 3 sets of 10 slow contractions (6 to 8 s) and a rest period equivalent to the contraction time, and finally 3 to 4 fast contractions in the supine, sitting and standing positions for at least 3 times a day. Exercises are done at home for 10 consecutive weeks (25 to 35 weeks of pregnancy). Non-diabetic control: A pamphlet regarding PFM training will be given.

Main outcome variables
Quality of life, bladder base displacement, strength of pelvic floor muscles, endurance of pelvic floor muscles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160601028203N2**
Registration date: **2022-10-24, 1401/08/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-24, 1401/08/02**
Update count: **0**

Registration date
2022-10-24, 1401/08/02

Registrant information

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Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-01-21, 1401/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of Pelvic Floor Muscle Training in non-diabetic pregnant women with urinary incontinence

Public title
Effects of Pelvic Floor Muscle Training
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
first pregnancy gestational age of 25 week presence of urinary incontinence
Exclusion criteria:
High risk pregnancy presence of other neuromuscular disease use of other treatment for urinary inontinence twin pregnancy
Age
From **20 years** old to **30 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The creation of randomization sequence will be limited block randomization with random block size (block size: 2, 4, 6). In this way, the study participants are randomly placed in one of the two control or treatment groups. Web-based randomization method (www.sealedenvelope.com) is used to generate random sequence. Opaque sealed envelopes with a random sequence will be used to conceal the random allocation. This work is done with the help of a person who has no role in the research process. Based on the order of entry of eligible participants into the study, which are selected by the gynecologist, one of the envelopes will be opened and the group assigned to that participant will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
The evaluator will not know about the allocation of grouping of people participating in this study. Only the participants and the physiotherapist involved in training the exercises will know about the assignment of the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me
Street address
Physiotherapy department, Rehabilitation school of Shahid Beheshti University of Medical Sciences, Damavand Ave, Tehran
City
Tehran
Province
Tehran
Postal code
1616913111
Approval date
2021-11-28, 1400/09/07
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.611

Health conditions studied

1

Description of health condition studied
urinary incontinence
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Comparison of bladder base displacement with ultrasound to evaluate the strength of the pelvic floor muscles
Timepoint
Measuring of bladder base displacement at the beginning of the third trimester (28-25 weeks), late third trimester (35-32 weeks) and two months after delivery
Method of measurement
Measurement of bladder base displacement by ultrasound

Secondary outcomes

1

Description
measurement of quality of life
Timepoint
Early third trimester (25-28 weeks), late third trimester (35-32 weeks) and two months postpartum
Method of measurement

measurement of quality of life with incontinence quality of life (I-QOL) questionnaire

Intervention groups

1

Description
Intervention group: The protocol consisted of pelvic floor muscle strengthening exercises. Women were encouraged to perform three sets of ten slow contractions, holding each contraction for 6 to 8 seconds, followed by a rest period equal to the duration of the contraction. and finally three to four rapid contractions are performed in supine, sitting and standing positions for at least three times a day. Mothers do these exercises for 10 consecutive weeks (25 weeks of pregnancy to 35 weeks of pregnancy) and gradually the number of contractions increases. In each exercise, pay attention that the muscles of the pelvic floor are contracted and the muscles of other parts of the pelvis are relaxed. During the research, the examiner communicates with the mother two days a week through social networks and phone calls.

Category
Rehabilitation

2

Description
Control group: This group will be given the usual recommendations for care during this period and pelvic floor strengthening exercises in the form of pamphlets.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi Hospital

Full name of responsible person
Parisa Ghadiri Harati

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Safaieh, Shahid Ghandi Blvd., Sayad Shirazi St., Shahid Sadoughi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Seyedeh Sedigheh Sadat Naeimi

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parisa Ghadiri Harati

Position
Phd Candidate

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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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
Information about outcomes can be shared.

When the data will become available and for how long
one week

To whom data/document is available
All researchers and students can access these data.

Under which criteria data/document could be used
All researchers and students can access these data.

From where data/document is obtainable
Applicants can send their request to ghadiri.pt93@gmail.com to receive documents or data.

What processes are involved for a request to access data/document
Documents and data files can be accessed at the request of the applicant via email to ghadiri.pt93@gmaail.com.

Comments