Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Design
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; age: 20-30 years old; presence of Gestational Diabetes Mellitus

Intervention groups
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). Diabetic control: A pamphlet regarding PFM training will be given.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160601028203N3**
Registration date: **2023-04-05, 1402/01/16**
Registration timing: **prospective**

Last update: **2023-04-05, 1402/01/16**
Update count: **0**

Registration date
2023-04-05, 1402/01/16

Registrant information

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Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Pelvic Floor Muscle Training in 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 Gestational diabetes mellitus

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

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Province

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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

N39.3

ICD-10 code description

Stress incontinence (female) (male)

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)

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)

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

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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