

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of pelvic floor physiotherapy (exercise therapy and biofeedback) with weight loss protocol in the treatment of some clinical signs of obese women with urinary incontinence

Protocol summary

Study aim

Determining the effect of pelvic floor exercise and biofeedback with weight loss on quality of life score, severity of urinary incontinence, and pelvic floor muscle performance in obese women with urinary incontinence

Design

Clinical trial With control group Single Blind With parallel groups Non-random assignment

Settings and conduct

A study is conducted at the Physiotherapy Clinic in Iran University Medical Sciences. Obese women with urinary incontinence are divided into treatment and control groups. The implementation of pelvic floor exercises in clinic and at home is the same in both groups, and the difference in the treatment group is only in the weight loss protocol. An initial assessment is done at the first session and the final evaluation is done in the final session. The distribution of patients will be done according to the order of their referral. Evaluator and data analyzer will be blind to treatment type in groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: married women with a body mass index of 30-55 kg/m²; The presence of urinary incontinence at least once a week; Exclusion criteria: genitourinary infection; Pregnancy or delivery history in the last 6 months

Intervention groups

Intervention group: The entire course of treatment is 3 months, and pelvic floor exercises are performed once a week in the clinic (by biofeedback device for 30 to 45 minutes) and also daily at home. The weight loss protocol is performed by the patient with recommendations from the therapist for weight loss of about 700 grams per week. Control group: The same as the treatment group, pelvic floor exercises are performed daily at home. Biofeedback exercises are also done once a week at the clinic. This group does not

receive any weight loss protocol.

Main outcome variables

The severity of urinary incontinence; Quality of life; pelvic floor muscles function; Weight; Body mass index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140202016455N2**

Registration date: **2018-11-03, 1397/08/12**

Registration timing: **retrospective**

Last update: **2018-11-03, 1397/08/12**

Update count: **0**

Registration date

2018-11-03, 1397/08/12

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 22228051

Email address

vasaghi.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

2016-04-08, 1395/01/20

Actual recruitment end date

2017-01-14, 1395/10/25

Trial completion date

2017-04-19, 1396/01/30

Scientific title

The effect of pelvic floor physiotherapy (exercise therapy and biofeedback) with weight loss protocol in the treatment of some clinical signs of obese women with urinary incontinence

Public title

The effect of pelvic floor physiotherapy on the treatment of urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women Aged 25 to 65 Body mass index of 30-55 kg/m² The presence of real urinary incontinence at least once a week

Exclusion criteria:

Genitourinary infection Pregnancy or delivery history in the last 6 months History of surgery for urinary incontinence or any type of surgery in the pelvic region and the urogenital area Neurological urinary incontinence Functional urinary incontinence Coronary artery disease Uncontrolled hypertension

AgeFrom **25 years** old to **65 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **60**Actual sample size reached: **52****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

In this study, evaluator, Clinical care and data analyzer were blinded to treatment type in groups. The evaluator evaluated only the patients whom the researcher introduced to her in terms of the criteria of the study and there was no Information about type of treatment who receive. In order to ensure that the evaluator was not informed, the clinical attendant was present at the site and monitored how the evaluator contacted (in order not to be aware of the type of treatment received). Clinical care was only familiar with the patient's name and was completely blind for the type of treatment she received. Due to the patient's coding, The data analyzer also did not have any information about assigning codes to the patients and the type of treatment received by each

person.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University Medical Science

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Iran University of Medical Sciences, Hemmat Highway, Tehran

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Approval date

2015-12-27, 1394/10/06

Ethics committee reference number

IR.IUMS.REC.1394.9311340001

Health conditions studied**1****Description of health condition studied**

Urinary Incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

Primary outcomes**1****Description**

The severity of urinary incontinence

Timepoint

At the beginning and Immediately after treatment at the end of the 12th session

Method of measurement

International consultation on incontinence questionnaire -short form

2**Description**

Quality of life

Timepoint

At the beginning and Immediately after treatment at the

end of the 12th session
Method of measurement
Incontinence quality of life questionnaire

3

Description
Strength of pelvic floor muscles
Timepoint
At the beginning and Immediately after treatment at the end of the 12th session
Method of measurement
Standard prineometer, Oxford modified scale

4

Description
Weight
Timepoint
At the beginning and Immediately after treatment at the end of the 12th session
Method of measurement
Standard scale

5

Description
Body Mass Index
Timepoint
At the beginning and Immediately after treatment at the end of the 12th session
Method of measurement
Standard Scale, Standard Strip meter

6

Description
Pelvic floor muscles endurance
Timepoint
At the beginning and Immediately after treatment at the end of the 12th session
Method of measurement
Standard prineometer, Oxford modified scale

Secondary outcomes

1

Description
Waist circumference
Timepoint
Before and after treatment
Method of measurement
Strip meter

2

Description
Hip circumference
Timepoint
Before and after treatment
Method of measurement
Strip meter

3

Description
Neck circumference
Timepoint
Before and after treatment
Method of measurement
Strip meter

4

Description
Waist to hip ratio
Timepoint
Before and after treatment
Method of measurement
Strip meter

5

Description
Waist to height ratio
Timepoint
Before and after treatment
Method of measurement
Strip meter

Intervention groups

1

Description
Intervention group: In addition to biofeedback therapy (Enraf, build the Netherlands) and pelvic floor exercises, which included modified Kegel and knack exercises, the intervention group received weight loss treatment. The weight loss program was performed by the patient himself on the advice of the therapist. The proposed diet was scheduled to be based on the advice of physicians for weight loss of about 700 grams per week. Pelvic floor exercises performed regularly and daily at home. Exercises should be performed three times a day at home so that each time it contains 2 repetitions and each repetition has 10 contractions. Between each contraction requires a few seconds of rest (according to the progress of the therapeutic sessions), and also between the repetitions we need for two minutes of rest. The exercises are in a variety of situations, lying, sitting, and standing up to progress during performance. Exercise for fast fibers was performed three times a day at home. From the third week of training, knack training also began. The exercise with biofeedback started from the second week and was performed once a week at the clinic. Biofeedback training started in short time (3 sec contraction and 8 second rest) and total duration of 10 minutes, and gradually began to contraction and rest for 10 seconds for a total of 20 minutes. The practice with the ball and tilt board was also started from the 9th session. The total treatment time is about 30 to 45 minutes and the entire treatment period is three months.
Category
Rehabilitation

2

Description

Control group: The control group received only pelvic floor exercises and biofeedback therapy (Enraf, build the Netherlands). the following protocol was selected for exercises at home: Exercises should be performed three times a day at home so that each time it contains 2 repetitions and each repetition has 10 contractions. Between each contraction requires a few seconds of rest (according to the progress of the therapeutic sessions), and also between the repetitions we need for two minutes of rest. The exercises are in a variety of situations, lying, sitting, and standing up to progress during performance. Exercise for fast fibers was performed three times a day at home. From the third week of training, knack training also began. The exercise with biofeedback started from the second week and was performed once a week at the clinic. Biofeedback training started in short time (3 sec contraction and 8 second rest) and total duration of 10 minutes, and gradually began to contraction and rest for 10 seconds for a total of 20 minutes. The practice with the ball and tilt board was also started from the 9th session. The total treatment time is about 30 to 45 minutes and the entire treatment period is three months.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Dr.Abdoreza Pazouki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Behnoosh Vasaghi Gharamaleki

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Latest degree

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable