Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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/m 2; 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/m 2 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
Age
From **25 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target 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
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
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 Incontinece
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 the12th 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 perfomed 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

Street address
Rasool Akram hospital, Niayesh St, Sattarkhan St

City
Tehran

Province
Tehran

Postal code
۱۴۴۵۶۱۳۱۳۱

Phone
+98 21 6653 5447

Email
Apazouki@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
DR. Seyed Kazem Malakooti

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 86701

Email
Malakoutik@yahoo.com

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

Street address
Madadkaran St, Shahnazari St, Mirdamad St

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ - ۱۵۴۵۹

Phone
+98 21 2222 8051

Email
Bvasaghi@gmail.com

Person responsible for scientific 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

Street address
Madadkaran St, Shahnazari St, Mirdamad St

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ - ۱۵۴۵۹

Phone
+98 21 2222 8051

Email
Bvasaghi@gmail.com

Person responsible for updating data

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

Street address
Madadkaran St, Shahnazari St, Mirdamad St

City
Tehran

Province
Tehran

Postal code
۱۳۴۸۷ - ۱۵۴۵۹

Phone
+98 21 2222 8051

Email
Bvasaghi@gmail.com

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