Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of trunk stabilization training versus pelvic floor muscle training on the ultrasonography indices, clinical indices and quality of life in women with stress urinary incontinence: A Randomized Controlled Trial

Protocol summary

Study aim

Comparison of the effect of exercise therapy based on trunk stabilizing muscles and pelvic floor muscle exercise therapy on ultrasound, clinical and quality of life indicators in women with stress urinary incontinence

Design

It is a randomized controlled clinical trial study, single-blind, with parallel design. In this study, 46 women with stress urinary incontinence will randomly divided into experimental and control groups.

Settings and conduct

This study will be conducted in Ahvaz Jundishapur University of Medical Sciences. The women with stress urinary incontinence will enter the study, through a simple sampling method, by referrals from urologists or gynecologists. All participants sign an informed consent form to take part in this study. The participants will be randomly divided into experimental (n = 23) and control (n = 23) groups. Participants will be assessed at all international classification of functioning (ICF) levels before and after 8 weeks of interventions.

Participants/Inclusion and exclusion criteria

The inclusion criteria are women with age between 20 and 55 years old, with experiencing stress urinary incontinence symptoms at least once during the past month. The exclusion criteria are pregnancy, history of systemic or neuromuscular disease or neurological disease, concomitant treatment for urinary incontinence or low back pain, urinary tract infection, severe low back pain or pelvic pain, and episiotomy.

Intervention groups

The intervention group, performs trunk stabilizing muscles exercise (include; diaphragm, pelvic floor and deep abdominal). The control group performs pure contraction of the pelvic floor muscles. In both groups, the exercises performs daily for 8 weeks.

Main outcome variables

Bladder base displacement, voiding diary, pelvic floor muscle strength, severity of urinary incontinence, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200710048069N1**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date

2020-09-01, 1399/06/11

Registrant information

Name

Maedeh Fani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3627 8341

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-31, 1399/05/10

Expected recruitment end date

2020-11-30, 1399/09/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of trunk stabilization training versus pelvic floor muscle training on the ultrasonography indices, clinical indices and quality of life in women with stress urinary incontinence: A Randomized Controlled Trial

Public title
The effect of exercise therapy of trunk stabilizing muscles in women with stress urinary incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women between the ages of 20 and 55 years old. Women who have experienced stress urinary incontinence at least once in the past month during activities that increase intra-abdominal pressure, such as coughing and sneezing.
Exclusion criteria:
Pregnancy History of episiotomy History of systemic or neuromuscular or neurological disease History of surgery or recent rehabilitation for urinary incontinence Hysterectomy Concomitant treatment for urinary incontinence or low back pain Urinary tract infection Medications that exacerbate or alleviate the symptoms of urinary incontinence Severe low back pain or pelvic pain
Age
From **20 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
The random sequence generation will be via restricted randomization (permuted block randomization) with random block size (block size: 2, 4, 6). Thus, participants in this study will be randomly assigned to one of the two control or experimental groups. The online randomization method (www.sealedenvelope.com) will be used to generate a random sequence. For allocation concealment, sequentially numbered, sealed, opaque envelopes will be used. This will be done with the help of someone who has no role in the research process. Based on the order of entry of eligible participants in the study, selected by gynecologists and urologists, one of the envelopes will be opened in order and the group allocation to that participant will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
The evaluator will not know about the group allocation of the participants in this study. Only the participants and the physical therapist involved in the training will know the group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Research Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan street
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Ahvaz
Province
Khouzestan
Postal code
6135733133
Approval date
2018-12-09, 1397/09/18
Ethics committee reference number
IR.AJUMS.REC.1397.669

Health conditions studied

1

Description of health condition studied
stress urinary incontinence
ICD-10 code
N39.3
ICD-10 code description
Stress incontinence (female) (male)

Primary outcomes

1

Description
Bladder base displacement
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Trans-abdominal sonography

2

Description
Voiding diary
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Voiding diary

3

Description
Pelvic floor muscle strength
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Axford scale

4

Description
Severity of urinary incontinence
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Severity index

5

Description
Quality of life
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group, will perform the exercise program based on Sapsford's design in the 5 steps. These include: 1. diaphragmatic breathing exercise (in supine, sitting and standing positions), 2. tonic activation of the transverse abdominal muscle and pelvic floor muscles (in standing position), 3. strengthening of the transverse abdominal, pelvic floor muscles and internal oblique muscles (in standing position), 4. Functional expiratory patterns such as coughing and sneezing (in standing position), and 5. tonic contraction of the transverse abdominal and pelvic floor muscles during strenuous activity such as running and jumping.The exercises will perform 1-2 times a day for 8 weeks.
Category
Rehabilitation

2

Description
The control group will perform the exercise protocol included sub-maximal and maximal contraction of pelvic floor muscles. The participants will instruct to contract pelvic floor muscles in isolation and to prevent other muscles contraction, such as the hip and abdominal muscles. To perform the sub-maximal contraction, the participants should keep the pelvic floor muscles contraction as long as possible with moderate intensity. The exercises would be performed 1-2 times a day, with 8-12 repetitions and for 8 weeks. To perform maximum pelvic floor muscles contraction, the participants would keep the pelvic floor muscles at maximum contraction for 4-5 seconds. The contractions will perform 1-2 times a day with 8 repetitions, for 8 weeks. The position of exercise are supine and then will progress to sitting and standing positions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Jundishapur University of Medical Sciences,
Full name of responsible person
Shahin Goharpey
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Shahin Goharpey
Position
Associated professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

Contact

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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

outcome measurements 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 this data.

Under which criteria data/document could be used

All researchers and students can access this data.

From where data/document is obtainable

Applicants can send their request to maedeh.fani@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 by sending email to maedeh.fani@gmaail.com.

Comments