

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 31 3627 8341

##### Email address

maedeh.fani@gmail.com

##### 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](http://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

**City**

Ahvaz

**Province**

Khuzestan

**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

#### **Street address**

Department of physical therapy, Faculty of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan street

#### **City**

Ahvaz

#### **Province**

Khuzestan

#### **Postal code**

6135733133

#### **Phone**

+98 61 3374 3102

#### **Email**

shgoharpey@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Ahvaz University of Medical Sciences

#### **Full name of responsible person**

Mohammad Badavi

#### **Street address**

Faculty of Medicine, Ahvaz Jundishapur University of Medical sciences, Golestan street

#### **City**

Ahvaz

#### **Province**

Khuzestan

**Postal code**

۶۱۳۵۷۳۳۱۳۳

**Phone**

+98 61 3374 3102

**Email**

badavim@yahoo.com

**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

**Street address**

Department of physical therapy, Faculty of rehabilitation sciences, Ahvaz Jundishapur University of Medical sciences, Golestan street

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

+98 61 3374 3102

**Email**

shgoharpey@yahoo.com

**Person responsible for scientific 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

**Street address**

Department of physical therapy, Faculty of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical sciences, Golestan street

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

+98 61 3374 3102

**Email**

shgoharpey@yahoo.com

**Person responsible for updating data****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**

musculoskeletal disorder

**Street address**

Department of physical therapy, Faculty of rehabilitation sciences, Ahvaz Jundishapur University of Medical Sciences, Golestan street

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135733133

**Phone**

+98 61 3374 3102

**Email**

shgoharpey@yahoo.com

**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@gmail.com.

**Comments**