

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### A comparative study of whole body vibration training and exercise therapy in treating females stress urinary incontinence

#### Protocol summary

2012-01-28, 1390/11/08

#### Summary

The main purpose of this study was to compare the effect of pelvic floor muscle exercises and vibration therapy in control of SUI. The study is an assessor blind randomized clinical parallel group trial which is approved by the Ethical Committee of Tehran University of Medical Sciences and each subject will sign informed written consent. The patients with stress incontinence that fulfill the inclusion criteria will be examined by gynecologist and after that will be introduced to sports medicine clinics. Participants will be randomly allocated in two treatment groups; vibration therapy (WBVT) and exercise therapy (ET). Participants will be familiarized with testing procedures at the first session and also the research questionnaire and IQOL questionnaire will be completed. The pelvic floor muscle contraction will be tested and graded according to the modified Oxford grading system, also pelvic floor muscle dynamic and static endurance tests will be evaluated. All subjects in ET group will follow a definite exercise therapy program under supervision for 4 weeks. The WBVT group will do exercises on vibration platform (Powerplate, USA) for 4 weeks. Subjects will be evaluated pre and post interventions for outcomes (decreasing of UI symptoms, increasing pelvic floor muscle strengths and endurance, quality of their life

#### Registrant information

##### Name

Azar Moezy

##### Name of organization / entity

Iran university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6435 2446

##### Email address

moeziazr@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2011-02-20, 1389/12/01

#### Expected recruitment end date

2012-09-22, 1391/07/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparative study of whole body vibration training and exercise therapy in treating females stress urinary incontinence

#### Public title

A comparative study of whole body vibration training and exercise therapy in treating females stress urinary incontinence

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

#### General information

##### Acronym

WBVT & Exercise therapy - SUI

##### IRCT registration information

IRCT registration number: **IRCT201012285486N1**

Registration date: **2012-01-28, 1390/11/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

Inclusion criteria: the development of genuine stress incontinence based on patient history, medical examination, a cotton-swab test urine culture; not being pregnant, breast feeding and menopause; age between 35 to 50 years; no history of exercise therapy for SUI in past 3 months; lack of neurological diseases such as MS, CVA, Spina bifida; no risk factor for pelvic visceral prolapse and outlet obstruction and detrusor instability; no high residual urine volume; no outlet obstruction and chronic constipation; lack of chronic disease, chronic respiratory disease; no contraindications for Vibration therapy and exercise therapy; no history of surgical treatment for incontinence; no history of pelvic cancers; no history of taking drugs that affect the urine; an read and write; Exclusion criteria: unwillingness of the patient for continuing the treatment sessions; pregnancy and diseases that may impede participation in the study; absence of patients in treatment sessions and genital and urinary infection;

**Age**

From **35 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of vice chancellor for research  
,Tehran University of Medical Sciences

**Street address**

Keshavarz Bluv

**City**

Tehran

**Postal code****Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

8521 22/10/89 مورخ

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

Stress Urinary incontinence

**ICD-10 code**

N39.3

**ICD-10 code description**

Stress incontinence

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

Urinary Incontinence

**Timepoint**

Before and after the intervention

**Method of measurement**

Assesment and examination

**2****Description**

IQOL Questionnaire

**Timepoint**

Before and after the intervention

**Method of measurement**

IQOL Questionnaire score

**Secondary outcomes****1****Description**

Pelvic floor muscle strength

**Timepoint**

Before and after the intervention

**Method of measurement**

The pelvic floor muscle strength and endurance with  
Manual Muscle Testing and completed questionair

**Intervention groups****1****Description**

Pelvic floor muscles strengthening exercises in the  
exercise therapy group

**Category**

Rehabilitation

**2****Description**

Whole body vibration training in WBVT group

**Category**

Rehabilitation

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid Akbarabady hospital and Hazrat rasol akram hospital ,sport medicine clinic

**Full name of responsible person**

Dr azizeh farzinmehr

**Street address**

Neyaesh Street

**City**

Tehran

PhD - assistant prof.

**Other areas of specialty/work****Street address**

Sports Medicine department -Medical School- Tehran university of medical sciences -Hemat Highway -

**City**

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**Postal code****Phone**

+98 21 8294 3424

**Fax****Email**

Moeziarz@sina.tums.ac.ir

**Web page address**

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research Tehran university of medical sciences

**Full name of responsible person**

Ms Alamdar

**Street address**

Keshvarz Bluv

**City**

Tehran

**Grant name**

معاونت پژوهشی دانشگاه علوم پزشکی تهران

**Grant code / Reference number**

90-01-30-12331

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research Tehran university of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Tehran university of medical sciences

**Full name of responsible person**

Dr Azar Moezy

**Position**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

TUMS

**Full name of responsible person**

Dr Azar Moezy

**Position**

phD

**Other areas of specialty/work****Street address**

Sports Medicine department -Medical School- Tehran university of medical sciences -Hemat Highway

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## Person responsible for updating data

**Contact**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*