

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of pelvic floor muscle exercise training on urinary incontinence and quality of life in patients with multiple sclerosis

#### Protocol summary

##### Summary

Objective: Determine the effect of pelvic floor muscle training for urinary incontinence and quality of life in patients with multiple sclerosis. Design: This study is a clinical trial, quasi-experimental , before and after. How to do: The study included 50 male and female patients with multiple sclerosis MS clinic of Imam Khomeini Hospital in Tehran that the patient will be done after obtaining written consent. Sampling methods are available . Before the intervention, demographic questionnaire , urinary incontinence, quality of life and Depression, Anxiety and Stress will be completed . Patients in relation to the pelvic floor muscles will be trained by the researcher . The exercises 3 times a day for 12 consecutive weeks will be patient at first contraction for 3 seconds and subsequent 5 seconds sleep then gradually term contractions increase and the number of contractions to 90 to 100 contractions per day will brings. Educational pamphlets regarding urinary incontinence and pelvic floor muscle training in multiple sclerosis and its Czech list report will be given to patients . Patient questionnaires for urinary incontinence and quality of life will be complete by the end of the third month. During the study, researcher will attend one day a week at the MS Clinic and per week in the first month, the second month and the third month following the end of the telephone with the patient will be contacted.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014010416063N1**

Registration date: **2014-03-25, 1393/01/05**

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

Last update:

Update count: **0**

##### Registration date

2014-03-25, 1393/01/05

##### Registrant information

###### Name

Habib Shareinia

###### Name of organization / entity

Gonabad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 53 3722 9878

###### Email address

h-shareinia@razi.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2014-02-17, 1392/11/28

##### Expected recruitment end date

2014-07-21, 1393/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of pelvic floor muscle exercise training on urinary incontinence and quality of life in patients with multiple sclerosis

##### Public title

The effect of pelvic floor muscle exercises on urinary incontinence and quality of life in patients with multiple sclerosis

##### Purpose

Health service research

## Inclusion/Exclusion criteria

Inclusion criteria: The risk of urinary incontinence due to multiple sclerosis according to the neurologist diagnosed , having a degree of disability (EDSS: Expanded disability status scale) is less than 7 according to the diagnosis of neurologist, literacy , age 50-18 years , no severe cognitive problems , lack of patient suffering from the disease attacks during the past three months , the patient is not pregnant, the unchanged drug effects on urinary incontinence if you take a month before the study , no use of diuretics and antihypertensive drugs , lack of chronic heart and lung disease , no menopause , no urinary tract infection , history of diabetes , history of prostate and gynecologic surgery , no history of cesarean section or vaginal delivery during the last six months .

Exclusion criteria : Unwillingness to continue participation in the study for any reason, an acute medical condition during the study, to develop an acute attack of the disease, having an excessive fatigue so that the patient can not exercise and the patients drugs affecting urinary incontinence it is changed during the study.

### Age

From **18 years** old to **50 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd

##### City

Tehran

##### Postal code

##### Approval date

2014-02-17, 1392/11/28

### Ethics committee reference number

130/2715/92/s

## 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

Urinary incontinence

#### Timepoint

Before training and after three months of training

#### Method of measurement

Questionnaire ICIQ-UI SF

## Secondary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before training and after three months of training

#### Method of measurement

Questionnaire Qualiveen

### 2

#### Description

Stress, Anxiety and Depression

#### Timepoint

Before training and three months After training

#### Method of measurement

Questionnaire DASS-21

## Intervention groups

### 1

#### Description

Patients in relation to the pelvic floor muscles will be trained by the researcher. The exercise consists of a series of pelvic floor muscle contractions in different modes, including lying on his back with knees bent, sitting and standing which patients will be advised at the beginning of the contraction for 3 seconds, followed by 5 seconds of rest have done and duration of contractions gradually increased to reach 10 seconds. The exercises 3 times a day for 12 consecutive weeks and will increase gradually until contractions reached 90 to 100

contractions per day.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

MS clinic of Imam Khomeini Hospital in Tehran

**Full name of responsible person**

Habib Shareinia

**Street address**

Imam Khomeini Hospital, Dr Mirkhani St, Tohid Sq

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Research Council of Tehran University of Medical Sciences

**Full name of responsible person**

Doctor Masood Younesian - Vice President of Research and Technology

**Street address**

Keshavarz St, Qods St., Central Building, Sixth Floor, Tehran University of Medical Sciences, Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Council of 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**

Habib Shareinia

**Position**

Nursing Graduate Student

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

School of Nursing and Midwifery Tehran University of Medical Sciences, Dr Mirkhani St, Tohid Sq Tehran

**City**

Tehran

**Postal code****Phone**

+98 21 6692 7171

**Fax****Email**

shareinia.msn@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Doctor Forough Rafii

**Position**

PhD in Nursing-Associate Professor

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

School of Nursing and Midwifery Iran University of Medical Sciences, Vali Asr St, Vanak Sq , Rashid Yasami St

**City**

Tehran

**Postal code****Phone**

+98 21 8888 2886

**Fax****Email**

foroughrafii@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Habib Shareinia

**Position**

Nursing Graduate Student

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

School of Nursing and Midwifery Tehran University of Medical Sciences, Dr Mirkhani St, Tohid Sq Tehran

**City**

Tehran

**Postal code****Phone**

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**Fax****Email**

shareinia.msn@gmail.com

**Web page address**

## **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*