Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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/د

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

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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

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Person responsible for scientific inquiries

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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