

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of pelvic floor muscle exercises therapy on the fatigue and quality of life in women with multiple sclerosis suffering from urinary disorders

Protocol summary

Study aim

To estimate the effect of pelvic floor muscles exercise therapy program on fatigue and quality of life in women with urinary disorders due to multiple sclerosis.

Design

This study is an experimental and single-blind clinical trial with parallel groups. In this study, available participations will include based on inclusion criteria and as absolute random will be divided into two groups using sealed envelopes according to the EDSS and type of urinary tract disorder.

Settings and conduct

the intervention is performed in the school of Rehabilitation Sciences of Iran University of Medical Sciences. In this study, both the assessor and the data analyzer are blind.

Participants/Inclusion and exclusion criteria

inclusion criteria: Women whose MS diagnosis has been confirmed by a neurologist and aged 18-50 years. Women with urinary disorders and "overactive bladder score" equal or more than 8, have relapse and remitting type of MS and have no new attack within the last 3 months. Additionally, dosage of the urinary medications remain unchanged within the last 3 months and having the "Expanded Disability Status Scale" score less than 7 based on the physician diagnosis. exclusion criteria: Individuals will exclude if they have the "Mini-Mental State Examination Test" score below 18, be pregnant or have the urinary tract infection.

Intervention groups

At first, the specific pelvic floor exercise therapy, along with informing people of the pelvic floor muscles, are performed for intervention group. These exercises will be done at home by participant for two months. Sequence of exercises are: warm up, main exercises and cool down. The control group, based on physician prescription, will receive urinary medications.

Main outcome variables

In this study, the Fatigue is the main outcome variable.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140222016680N7**

Registration date: **2020-04-13, 1399/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-13, 1399/01/25**

Update count: **0**

Registration date

2020-04-13, 1399/01/25

Registrant information

Name

Shohreh Noorizadeh Dehkordi

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of pelvic floor muscle exercises therapy on the fatigue and quality of life in women with multiple sclerosis suffering from urinary disorders

Public title
The effect of pelvic floor muscle exercises therapy program on the fatigue and quality of life in women with multiple sclerosis suffering from urinary disorders

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women whose MS diagnosis has been confirmed by a neurologist. Women with age range between 18-50 years. Women with urinary disorders and "overactive bladder" score equal or above 8 Women with relapse and remitting type of MS and they have not had a new attack within the last three months. Women whose dosage of the urinary medications remains unchanged within the last three months. Women who have an "Extended Disability Status Scale" score below 7 based on physician diagnosis.
Exclusion criteria:
1. Individuals who have "Mini-Mental State Examination" score below 18 2. Women who are pregnant. 3. Women who have urinary tract infection.

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

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
People as absolute random will be divided into two groups using random sealed envelopes. They will be selected randomly by a person who is unaware of the groups. Random blocks (permuted block randomization) with four blocks will be used for randomization. According to the sample size of 30, eight blocks will be generated using the online site (www.sealedenvelope.com). For concealment in the randomization process, unique code will be used on each envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description

In this study, Assessor who evaluates the outcome measures of study will be blind to the allocation of the two treatment groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

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ran University of Medical Sciences, Hemmat Expressway, Tehran, Iran

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۱۴۴۹۶۱۴۵۳۵

Approval date

2019-12-28, 1398/10/07

Ethics committee reference number

IR.IUMS.REC.1398.1007

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

The amount of fatigue

Timepoint

Measurement of fatigue before and immediately after intervention and one months after intervention

Method of measurement

by using the Modified fatigue impact scale questionnaire

Secondary outcomes

1

Description

quality of life

Timepoint

To measure quality of life before and immediately after intervention and one months after intervention

Method of measurement

by using the Qualiveen-30 questionnaire-short form

Intervention groups

1

Description

intervention group: This group only perform pelvic floor exercises at home once a day for two months.

Category

Rehabilitation

2

Description

Control group: They receive medication based on physician prescription to control their urinary disorder.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram Hospital

Full name of responsible person

Shohreh Noorizadeh Dehkordi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Cancellor for Research of Iran University of Medical Sciences

Full name of responsible person

Seyyed Abbas Motevalian

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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

Vice Cancellor for Research of Iran 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

Iran University of Medical Sciences

Full name of responsible person

Shohreh Noorizadeh Dehkordi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available