Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 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 and 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

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Iran (Islamic Republic of)

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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

Street address

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 recieve 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

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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

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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