Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of pelvic floor muscle training and breathing exercise on pelvic floor muscle activity, diaphragm activity, and urinary symptoms in patients with multiple sclerosis

Protocol summary

Study aim

Investigating the effect of PFM exercise and breathing exercises on PFM activity, diaphragm muscle activity, and urinary symptoms in MS patients with urinary disorders.

Design

Randomized controlled trial, with a factorial design on 50 patients. Randomization is done using the Randomization website.

Settings and conduct

Patients with relapsing-remitting MS are included in the study, taking into account the inclusion and exclusion criteria and being eligible after diagnosis by a specialist doctor. Then participants will be given a consent form and personal information. Patients are divided into two groups. The participants in the control group perform PFM exercises and participants in the intervention group perform breathing exercises along with the PFM exercises. All evaluations and exercises will be done in the laboratory of the Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran

Participants/Inclusion and exclusion criteria

Diagnosis of relapsing-remitting MS disease; Absence of cardiovascular diseases, kidney diseases, rheumatism, visceral diseases, other neurological diseases (other than MS); malignancies and infections; Absence of pregnancy or history Giving birth in the last 6 months; Not having a history of surgery to treat urinary incontinence; Absence of prolapse of pelvic organs with severity higher than 2

Intervention groups

Intervention group: the group receiving PFM exercises along with breathing exercises for 8 weeks and 4 days a week Control group: the group receiving PFM exercises for 8 weeks and 4 days a week

Main outcome variables

Urinary incontinence diagnosed by a physician; PFM function: bladder base displacement measured by ultrasound imaging; displacement: using diagnostic ultrasound; Diaphragm muscle function: Diaphragm displacement and thickness will be investigated by ultrasound.

General information

Reason for update

Acronym

EDSS: Expand Disability Status Scale; ICIQSF: Incontinence Questionnaire Short Form; MMSE: Mini-Mental State Examination; MS: Multiple Sclerosis; PFM: pelvic floor muscle; RCT: Randomized controlled trial

IRCT registration information

IRCT registration number: **IRCT20180916041051N3**
Registration date: **2024-05-23, 1403/03/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-23, 1403/03/03**
Update count: **0**

Registration date

2024-05-23, 1403/03/03

Registrant information

Name

Shabnam Shahali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 8769

Email address

shahali.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01
Expected recruitment end date
2025-11-22, 1404/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of pelvic floor muscle training and breathing exercise on pelvic floor muscle activity, diaphragm activity, and urinary symptoms in patients with multiple sclerosis

Public title
Effectiveness of pelvic floor exercises and breathing exercises on urinary disorders of people with multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18to50 years Diagnosis of relapsing-remitting MS disease MMSE scale score greater than 24 EDSS scale score less than 3.5 Not suffering from cardiovascular diseases, kidney diseases, rheumatism, visceral diseases, other neurological diseases (other than MS), malignancies and infections No pregnancy or history of childbirth in the last 6 months Not having a history of surgery to treat urinary incontinence Absence of prolapse of pelvic organs with intensity higher than 2 Not having a score of 19-21 from the ICIQ-SF questionnaire Not having a history of MS relapse in the last 3 month Ability to understand and write concepts and information Not having chronic obstructive pulmonary disease, bronchitis and tuberculosis Absence of MS plaques in the medulla (due to the presence of respiratory control areas) Body mass index (BMI) below 30
Exclusion criteria:
The patient's unwillingness to participate in 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)
Randomized
Randomization description
Randomization is done using the Randomization website. Both groups will be matched in terms of demographic characteristics. They will be randomly divided into two treatment groups with a ratio of 1:1. Random allocation is done by the variable block method, which includes 4-letter blocks, made of letters A and B. The obtained treatment allocation is placed in sealed and numbered envelopes in the form of letters A and B. This process is done by someone outside the research team before the start of the study. After the initial evaluations by the examiner, the numbered envelopes are presented to him according to the sequential number of each person entered into the study, and the therapeutic intervention is adjusted based on the letters inside the envelope. The examiner is unaware of the letters inside the envelope.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial
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
Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2024-04-14, 1403/01/26
Ethics committee reference number
IR.IUMS.REC.1403.027

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of urinary incontinence
Timepoint
It is checked at the beginning of the study (before the intervention) and the last session

Method of measurement
ICIQSF questionnaire

Secondary outcomes

1

Description
PFM function
Timepoint
It is checked at the beginning of the study (before the intervention) and the last session
Method of measurement
It is measured by ultrasound imaging

2

Description
Diaphragm muscle function
Timepoint
It is checked at the beginning of the study (before the intervention) and the last session
Method of measurement
It is measured by ultrasound imaging

Intervention groups

1

Description
Intervention group: Receiving breathing exercises and PFM exercises. Breathing exercises will be done using the Power Breathe classic device (POWERbreathe International Ltd, England). This device strengthens the respiratory muscles by creating appropriate pressure (10-15 mmHg). Participants will use this device while doing PFM exercises at the same time. Participants will do exercises 4 days a week for 8 weeks (24 sessions) under the supervision of a physiotherapist.
Category
Rehabilitation

2

Description
Control group: Receiving PFM exercises. Exercises will be done in supine, sitting, quadruped, standing, and walking. The participant is asked to contract the PFM and hold each contraction for 5-10 seconds. Exercises will be performed three times daily (morning, evening, and night) with 8-10 repetitions in each exercise set. Participants will do exercises 4 days a week for 8 weeks (24 sessions) under the supervision of a physiotherapist.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
دانشکده ی توانبخشی دانشگاه علوم پزشکی ایران
Full name of responsible person
شبنم شاه علی
Street address
Madder Square, Maddkaran St., Faculty of Rehabilitation, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۵۴۵۹۱۳۴۸۷
Phone
+98 21 2226 9608
Email
shabnamshahali@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
رضا فلک
Street address
Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
Falak.r@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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

شبنم شاه علی

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Madder Square, Maddkaran St., Faculty of Rehabilitation, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۵۴۵۹۱۳۴۸۷

Phone

+98 21 2222 8051

Email

shabnamshahali@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

هلاکو محسنی فر

Position

Assistance Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Madder Square, Maddkaran St., Faculty of Rehabilitation, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۵۶۸۶۴۸۵۱۱

Phone

+98 21 2222 8051

Email

Mohsenifarpt@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shabnam Shahali

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Madder Square, Maddkaran St., Faculty of Rehabilitation, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۵۶۸۶۴۸۵۱۱

Phone

+98 21 2222 8051

Email

shabnamshahali@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data related to the main outcomes are shared

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use of the data can be done for further research work in the future.

From where data/document is obtainable

Iran University of Medical Sciences, Faculty of Rehabilitation, Madadkaran St., Madar Square, Tehran. Postal code: 1545913487. shabnamshahali@yahoo.com

What processes are involved for a request to access data/document

First, the person sends a message to the given email, after that the information is provided to the person by considering the job of the person who is working in the university and seeing the articles of the person who is identified as a researcher.

Comments