Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The effect of dynamic neuromuscular stabilization exercises on overactive bladder and quality of life in women with multiple sclerosis

Protocol summary

Study aim
The effect of dynamic stabilization exercises on emergency urinary incontinence and quality of life in patients with multiple sclerosis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized

Settings and conduct
Women with a diagnosis of multiple sclerosis (by a neurologist) who have urinary incontinence are referred to the physiotherapy department of Kashani Hospital for inclusion in the study.Patients are then randomly assigned to two groups. Patients do not know which group they or other patients belong to.One group receives Kegel exercises and the other group receives dynamic neuromuscular stabilization exercises.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women between the ages of 18 and 55 with a diagnosis of multiple sclerosis whose disease status is stable. Exclusion criteria: other neurological diseases.

Intervention groups
Intervention group: Receive dynamic neuromuscular stabilization exercises. These exercises are performed in different positions that are actually modeled on the positions of the growing baby. In each training session, 3 different situations are taught. Each exercise is maintained 3 times for 10 seconds and the patient is given 10 seconds of rest between each. Control group: Receive Kegel exercises. This exercise involves the patient contracting the pelvic floor muscles under the supervision of a therapist. In each session, moderate and intense exercises are performed. Moderate-intensity exercise lasts between 6 and 10 seconds, and high-intensity exercise lasts between 1 and 3 seconds. The rest period between two contractions lasts between 1 and 12 seconds. Both groups go to physiotherapy for 6 weeks and twice a week for training and exercises under the supervision of a physiotherapist.

Main outcome variables
Pelvic floor muscle strength, urinary incontinence and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200101045970N6**
Registration date: **2022-05-29, 1401/03/08**
Registration timing: **prospective**

Last update: **2022-05-29, 1401/03/08**
Update count: **0**

Registration date
2022-05-29, 1401/03/08

Registrant information

Name
Ehsan Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-20, 1401/03/30

Expected recruitment end date
2022-09-20, 1401/06/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dynamic neuromuscular stabilization exercises on overactive bladder and quality of life in women with multiple sclerosis

Public title

Evaluation of exercise therapy on quality of life in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of relapsing-remitting multiple sclerosis whose disease condition has stabilized (in the last 4 months. No change in symptoms) According to the Expanded Disability Status Scale (EDSS) questionnaire, their disability should be less than or equal to 5.5. Women who have experienced emergency incontinence at least once in the past month.

Exclusion criteria:

Pregnancy Presence of any neurological disease (except multiple sclerosis) or kidney disease History of childbirth in the last 6 months History of gastrointestinal surgery and abdominal surgery in less than 6 months Infection of the lower urinary tract Existence of musculoskeletal pain such as back pain Taking the drug for urinary incontinence (in case of discontinuation of the drug with the opinion of a doctor can be included in the study) Being a virgin

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are randomly divided into one of two experimental and control groups after examining the inclusion and exclusion criteria. In this study, due to the small number of samples, in consultation with a statistician, it was decided to use the random blocking method. Blocking is usually used to balance the number of samples assigned to each of the groups studied. The statistician used the website https://www.sealedenvelope.com/simple-randomiser/v1/lists, Considering that we had 2 groups, they designed 15 two-person blocks. . A person who divides patients into two groups based on this table is unaware of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients are unaware of the groups. In this study, exercise therapy is presented in both experimental and control groups, but they are different. In this study, patients try to come at different times and do not even contact each other so that they do not know the details of each other's exercises. Also, the person doing the assessments is unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Nursing, Management and Rehabilitation - Isfahan University of Med

Street address

Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.

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Province

Isfehan

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8174673461

Approval date

2022-04-08, 1401/01/19

Ethics committee reference number

IR.MUI.NUREMA.REC.1401.028

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

Pelvic floor muscle strength

Timepoint

Before treatment, after 3 weeks from the beginning of the sessions, after the end of the sessions and 2 months

after the end of the last treatment session

Method of measurement

The modified Oxford Scale, a 6-point scale, is used to assess pelvic floor muscle strength.

2

Description

Quality of Life

Timepoint

Before treatment, after 3 weeks from the beginning of the sessions, after the end of the sessions and 2 months after the end of the last treatment session

Method of measurement

The Lower urinary tract symptom-quality of life questionnaire is used to assess the effect of urinary incontinence on the quality of life of these people.

Secondary outcomes

1

Description

urinary incontinence

Timepoint

Before treatment, after 3 weeks from the beginning of the sessions, after the end of the sessions and 2 months after the end of the last treatment sessio

Method of measurement

The severity index of urinary incontinence in women is used to assess the rate of urinary incontinence

Intervention groups

1

Description

Intervention group: Receive dynamic neuromuscular stabilization exercises. These exercises are performed in different positions that are actually modeled on the positions of the growing baby. Exercises start with simple situations and gradually become more complex. In fact, the exercises start with the supine and then progress to the rolling, sitting, bear and squat-like postures. In each training session, 3 different situations are taught. Each exercise is maintained 3 times for 10 seconds and the patient is given 10 seconds of rest between each. The workout lasts for 6 weeks. The patient goes to physiotherapy twice a week.

Category

Rehabilitation

2

Description

Control group: Receive Kegel exercises. Kegel exercises strengthen the pelvic floor muscles, which support the uterus, bladder, small intestine and rectum.This exercise involves the patient contracting the pelvic floor muscles under the supervision of a therapist. In each session, moderate and intense exercises are performed. Moderate-intensity exercises last between 6 and 10 seconds, and high-intensity exercises last between 1 and 3 seconds. The exercises start from the supine position and are gradually taught in different positions such as sitting and standing. The patient is treated twice a week for 6 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Kashani Hospital

Full name of responsible person

Ehsan Ghasemi

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Ayatollah Kashani Hospital, Main Street of Ayatollah Kashani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Mansour Siavash Dastjerdi

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Ehsan Ghasemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Latest degree

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Other areas of specialty/work

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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

Because of confidentiality

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

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Study protocol, informed consent form and clinical study report

When the data will become available and for how long

The study protocol and consent form are now available in the proposal. The clinical study report will be published after the work is completed.

To whom data/document is available

All researchers working in scientific institutes can access the proposal.

Under which criteria data/document could be used

To be aware of the study conditions and get acquainted with scientific concepts.

From where data/document is obtainable

Contact Dr. Ehsan Ghasemi via email or mobile.

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

Immediately after sending the email and receiving the request.

Comments