Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of dynamic neuromuscular stabilization exercises on stress and combined urinary incontinence in women with multiple sclerosis

Protocol summary

Study aim

The effect of dynamic neuromuscular stabilization exercises on urinary incontinence in patients with multiple sclerosis

Design

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, to design a suitable blocking table. Divides patients according to this table is unaware of the study.

Settings and conduct

The place of this study is Isfahan, Ayatollah Kashani St., Kashani Hospital, physiotherapy ward and the time of its conduct is 2021.Study begins with obtaining permission from the ethics committee. Volunteers attend the physiotherapy department of Kashani Hospital. All stages of the work and the purpose of the research for patients are described in detail and the consent form is completed by them. In this study, patients are unaware of the groups. In both experimental and control groups, exercise therapy is performed, but the exercises are different.Also, the person doing the assessments is unaware of the groups.

Participants/Inclusion and exclusion criteria

Women diagnosed with multiple sclerosis (by a neurologist) who have urinary incontinence. Inclusion criteria include having a low disability to participate in the study and having at least one urinary incontinence in the past month. Exclusion from the study is other neurological diseases.

Intervention groups

In this study, the control group of Kegel exercises and the experimental group of dynamic neuromuscular stabilization receive.

Main outcome variables

Pelvic floor muscle strength, urinary incontinence, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200101045970N5**
Registration date: **2021-10-27, 1400/08/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-27, 1400/08/05**
Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Ehsan Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 3089

Email address

eghasemi@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of dynamic neuromuscular stabilization exercises on stress and combined urinary incontinence in women with multiple sclerosis

Public title
The effect of stabilizing exercises on urinary incontinence in patients with MS

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women between the ages of 18 and 55. Diagnosis of multiple sclerosis relapsing-remitting whose disease condition has stabilized (in the last 4 months. No change in symptoms) According to the EDSS questionnaire, their disability should be less than or equal to 5.5. Women who have experienced stress incontinence at least once in the past month.

Exclusion criteria:
Pregnancy Existence 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 Recurrence of the disease during the project Existence of musculoskeletal pain such as back pain Taking the drug for urinary incontinence (in case of discontinuation of the drug can be included in the study with the opinion of a doctor) 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, 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, to design a suitable blocking table. Divides patients according to 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
Faculty of Nursing, Management and Rehabilitation - Isfahan University of Medical Sciences (Research

Street address
Hezar Jirib

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2021-10-01, 1400/07/09

Ethics committee reference number
IR.MUI.NUREMA.REC.1400.130

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
The rate of 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

Secondary outcomes

1

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 LUTS-QOL questionnaire is used to assess the effect of urinary incontinence on the quality of life of these people.

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. The workout lasts for 6 weeks. The patient goes to physiotherapy twice a week.
Category
Rehabilitation

2

Description
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 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
Kashani Hospital
Full name of responsible person
Ehsan Ghasemi
Street address
kashani
City
Isfahan
Province
Isfehan
Postal code
8183983434
Phone
+98 31 3233 0091
Fax
Email
kashani@mui.ac.ir
Web page address
https://kashani.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
shaghayegh haghjoo
Street address
Hezar Jreeb
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 7898
Email
research@mui.ac.ir
Web page address
https://research.mui.ac.ir/
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

Street address

Hezar Jreeb

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3669 3089

Email

eghasemi@rehab.mui.ac.ir

Person responsible for scientific 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

Street address

Hezar Jreeb

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3669 3089

Email

eghasemi@rehab.mui.ac.ir

Person responsible for updating data

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

Street address

Hezar Jreeb

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3669 3089

Email

eghasemi@rehab.mui.ac.ir

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

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments