

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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**

Isfahan

**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 session

### **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**

Isfahan

#### **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**

Isfahan

#### **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

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**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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

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Ehsan Ghasemi

**Position**

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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**

-

**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**