

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of Swiss ball and Kegel exercise on pelvic floor muscles strength and severity of urinary incontinence in women with multiple sclerosis

Protocol summary

Study aim

Comparison the effect of Swiss ball and Kegel exercise on pelvic floor muscles strength and severity of urinary incontinence in women with multiple sclerosis

Design

This study is a controlled clinical trial, single-blind and with parallel groups. 56 female MS patients with urinary incontinence will be randomly assigned to one of two groups: G1(28Swiss ball);G2(28Kegel).

Settings and conduct

In this study among patients admitted to the MS society of Ahvaz Golestan Hospital, their selection will be done based on inclusion criteria. All of the patients are blind to the randomization and are randomly allocated to one of the two groups: Intervention and control group. The intervention will be performed for 12 weeks in both groups. Evaluation with Pelvic floor muscles testing (By Prenometer) and ICIQ-UI SF questionnaire completion will be done for the two groups before intervention and at the end of the third month.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with definitive diagnosis of MS; have symptoms of urinary incontinence; expanded disability status scale less than 5; being married; 18-45 years old; relapsing--remitting form of MS; no history of delivery during the last 6 months. Exclusion criteria: Severe cognitive problems; MS attack relapsed over the past three months; pregnancy; postmenopausal; urinary tract infection; having fatigue too; pelvic organ prolapse.

Intervention groups

Intervention : Swiss ball group control:Kegel group

Main outcome variables

Pelvic floor muscle strength; urinary incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181204041841N1**

Registration date: **2019-02-16, 1397/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-16, 1397/11/27**

Update count: **0**

Registration date

2019-02-16, 1397/11/27

Registrant information

Name

Nosrat Zaheryan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3446 2503

Email address

zaheryan_n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Swiss ball and Kegel exercise

on pelvic floor muscles strength and severity of urinary incontinence in women with multiple sclerosis

Public title

The effect of exercise on urinary incontinence

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

women with definitive diagnosis of MS Have symptoms of urinary incontinence Expanded disability status scale (EDSS) score less than 5(According to the diagnosis of the neurologist) Being married 18-45 years of age Relapsing--remitting form of MS No history of cesarean section or vaginal delivery during the last 6 months Having the reading and writing literacy

Exclusion criteria:

Severe cognitive problems MS attack relapsed over the past three months pregnancy Use diuretics and hypotensive drugs postmenopausal urinary tract infection history of diabetes Having fatigue too(increased muscle weakness) pelvic organ prolapse and previous gynecological surgery BMI Above 30

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 56 women with MS and urinary incontinence will be selected based on inclusion criteria. All of the patients are randomly assigned to one of the following two groups according to a computer-generated randomization list: G1 Swiss ball (n=28) and G2 Kegel exercise (n=28)

Blinding (investigator's opinion)

Single blinded

Blinding description

It is a single- blind study. In this study, the researcher after obtaining informed consent from the patients, will design two intervention groups for them. These two groups are: G1(Swiss ball) and G2(Kegel exercise), So 56 MS patients with urinary incontinence are randomly assigned to one of two groups and all of the patients are blind to the randomization.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University Of Medical Sciences and Health Services

Street address

Ahvaz Jundishapur University Of Medical Sciences and Health Services, Golestan Blvd, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2018-08-01, 1397/05/10

Ethics committee reference number

IR.AJUMS.REC.1397.312

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 muscles strength

Timepoint

Before the start of the intervention and 12 weeks after the beginning of the exercises

Method of measurement

Perineometer

2**Description**

urinary incontinence

Timepoint

Before the start of the intervention and 12 weeks after the beginning of the exercises

Method of measurement

ICIQ - UI SF questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the Swiss ball group will perform pelvic floor muscle exercises with assistance of Swiss ball and in the rehabilitation clinic of Ahvaz University of Medical Sciences under the supervision of the researcher. These exercises will be performed three times per week for 12 weeks and each session lasts 45 minutes. All patients are evaluated and compared before the intervention and at the end of the third month. These evaluations are include: Pelvic floor muscles testing (By Prenometer) and ICIQ- UI SF questionnaire completion.

Category

Treatment - Devices

2

Description

Control group: In the Kegel group, the patients will be trained how to perform pelvic floor muscle exercises. These exercises are include: sleeping on the back with bended knees, Sitting and standing and will be done at home. These contractions start at 3 seconds and gradually takes up to 10 seconds. These exercises are performed three times per day for 12 consecutive weeks. All patients are evaluated and compared before the intervention and at the end of the third month. These evaluations are include: Pelvic floor muscles testing (By Prenometer) and ICIQ- UI SF questionnaire completion.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khuzestan MS society

Full name of responsible person

Nosrat Zaheryan

Street address

Khuzestan MS society , School of Rehabilitation,
Ahvaz Jundishapur University Of Medical Sciences,
Golestan Blvd

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3374 3101

Fax

+98 61 3336 1984

Email

ms_ahwaz@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Badvi

Street address

Ahvaz Jundishapur University Of Medical Sciences and
Health Services,Golestan Blvd

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3336 1984

Fax

+98 61 3336 1984

Email

itc@ajums.ac.ir

Web page address

<http://vchrducation.ajums.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Nosrat Zaheryan

Position

Masters student Of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School Of Nursing and Midwifery, Ahvaz Jundishapur
University Of Medical Sciences, Golestan Blvd

City

Ahvaz

Province

Khuzestan

Postal code
61357-15794
Phone
+98 61 3446 2503
Fax
+98 61 3336 1984
Email
zaheryan_n@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Nosrat Zaheryan
Position
Masters student Of Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
School Of Nursing and Midwifery, Ahvaz Jundishapur
University Of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3446 2503
Fax
+98 61 3336 1984
Email
zaheryan_n@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person

Nosrat Zaheryan
Position
Masters student Of Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
School Of Nursing and Midwifery, Ahvaz Jundishapur
University Of Medical Sciences, Golestan Blvd
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3446 2503
Fax
+98 61 3336 1984
Email
zaheryan_n@ajums.ac.ir

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