Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 socity of Ahvaz Golestan Hospital, their selection will be done based on inclusion criterai. 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

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Iran (Islamic Republic of)

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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
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Ahvaz Jundishapur University Of Medical Sciences and Health Services,Golestan Blvd, Ahvaz
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Khouzestan
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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
Khuozestan MS socity

Full name of responsible person
Nosrat Zaheryan

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Sponsors / Funding sources

1

Sponsor

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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
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

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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