Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of pelvic floor muscles exercise with mindfulness on sexual function in women with multiple sclerosis

Protocol summary

Summary

Objective: The effect of pelvic floor muscle exercise with mindfulness on sexual function in women with multiple sclerosis. The study population: consist of multiple sclerosis patients who have had recorded accounts in Vice-Chancellor in treatment affairs of Yasuj University of Medical Sciences. Inclusion and exclusion criteria: Inclusion criteria include diagnosis of multiple sclerosis by a physician; having at least literacy and having at least conditions for participate to study. Exclusion criteria included relapses during the intervention. Sample size: 25 patients pelvic floor muscle exercise group (group 1), 25 patients in the group mindfulness (Group 2) and 25 patients in the group pelvic floor muscles exercise with mindfulness(Group 3) and 25 patients in the control group were allocated. In Group 1 pelvic exercise program presented As a group to research units And they will be asked during an 8-week, two times a day to do exercise, so that way every time exercises should be 10 contraction 5 to 10 seconds in a state lying, sitting and standing and subsequent 10 seconds of rest is recommended. In Group 2, during 8 weeks, once a week, every 90 minutes for group runs mindfulness program. In Group 3 during the 8-week Both pelvic floor muscle exercises and mindfulness will be implemented.In group 4, there will be no intervention and only routine treatments will be received. Primary Outcome: sexual function in women with MS

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016041426847N1**
Registration date: **2016-04-14, 1395/01/26**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-04-14, 1395/01/26

Registrant information

Name
Fatemeh Mosalanejad
Name of organization / entity
Yasuj Univercity of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 74 3323 5141
Email address
fatemeh.mosalanejad@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2016-04-02, 1395/01/14

Expected recruitment end date

2016-06-03, 1395/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pelvic floor muscles exercise with mindfulness on sexual function in women with multiple sclerosis

Public title

effects of Physical and psychological interventions on sexual function in MS patients

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of multiple sclerosis by a physician, at least in the last 6 months; female; informed consent, patient willingness to participate in the study, sexual activity during the past six months, married, monogamous husband, not far from wife; no risk of acute or chronic disease other than multiple sclerosis; no exposure to severe crisis as the death of someone close in the last six months; age range above 18 years; Lack of menopause; at least read and write; nulliparity in the last 6 month, no known risk of mental disorders; scores below 28 on sexual function questionnaire. Exclusion criteria: lack of patient motivation to continue working; relapses during the intervention; the absence of samples in more than one session, having tired too so that the patient is not able to do the exercises, the separation wife; pregnancy; the migration of disease and death.
Age
From **17 years** old to **54 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
One hundred patients with multiple sclerosis by blocking will be divided into four groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd., Yasuj, Iran
City
Yasuj
Postal code
Approval date
2016-03-06, 1394/12/16
Ethics committee reference number
IR.YUMS.REC.1394.136

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
sexual function
Timepoint
Before the intervention, at the end of the eighth week and one month after end of intervention
Method of measurement
Female Sexual Function Index

Secondary outcomes

empty

Intervention groups

1

Description
In Group 1 pelvic exercise program presented As a group to research units And they will be asked during an 8-week, two times a day to do exercise, so that way every time exercises should be 10 contraction 5 to 10 seconds in a state lying, sitting and standing and subsequent 10 seconds of rest is recommended.
Category
Behavior

2

Description
In Group 2, during 8 weeks, once a week, every 90 minutes for group runs mindfulness program.
Category
Behavior

3

Description
In Group 3 during the 8-week Both pelvic floor muscle exercises and mindfulness will be implemented.
Category
Behavior

4

Description
Added at 2017-10-09: In Group 4 (control) receive no specific intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Office of an assisstant of treatment of Yasuj University of Medical Science
Full name of responsible person
Dr Ardashir Afrasiabifar
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj, Iran
City
Yasuj

2

Recruitment center
Name of recruitment center
Yasuj University of Medical Science
Full name of responsible person
Dr Ardeshir Afrasiabifar
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj, Iran
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Yasuj University of Medical Sciences
Full name of responsible person
Dr. Mehdi Akbartabar Tori
Street address
Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd., Yasuj, Iran
City
Yasuj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Yasuj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Yasuj University of Medical Sciences
Full name of responsible person
Dr Ardeshir Afrasiabifar
Position
Ph.D of Medical Surgical Nursing- Associate Professor
Other areas of specialty/work
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj, Iran
City
Yasuj
Postal code
Phone
+98 74 3323 5141
Fax
+98 74 1223 4115
Email
afrasiabifar@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yasuj University of Medical Science
Full name of responsible person
Dr Ardeshir Afrasiabifar
Position
Ph.D of Medical Surgical Nursing- Associate Professor
Other areas of specialty/work
Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj, Iran
City
Yasuj
Postal code
Phone
+98 74 3323 5141
Fax
+98 74 1333 7370
Email
afrasiabifar@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Yasuj Univercity of Medical Sciences

Full name of responsible person
Fatemeh Mosalanejad

Position
Master student of nursing

Other areas of specialty/work

Street address
Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj, Iran

City
Yasuj

Postal code

Phone
+98 71 5444 8162

Fax

Email
fatemeh.mosalanejad@yums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty