

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 assistant 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

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Full name of responsible person

Dr Ardeshir Afrasiabifar

Street address

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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

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Full name of responsible person

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Position

Master student of nursing

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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