

Supervised pelvic floor muscle training improves sexual function and diminishes sexual distress in women with multiple sclerosis

Submission date 03/07/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/07/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 03/09/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Pelvic floor muscle training (PFMT) contributes to better sexual function, as muscle strength and ability to properly contract to improve vaginal receptivity and responsiveness, orgasm and sexual pleasure. Multiple sclerosis (MS) is the most common chronic nervous system disorder leading to sexual dysfunction, with a prevalence of 40-70%. More than a third of MS patients experience signs of pelvic floor weakness. The primary outcome of this study is to evaluate the effect of PFMT on improving sexual function and sexual distress in women suffering from MS.

Who can participate?

Adult women aged 18-45 years old with MS

What does the study involve?

In this study, women suffering from MS will be included in an intervention Group A (12 weeks of PFMT), and in a control Group B (observation group; negative control group). All women will be assessed with the Female Sexual Function Index (FSFI) and Female Sexual Distress Scale-Revised (FSDS-R) at the study's beginning and end.

What are the possible benefits and risks of participating?

Possible benefits include better sexual function. No risks are expected from the pelvic floor exercises.

Where is the study run from?

Ey Prattein Rehabilitation Centre (Greece)

When is the study starting and how long is it expected to run for?

May 2021 to May 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Athanasios Zachariou (Assistant Prof Urology), zahariou@otenet.gr (Greece)

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Supervised pelvic floor muscle training improves sexual function and diminishes sexual distress in women with multiple sclerosis: a randomized controlled study

Study objectives

Pelvic floor muscle training (PFMT) contributes to better sexual function, as muscle strength and ability to properly contract improve vaginal receptivity and responsiveness, orgasm and sexual pleasure. Multiple sclerosis (MS) is the most common chronic nervous system disorder leading to sexual dysfunction, with a prevalence of 40-70%. More than a third of MS patients experience signs of pelvic floor weakness. The primary outcome of this study is to evaluate the effect of PFMT on improving sexual function and sexual distress in women suffering from MS.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 01/09/2021, KENTAVROS Center for Physical Medicine and Rehabilitation (Apollonos 94, Volos, 38222, Greece; +30 2421043000; info@kentavros.com.gr), ref: 12/2021

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospice, Hospital

Study type(s)

Quality of life

Participant information sheet

See trial outputs table

Health condition(s) or problem(s) studied

Supervised pelvic floor muscle training improves sexual function and diminishes sexual distress in women with multiple sclerosis

Interventions

The intervention included women suffering from MS with an EDSS score <4 and divided them into two groups.

In Group A, women followed a program of supervised pelvic floor muscle training (PFMT) for 12 weeks, and women in Group B comprised the control group. The total duration of the intervention was 12 weeks.

At the beginning and end of the study, all women completed the FSFI and FSDS-R questionnaires to assess their sexual function/distress and evaluate if there were any differences between the two groups.

1. Method of randomization. Women were consecutively randomized into the two groups. Consecutive sampling is a non-probability sampling technique where samples are picked at the ease of the investigator, more like convenient sampling. In that way, we produced two groups with an equal number of women.
2. The principal investigator, doctor, and physiotherapist evaluated the pelvic floor to provide evidence that the woman could perform pelvic floor muscle exercises. All work in the rehabilitation center and are members of the pelvic floor unit. They already have the necessary specific training and are all considered specialists in their topic.
3. The instruction of the PFMT was face-to-face, but during the study period, there were a lot of telephone communications to strengthen our patients and increase adherence to the program.
4. All the necessary interventions occurred on the premises of Kentavros Rehabilitation Center.

Intervention Type

Behavioural

Primary outcome measure

Effect of pelvic floor muscle training (PFMT) on improving sexual function and sexual distress in women suffering from MS measured using the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale-Revised (FSDS-R) questionnaires scores at the beginning and end of the twelve-week study

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/05/2021

Completion date

01/05/2023

Eligibility**Key inclusion criteria**

1. 18 years of age or older
2. Diagnosis of relapsing-remitting MS
3. Stable condition for a minimum period of six months
4. Kurtzke's Expanded Disability Status Scale (EDSS) score < 4
5. Women sexually active for at least four weeks
6. Cognitive ability to complete the questionnaires and study protocol
7. Ability to contract PFM evaluated by the primary investigator

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

60 divided into two groups

Total final enrolment

84

Key exclusion criteria

1. Previous pelvic floor muscle training program
2. Ongoing pregnancy
3. Child delivery within the previous six months
4. Urinary or faecal incontinence
5. Pelvic organ prolapses greater than stage I
6. Perimenopause or menopause period

Date of first enrolment

01/09/2021

Date of final enrolment

01/02/2023

Locations**Countries of recruitment**

Greece

Study participating centre

Ey Prattein Rehabilitation Centre

94 Apollonos Street

Volos

Greece

38222

Sponsor information**Organisation**

KENTAVROS

Sponsor details

Center for Physical Medicine and Rehabilitation

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Sponsor type

Hospital/treatment centre

Website

<https://www.kentavros.com.gr>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
KENTAVROS Center for Physical Medicine and Rehabilitation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed journal

Intention to publish date
15/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Athanasios Zachariou (Assistant Prof Urology), zahariou@otenet.gr.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Patient consent form		06/07/2023	No	Yes
Results article		12/01/2024	03/09/2024	Yes	No