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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

Registration date
06/07/2023

Overall study status
Completed

Last Edited
03/09/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
KENTAVROS Center for Physical Medicine and Rehabilitation

Results and Publications

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?
Results article		12/01/2024	03/09/2024	Yes	No
Participant information sheet	Patient consent form		06/07/2023	No	Yes