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Analysis of the influence of electrostimulation and exercises on pelvic floor muscles tension in young, healthy women

Submission date 17/07/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/07/2022	**Overall study status** Completed	
Last Edited 25/07/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The pelvic floor is an extremely important place in a woman's body. Like any other area of the organism, this one can also undergo various types of related dysfunctions with disturbed muscle tone present there. There are many factors that can contribute to the development of pelvic floor dysfunction, such as: physiological childbirth, menstrual cycle, previous lower urinary tract infections, comorbidities, medications taken, profession and many others. Therefore, it is necessary to look for therapeutic methods that will prove effective in strengthening the pelvic floor muscles in young, healthy women, and thus in the prevention of the occurrence of dysfunctions in the genitourinary system in the next stages of their lives.

The aim of the study is the electromyographic analysis of the effect of endovaginal electrostimulation and exercises on the pelvic floor muscle tone in young women, showing no dysfunction in the genitourinary system. The study will assess whether the applied physioprophylactic procedures will be effective in increasing PFM tension, and thus in the prevention of dysfunction of this muscle group.

Who can participate?
Women who have not previously given birth, aged 19-29 years, without pelvic floor dysfunction.

What does the study involve?
Women will be randomly assigned to one of three groups: two test groups with pelvic floor electrostimulation and exercise, and a control group with exercise only. Bioelectrical activity of pelvic floor muscles are measured before and after treatment and during follow-up visits 1 and 3 months after the end of the study.

What are the possible benefits and risks of participating?
Participants will receive a complete physioprophylaxis program that can improve pelvic floor muscle tone. There is no risk involved in participating.

Where is the study run from?
University of Opole (Poland)

When is the study starting and how long is it expected to run for?
March 2022 to December 2023

Who is the main contact?
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Additional identifiers

Protocol serial number
KB-254/2022

Study information

Scientific Title
Electromagnetic electrostimulation and exercises in the physioprophylaxis of pelvic floor dysfunction

Study objectives
1. Pelvic floor muscles exercises improve the bioelectrical activity of the pelvic floor muscles.
2. Endovaginal electrostimulation improve the bioelectrical activity of the pelvic floor muscles.
3. The frequency used in endovaginal electrostimulation affects the bioelectric activity of the pelvic floor muscles

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/03/2022, Research Ethics Committee from Wroclaw Medical University (1 Pasteur Street, 50-367, Wroclaw, Poland; +48 (0)717841014; bioetyka@umed.wroc.pl), ref: KB-254/2022

Primary study design
Interventional

Study design
Prospective randomized clinical study with follow-up analysis

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Bioelectric activity of pelvic floor muscles

Interventions
After baseline assessments, the participants will be randomly assigned (using an online tool) to:

1. Endovaginal electrostimulation using the 50 Hz frequency and pelvc floor muscles exercises
2. Endovaginal electrostimulation using the 10 Hz frequency and pelvc floor muscles exercises
3. Pelvic floor muscles exercises

The individuals receiving the treatment will be blinded. A computer-generated list of random numbers will be used and concealed from the researchers enrolling and assessing the participants. The outcome assessors and data analysts will be kept blinded to the allocation.

The therapy programme lasts 8 weeks during which all the participants will perform pelvic floor exercises at home 3 times a week. Women will exercise according to the schedule (3 series, 9 contractions in series, contraction time 6s, rest time 12s, 3 quick contractions at the end of each series (1,2,3s), a 2-minute recovery between sets). Additionally, in two groups, women will undergo endovaginal electrostimulation 3 times a week. A single treatment will take 20 minutes.

In group 1, it is planned to use a frequency of 50 Hz and in the second group, a frequency of 10 Hz. The remaining treatment parameters for both groups will be identical (pulse time 200 μs, contraction time 5s, rest time 10s, intensity to the patient's feelings).

All participants will undergo assessment of the bioelectrical activity of pelvic floor muscles before the start of treatment, after intervention and 1 and 3 months after the therapy programme.

Intervention Type
Behavioural

Primary outcome(s)
Bioelectrical activity of pelvic floor muscle measured using an endovaginal electrode, an EMG apparatus and integrated computer software. An assessment of the bioelectrical activity of pelvic floor muscle using the Glazer protocol. The measurements will be performed before the therapy, after the therapy, i.e. 8 weeks later and 4 and 12 weeks after the end of intervention

Key secondary outcome(s)
Assessment of the bioelectric activity of the pelvic floor muscles using the glazer protocol:
1. One 60-second rest (pre-baseline) - the women were instructed to feel the pelvic floor in a resting position.
2. Five 2-second phasic (flick) contractions with a 2-second rest in-between - the women were instructed to contract the PFM as quickly as possible, and then quickly and fully relax the PFM immediately after contraction.
3. Five 10-second tonic contractions with a 10-second rest in-between - the women were instructed to contract the PFM as strongly as possible, maintain the contraction for 10seconds, and then fully relax the PFM after contraction, remaining relaxed for 10seconds.
4. One 60-second endurance contraction - the women were instructed to contract the PFM at such a level as to hold it for 60 seconds.
5. One 60-second rest (post-baseline) - the women were instructed to feel the pelvic floor in a resting position.
The measurements will be performed before the therapy, after the therapy and 1 and 3 months after the end of the intervention.

Completion date
30/12/2023

Eligibility

Key inclusion criteria
1. Women aged 19 - 29 years
2. Nulliparous
3. Women who have already had intercourse
4. Women without pelvic floor dysfunction

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 Years

Upper age limit
29 Years

Sex
Female

Key exclusion criteria
1. Women before 19 and after 29 years of age
2. Women who gave birth
3. Virgins
4. Pelvic floor dysfunction
5. Sensory deficits
6. Pacemakers and other electronic implants
7. Metal implants
8. Psychiatric disorders
9. Cancer
10. Infections
11. Fever
12. Acute inflammation
13. Hypersensitivity to electricity

Date of first enrolment
08/08/2022

Date of final enrolment
30/12/2023

Locations

Countries of recruitment
Poland

Study participating centre
University of Opole Institute of Health Sciences
68 Katowicka Street
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Sponsor information

Organisation
Opole University

ROR
https://ror.org/04gbpnx96

Funder(s)

Funder type
University/education

Funder Name
Uniwersytet Opolski

Alternative Name(s)
University of Opole, Opole University, UO

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (j.taradaj@awf.katowice.pl)

IPD sharing plan summary
Available on request