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Pelvic floor muscle training with surface electromyography

Submission date
21/07/2016

Recruitment status
No longer recruiting

Registration date
25/07/2016

Overall study status
Completed

Last Edited
06/09/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English Summary
Background and study aims
The pelvic-floor muscles are a layer of muscles which hold the bladder, womb and bowel (pelvic organs) in place. They are very important for stabilising the body, supporting organs in the pelvis and determining the quality of sexual life. As women get older and have children, the pelvic floor muscles become weaker, and so exercising these muscles is key to preventing problems such as urinary incontinence and reduced sensitivity surging sex. Exercise professionals rarely learn about pelvic floor exercises, and so this area of the body is often overlooked in physical activity programs. Tensing the pelvic floor muscles before doing something that increases abdominal (tummy) pressure (such as coughing, laughing or heavy lifting) can help to reduce the amount of urine that comes out in women suffering from incontinence. Unfortunately, because pelvic floor training is often missed out of exercise programs, many women do not know how to do this properly. Some recommend using a technique called biofeedback (learning to control bodily functions through electronic feedback), but others feel that written or verbal instructions are enough. The aim of this study is to investigate which of these techniques is most effective in teaching women how to improve pelvic floor muscle function and tensing techniques.

Who can participate?
Healthy women aged between 18 and 45.

What does the study involve?
Participants are randomly allocated to one of four groups. At the beginning of the study, all women undergo pelvic-floor muscle assessment with the use of electromyography (EMG). This involves having a probe placed in the vagina with electrodes (sticky pads that conduct electricity) begin placed on the skin around the pelvis so that the electrical activity during pelvic floor muscle tensing can be measured. Those in the first group receive usual advice, in the form of verbal instructions about how to tense the pelvic floor muscles and a written program of exercises which get progressively harder to train and strengthen the muscles (involving tensing the muscles in different positions more strongly over a six week course). Those in the second group receive biofeedback and unsupervised training. This involves being given the same verbal and written instructions as the first group to practice on their own, with the addition of one session of instructions about muscle activation while viewing the EMG taken at the start of the study. Those in the third group receive biofeedback and supervised training. This involves the

same process as in group two except that they meet with an exercise professional to do the training program with (instead of alone). Those in the fourth group do not receive any feedback on the EMG test or any advice on how to do pelvic floor exercises. After six weeks, women repeat the EMG test in order to find out if there has been any change to their pelvic floor muscle function or tensing technique.

What are the possible benefits and risks of participating?
Women may expect that after completing the training program they improve their pelvic-floor muscle condition, body awareness and effectiveness in preventing urine leakage during daily activities. There are no notable risks involved with taking part in this study.

Where is the study run from?
Gdansk University of Physical Education and Sport (Poland)

When is the study starting and how long is it expected to run for?
December 2013 to June 2018

Who is funding the study?
Gdansk University of Physical Education and Sport (Poland)

Who is the main contact?
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Study website
http://awf.gda.pl/index.php?id=781

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KB - 8/13; KB - 22/15

Study information

Scientific Title
The influence of Pelvic Floor Muscle Training with surface Electromyography on selected EMG parameters among women in reproductive age undergoing different modes of exercise instructions and supervision

Acronym
PFMTe Project

Study hypothesis
1. Women undergoing different modes of instructions and supervision related to pelvic-floor muscle exercises present different training effects regarding selected EMG parameters
2. The most effective training mode is the verbal instructions on pelvic-floor muscle exercise supported by EMG biofeedback and instructor's supervision

Ethics approval required
Old ethics approval format

Ethics approval(s)
Komisja Bioetyczna przy Okręgowej Izbie lekarskiej w Gdańsku (Bioethical Commission of the Regional Medical Chamber in Gdansk), ref: B - 8/13 (pilot) and KB - 8/14 (main study)

Study design
Single-centre assessor-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Condition

Pelvic floor muscle function

Interventions

Women are randomly allocated to one of four groups.

Group 1: Participants receive usual advice and unsupervised training. This involves verbal and written instructions for the pelvic-floor muscle activation after the initial test (described below). They also receive a written program of pelvic-floor exercises (described below) and a training diary to record the completed sessions. They execute these exercises for six weeks without any supervision.
Group 2: Participants receive biofeedback and unsupervised training. This involves verbal and written instructions for the pelvic-floor muscle activation after the initial test (described below) and one session of instructions about muscle activation while viewing the EMG (EMG biofeedback session).They also receive a written program of pelvic-floor exercises (described below) and a training diary to record the completed sessions. They execute these exercises for six weeks without any supervision.
Group 3: Participants receive biofeedback and supervised training (incorporated into general health-enhancing exercise programme -added 16/04/2018). This involves verbal and written instructions for the pelvic-floor muscle activation after the initial test (described below) and one session of instructions about muscle activation while viewing the EMG (EMG biofeedback session).They also receive a written program of pelvic-floor exercises (described below) and a training diary to record the completed sessions. They meet an exercise professional to implement the training program.
Group 4: Participants don't receive get any feedback on the EMG test or any advice how to exercise pelvic-floor muscles.

The instructions given to participants how to contract pelvic-floor muscles:
"If you are not certain that you are tightening pelvic-floor muscles, you should locate them at the beginning of each session:
1. Contract pelvic-floor muscles for 3-5 seconds, as if you were trying to stop a flow of urine or squeeze a tampon. Then relax these muscles. Try recognizing the difference between tightening and relaxing these areas.
2. Put your hands on your abdomen and contract abdominal muscles for 3-5 seconds as if you wanted to grunt or cough. Then relax those muscles. Try feeling the difference between tightening and relaxing abdominal muscles.
3. Put your hands on your buttocks and contract gluteal muscles for 3-5 seconds, lifting slightly your hips off the floor. Then relax those muscles. Try feeling the difference between tightening and relaxing gluteal muscles.
4. Put your hands on the inside of your thighs and contract thigh adductor muscles for 3-5 seconds pushing one knee into the other. Then relax those muscles. Try feeling the difference between tightening and relaxing the thigh adductor muscles.
5. Breathe deeply in and out relaxing all the above muscles
6. Try keeping the abdominal, gluteal and thigh muscles relaxed and once again contract the pelvic-floor muscles for 3-5 sec., as if you tried stopping urine flow or squeezing a tampon".

All participants undergo the pelvic-floor muscle assessment with the use of electromyography (EMG). After the initial test the women in groups 1-3 are given verbal and written instructions for the pelvic-floor muscle activation. Women in both biofeedback (2 and 3) groups also receive one session of instructions about muscle activation while viewing the EMG (EMG biofeedback session). Groups 1-3 receive a written program of pelvic-floor exercises and a training diary to record the completed sessions. Groups 1 and 2 exercise without any supervision, group 3 meet an exercise professional to implement the training program. Women from control group don't

get any feedback on the EMG test or any advice how to exercise pelvic-floor muscles. After six weeks all women are retested for the pelvic-floor muscle EMG activity.

Pelvic-floor muscle activation exercises:
Participants take part in a six weeks course of pelvic floor exercises increasing in difficulty based on Miller's program (2012).
Week 1: Participants learn to activate pelvic-floor muscles through short contractions. This is done by completing 5 series of 10 contractions with breaks of 30 seconds between series five times a week (total approximately 5 minutes).
Week 2: Participants complete fuller activation of the pelvic-floor muscles through short, increasingly stronger contractions. This involves each repetition of the exercise containing 3 increasingly stronger contractions (flicks) and slow reduction in tension up to complete relaxation. Count: '1, 2 3 – relax', in each repetition of the exercise. This is done by completing 5 series of 10 contractions with breaks of 30 seconds between series five times a week (total approximately 5 minutes).
Week 3: Women learn to maintain sustained holds of moderate intensity. Each repetition consists of 3 increasingly stronger flicks, maintaining sustained hold, gradually extending the duration (from 3 to 10 seconds), and then slowly reducing the tension up to full relaxation. The contraction of the pelvic floor should be directed upwards and inwards. During the sustained holds, the pelvic-floor muscles should be activated as strongly as possible, without contracting other groups of muscles. 10 repetitions in a series with a 10 second break between repetitions, contraction at the highest level to be kept for 3 – 10 seconds (gradually extending the duration together with the increase in the muscle power), 3 series with breaks of 30 seconds between the series, 5 times a week (total approximately 10 minutes).
Week 4: Women undertake maximum hold of high intensity in order to increase the mass and power of the muscles. Each exercise repetition consists of 3 increasingly stronger flicks, maintaining maximum hold until the feeling of tiredness, execution of 5 pulsating flicks before relaxing and then slow reduction of tension up to full relaxation. Five repetitions in a series, 10 seconds breaks between repetitions, maintenance of maximal hold (above 10 seconds) extending it by short pulsating contractions before relaxation; 3 series, with 30 second breaks between the series, 5 times a week (total approximately 10 minutes).
Week 5: Women learn to improve speed, strength and endurance of the pelvic-floor muscles. Increasing body awareness and differentiating moment of tension and relaxation of muscles, through one sequence of "complex activation" contains: 5 quick and maximal contractions with immediate relaxation (3 second pause between contractions), 5 maximal contractions (10 seconds contraction, 10 seconds pause), sustained hold lasting 60 seconds with immediate relaxation after the long contraction. Three sequences of contractions and relaxation, 30 second pauses between series, 5 times a week (total approximately 10 minutes).
Week 6: Women work on improving the ability of activating the pelvic-floor muscles in daily activities by working on the awareness of contracting the pelvic-floor muscles before sneezing, coughing, lifting objects. Five repetitions in a series, 10 seconds breaks between repetitions, maintenance of maximal hold (above 10 seconds) extending it by short pulsating contractions before relaxation; 2 or more series, with 30s breaks between the series; contracting pelvic-floor muscles each time before sneezing, coughing and lifting objects, for 5-10 minutes a week.

Participants in all study groups undergo follow up pelvic-floor muscle assessments at six weeks.

Intervention Type
Behavioural

Primary outcome measure

1. Pelvic-floor muscle function is measured using the TeleMyo™ 2400T Direct Transmission System (DTS), NORAXON EMG and Sensors System (Scottsdale, AZ, USA) at baseline and 6 weeks.

Added 16/04/2018:
2. The lif eimpact of urinary incontinence symptoms is assessed using the Incontinence Impact Questionnaire at baseline and 6 weeks.

Secondary outcome measures
Technique of the pelvic-floor muscle contraction is determined using a electromyography (EMG) data at baseline and 6 weeks.

Overall study start date
01/12/2013

Overall study end date
31/12/2022

Eligibility

Participant inclusion criteria
1. Women at the age of 18-45 years old (including pregnant women; nulliparous, primiparous or multiparous)
2. Health condition allows for physical activity
3. Availability to implement 6-week training program

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
500 participants

Total final enrolment
638

Participant exclusion criteria

1. History of pelvic-floor disorders
2. History of urogenital tract dysfunctions
3. Complicated pregnancy during the study
4. Any contraindications to physical activity

Recruitment start date
01/02/2014

Recruitment end date
28/02/2022

Locations

Countries of recruitment
Poland

Study participating centre
Gdansk University of Physical Education and Sport
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Sponsor information

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University/education

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ROR
https://ror.org/03rq9c547

Funder(s)

Funder type
University/education

Funder Name
Gdansk University of Physical Education and Sport

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.
Two publications in Polish journal Rocznik Naukowy 2015.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/01/2019		Yes	No
Results article	results	01/02/2020	07/02/2020	Yes	No
Results article	results in future exercise professionals	03/09/2019	04/02/2022	Yes	No
Results article	results of high-impact aerobics programme	20/08/2021	04/02/2022	Yes	No
Results article	results of one-time biofeedback EMG session	12/08/2021	04/02/2022	Yes	No
Results article	sEMG training results	14/08/2018	04/02/2022	Yes	No
Results article	training-related changes in EMG activity	14/09/2018	04/02/2022	Yes	No
Other publications	conducted as part of this study: influence of one-time biofeedback electromyography session	29/08/2022	03/09/2024	Yes	No
Other publications	Conducted as part of this study: Improving the Technique of Pelvic Floor Muscle Contraction	12/05/2022	06/09/2024	Yes	No