BIOFEEDBACK VERSUS VAGINAL PALPATION TO TEACH A VOLUNTARY PELVIC FLOOR MUSCLE CONTRACTION TO WOMEN INCAPABLE OF PERFORMING IT. A NON-INFERIORITY RANDOMIZED CONTROLED TRIAL

Brief summary:

Pelvic floor muscle training (PFMT) is the first line treatment of urinary incontinence (UI), anal incontinence (AI) and mild/moderate pelvic organ prolapse (POP) in women. However, 25 to 40% of women with pelvic floor dysfunction symptoms are unable to voluntarily contract their pelvic floor muscle (PFM) and PFM proprioception of this population is specially reduced. Literature is scarce about methods to facilitate a voluntary PFM contraction and improve PFM proprioception therefore, a specific protocol structured to teach PFM contraction is needed. The use of biofeedback could facilitate women´s capacity to voluntary contract their PFM.

Study design:

Randomized, parallel (two arm), trial comparing biofeedback (experimental arm) versus vaginal palpation (active control, i.e. usual practice) to achieve a correct voluntary pelvic floor muscle contraction in women who cannot perform a correct contraction (i.e. grade 0, 1 or 2 on the Modified Oxford Scale). The trial hypothesis is that there is no difference between the two trial arms in the proportion of women achieving a correct voluntary contract (grade 3 or better).

Detailed description:

Arms of intervention: The study has two arms of interventions to which the patient will be randomly allocated to, both aiming is to provide an awareness/proprioception protocol with the purpose of enabling women to do a correct contraction: a proprioception protocol associated with vaginal palpation and feedback (CG) and the same protocol associated with biofeedback (BG). It will be a 12-weeks intervention delivered once a week during a 60-minute session by one of the two experienced physiotherapists who will provide the interventions in this study.

The training protocol will be the same for both groups and will vary according to PFM function assessed at 0, 3, 6 and 9-week timepoint. The resting time after each contraction will be the double of the contraction duration, therefore if it is performed a 3-second contraction, it will be a 6-second rest. The first session will aim to improve some skills as understanding, searching, and finding PFM, the educational component of this session was structured considering Health Belief Model and will be conducted with the following information: 1) General information (female genital anatomy, female intern organs, pelvic floor muscle anatomy, pelvic floor muscle function), 2) specific information about urinary incontinence (definition of urinary incontinence, predictors of risk for urinary incontinence, impact on quality of life), 3) the relation between PFM and urinary incontinence, 4) pelvic floor muscle training as first line treatment for urinary incontinence, 5) how to include PFM proprioception protocol into daily life. It will be used as educational materials images and draws of the region and an educational booklet will be delivered to them. It will be shown to then a video of a PFM contraction emphasizing how the correct PFM contraction is supposed to be. The other sessions will focus will vary according to PFM function accessed at each timepoint:

- Participants classified with MOS 0 or 1: PFM protocol will aim on learning a PFM contraction and improve PFM perception
- Participants classified with MOS = 2: PFM protocol will aim on teaching how to control PFM contraction
- Participants classified with MOS ≥ 3: PFM protocol will aim on improving PFM strength

The resting time after each set will be 3 minutes and the protocol will evolve as following:

- **WEEK 1: In clinics:** 30 minutes: educational component as previous discussed. 30 minutes: The studied protocol will be explained as well as the need to fulfill a diary with their home training routine that should be delivered to the evaluator at the 12-week assessment. At each session, the physiotherapist will oversee the diary, take notes about the frequency of training, and orientate if necessary. To promote a first contact with their PFM, it will be performed 1 set of PFM contraction associated with vaginal palpation or biofeedback of 6 fast contraction according to the randomized group. The resting time after each contraction will be five seconds. Possible doubts will be clarified. **At home:** All participants will be oriented to perform 3 sets of 6 fast contraction daily during the following week in the supine position. The resting time after each contraction will be five seconds and after each set will be 2 minutes.
- **WEEK 2-3**: **In clinics:** Training diary will be overseen, and possible doubts will be clarified. Training protocol will be different according to PFM function assessed on week 0. MOS 0: 3 sets of 6 fast contraction. The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 6 fast contraction and 3 sets of 6 contractions sustained for 3 seconds. The resting time after each contraction will be five seconds and 2 minutes after each set. **At home:** Training protocol will be different according to PFM function assessed on week 0. MOS 0: 3 sets of 6 fast contraction in supine position. The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 6 fast contraction and 3 sets of 6 contractions sustained for 3 seconds in supine. The resting time after each contraction will be five seconds and 2 minutes after each set.
- **WEEK 4-6: In clinics:** Training diary will be overseen, and possible doubts will be clarified. Training protocol will be different according to PFM function assessed on week 3. MOS 0: 3 sets of 10 fast contraction. The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 10 fast contraction and 3 sets of 6 contractions sustained for 4 seconds. The resting time after each contraction will be six seconds and 2 minutes after each set. MOS ≥ 2: 3 sets of 10 fast contraction and 3 sets of 10 contractions sustained for 6 seconds. The resting time after each contraction will be ten seconds and 3 minutes after each set. **At home:** Training protocol will be different according to PFM function assessed on week 3. MOS 0: 3 sets of 10 fast contraction, each set on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 10 fast contraction and 3 sets of 6 contractions sustained for 4 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be six seconds and 2 minutes after each set. MOS ≥ 2: 3 sets of 10 fast contraction and 3 sets of 10 contractions sustained for 6 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be ten seconds and 3 minutes after each set.
- **WEEK 7-9: In clinics:** Training diary will be overseen, and possible doubts will be clarified. Training protocol will be different according to PFM function assessed on week 6. MOS 0: 3 sets of 10 fast contraction and 3 sets of 5 contraction sustained for 3 seconds. The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 10 fast contraction and 3 sets of 6 contractions sustained for 4 seconds. The resting time after each contraction will be six seconds and 2 minutes after each set. MOS ≥ 2: 3 sets of 10 fast contraction and 3 sets of 10 contractions sustained for 6 seconds. The resting time after each contraction will be ten seconds and 3 minutes after each set. **At home:** Training protocol will be different according to PFM function

assessed on week 6. MOS 0: 3 sets of 10 fast contraction and 3 sets of 5 contraction sustained for 3 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 10 fast contraction and 3 sets of 6 contractions sustained for 4 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be six seconds and 2 minutes after each set. MOS ≥ 2: 3 sets of 10 fast contraction and 3 sets of 10 contractions sustained for 6 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be ten seconds and 3 minutes after each set.

- **WEEK 10-12: In clinics:** Training diary will be overseen, and possible doubts will be clarified. Training protocol will be different according to PFM function assessed on week 9. MOS 0: 3 sets of 10 fast contraction and 3 sets of 5 contraction sustained for 3 seconds. The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 10 fast contraction and 3 sets of 6 contractions sustained for 4 seconds. The resting time after each contraction will be six seconds and 2 minutes after each set. MOS ≥ 2: 3 sets of 10 fast contraction and 3 sets of 10 contractions sustained for 6 seconds. The resting time after each contraction will be ten seconds and 3 minutes after each set. **At home:** Training protocol will be different according to PFM function assessed on week 6. MOS 0: 3 sets of 10 fast contraction and 3 sets of 5 contraction sustained for 3 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be five seconds and after each set will be 2 minutes. MOS 1: 3 sets of 10 fast contraction and 3 sets of 6 contractions sustained for 4 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be six seconds and 2 minutes after each set. MOS ≥ 2: 3 sets of 10 fast contraction and 3 sets of 10 contractions sustained for 6 seconds. Each set is supposed to be performed on a different position (i.e. supine, sitting and standing). The resting time after each contraction will be ten seconds and 3 minutes after each set.

CG: The participants will be placed in the supine position with flexion of the hip and knee and feet supported on the stretcher. Vaginal palpation will be used as a proprioceptive resource to facilitate PFM voluntary contraction. The physiotherapist responsible for conducting the treatment, wearing gloves, will perform a one or two-finger vaginal palpation, depending on participant's vaginal canal. The following examples of voice commands can be used by the physiotherapists to help women understand how to perform a PFM contraction: 1) "Squeeze my finger and pull, as if holding urine and avoiding the release of gas. Good, now relax"; 2) "Squeeze my finger and try to get it into your vagina. Good, now let my finger go, relax "; 3) “ok, now let’s try to squeeze a little more my finger, good, now let my finger go, relax. ”; 4) “I want you to close your eyes and pay all your attention to you vagina, are you feeling my finger into your vagina? Good! Now I want you to try to move my finger inward using you pelvic floor muscle. That’s perfect, now let my finger out your vagina”; 5) “Now, let’s take a deep breath and, while you are letting the air go off your lungs, try pulling your vaginal muscle up. Good, now relax!”; 6) “I want you to imagine that you are really needing to pee, but there is no bathroom nearby, so you need to really hold your pee. Hold your pee! Good, now relax”; 7) “You are during a good job, but let’s try a stronger contraction. I want you to imagine that you are really needing to poop and pee, but there is no bathroom nearby, so you need to really hold your poop and pee. Hold your poop and pee but do not use your butt muscle! That’s perfect! Now relax your vaginal muscle”; 8) Now we are going to do this training keeping my finger in your vagina and at the same time I'm going to hold two of your fingers in my hand, to simulate how your vagina should squeeze my fingers, ok?

I want you to imagine that your fingers are my fingers that are inside your vagina and that my hand is your vagina and when I squeeze your fingers it simulates the contraction of your pelvic floor muscles. So, I'm going to squeeze your fingers with my hand now and I want you to concentrate to squeeze my finger with the same strength but using your vaginal muscles, ok? Let's go, (physiotherapist makes a light pressure with the hand on the patient's fingers while saying): squeeze my finger!"; 9) "Pull my finger up. A little higher. That's right! Now let's relax"; 10) "Do you remember the video showing PFM contraction? Right, I want you to visualize that contraction and try to perform the same movement. Let's do it? All right, Close your vagina! Now relax"; 11) You are doing a terrific job, but let's try to contract a little less your butt. You need to concentrate in your vaginal muscle. Perfection! Let's relax"; 12) "Let's take a deep breath and while you are letting the air off our lungs, try to close your vagina, Now relax!"; 13) "ok, that's a perfect contraction, now tray to keep the strength during the whole contraction". Positive reinforcements will be verbalized after each PFM contraction. The training protocol will be tailored, and the evolution will be the same for CG and BPFMT.

BG: will receive the same protocol of CG but associated with biofeedback with an electromyographic sensor through the Miotol equipment (Miotec, Brazil). The participants of the BG will also be positioned in the supine position with flexion of the hip and knee and feet supported on the stretcher. The electromyographic sensor will be covered with neutral gel and inserted into the participant's vaginal canal. Participants will stretch their legs on the stretcher to start the muscle training protocol. Participants will see the visual response of the contraction on the computer screen. The software has five different interfaces for visualize PFM contraction and each participant will be able to choose the one that she prefers at each session: 1) pelvic floor muscle electromyographic sign itself; 2) pelvic floor muscle electromyographic signal transformed into the movement of a balloon; 3) pelvic floor muscle electromyographic signal transformed into the movement of an airplane; 4) pelvic floor muscle electromyographic signal transformed into the movement of a fairy; 5) pelvic floor muscle electromyographic signal transformed into the movement of a bird. The training protocol will be tailored, and the evolution will be the same for CG and BG. During the first session, it will be explained what is biofeedback and what means everything that appears on the software interface. Positive reinforcements will be verbalized after each PFM contraction using one of the following examples: 1) "Squeeze the probe with your vaginal muscle and try to lift a little more your contraction following the line. That's perfect! Now relax letting the (signal, bird, airplane, balloon or fairy) down"; 2) "Squeeze the probe with your vaginal muscle and try to keep your contraction on the line! Perfection! Now relax letting the (signal, bird, airplane, balloon or fairy) down"; 3) "You are doing a good job, but let's try a stronger contraction. Squeeze a little more your vaginal muscle, Let the (signal, bird, airplane, balloon or fairy) goes a little higher. That's really good! Now relax" 4) "ok, that's a perfect contraction, now tray to keep the strength during the whole contraction, keep the (signal, bird, airplane, balloon or fairy) in the line ".

The two groups will receive a booklet and guidance to perform the training protocol at home on alternate days and a diary to register their adherence to the program. The guided protocol will be the same used during the supervised training on that specific week. Women will be oriented to choose the position to practice unsupervised sessions (i.e. supine,lateral, sitting and/or standing).

Outcome measures: The primary outcomes will be to gain the ability to perform a voluntary PFM contraction assessed by vaginal palpation and classified by the modified oxford scale (MOS). Women able to perform PFM contraction with both occlusion of the vaginal opening and inward movement will be considered able to perform a voluntary PFM contraction, this is the description of MOS grade 3.

Before the assessment, all participants will receive verbal instruction on PFM anatomy and function, as well as the correct way to perform its contraction. After verbal instruction, the participant will be placed in supine position with flexion of the hip, knee and feet supported on the stretcher. The physiotherapist will insert the index finger into the participant's vaginal canal after obtaining her consent and the participants will be instructed to perform three PFM contractions with the following verbal command: "squeeze my finger and pull as hard as you can get". PFM function will be classified according to the modified oxford scale, those with a rating ≥ 3 will be considered capable of performing a correct voluntary PFM contraction. The assessment will be performed in five timepoints: moment 0, after three, six, nine and 12 weeks of treatment. Participants will be assessed by the same trained physiotherapist in all five timepoints. It is expected to have two physiotherapists with more than 5 years with experience in women's health physiotherapy.

Secondary outcomes will be presence of urinary incontinence (UI), UI severity and its impact on quality of life, self-perception of PFM contraction, adherence to supervised and unsupervised treatment, adverse effects, and satisfaction with treatment. Urinary symptoms will be assessed by the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI-SF), absence of UI will be considered as a score of 0 in the ICIQ-UI-SF. Self-perception of PFM contraction will be a self-reported measure classified according to MOS. Adherence to supervised and unsupervised treatment will be assessed with physiotherapist registration of sessions and participants' exercise diary respectively. Adverse effects will be assessed using the following question "Did you experienced any discomfort or warm during supervised treatment?" at the lest assessment timepoint. Satisfaction with treatment will be assessed using a numerical scale (0-10).

Eligibility: It will be included in this study: 1) Women aged 18 or over; 2) referred to the physiotherapeutic treatment of the Lucy Montoro Rehabilitation Center (Ribeirão Preto Medical School) or the Women's Health Reference Center (MATER) for any pelvic floor dysfunction; 3) unable to perform a PFM contraction (i.e. PFM function classified as 0 or 1 according to the modified oxford scale); 4) presence of urinary incontinence (i.e ICIQ-UI-SF score ≥ 3) and; 4) agree to participate in the research by signing the informed consent form.

It will not be included in this study: 1) Women whose pelvic floor dysfunction has an associated neuropathy; 2) vaginal or urological symptoms of possible infections; 3) pelvic organs prolapse that makes it impossible to evaluate or conduct treatment (stage > 2 according to Baden-Walker Scale); 4) pregnant women; 5) women with cognitive impairment and; 6) women with intolerance or pain that prevents the conduct of research protocols.

Women who become pregnant while conducting the study will be excluded from the research.

Randomization (sequence generation and allocation concealment): The randomization of the participants will be done using a computer-generated list of numbers (www.randomization.com). This list will be put in a sealed envelope and participants allocation will be concealed. The researcher responsible for assessment and inclusion of participants in the study will be blinded to which group participants will be allocated to. The research assistant who is responsible for generate the list of randomized numbers and seal the envelope as well as the research assistant responsible to perform patients' allocation will not be involved in the recruitment, assessment of participants or interventions.

Blinding of participants, and treatment providers: not possible

Blinding of outcome measurement: Primary outcome – blinded assessment by a physiotherapist not involved in delivery of therapy or with knowledge of group allocation. All other outcomes – not blinded because they are patient-reported.