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# A pelvic floor muscle training program in postmenopausal women: A randomized controlled trial☆

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ABSTRACT

*Objectives:* The purpose of this study was to investigate if a specific pelvic floor muscle training (PFMT) program effectively increases pelvic floor muscle (PFM) contractility and decreases anterior pelvic organ prolapse (POP) as well as urogynecological symptoms, in postmenopausal women. The mean outcome measure of this study was the pelvic floor surface electromyography (sEMG) activity.
*Study design:* A clinical, randomized, blinded-assessor and controlled study was conducted with 46 postmenopausal women. Thirty women completed this study (mean age of 65.93 years), divided into two groups: Treatment Group – TG ($n = 18$) and Control Group – CG ($n = 12$). The evaluation was carried out using digital palpation, sEMG, pelvic organ prolapse quantification (POP-Q) as well as validated questionnaires by the *International Consultation on Incontinence Questionnaires* to investigate urogynecological symptoms. The treatment protocol consisted of 12 group sessions, twice a week, with 30 min of duration each. These data were then submitted to statistical analyses by the *Statistical Analysis System for Windows software*, with a significance level of 5%.
*Results:* The pelvic floor muscle contractility increased after PFMT, evaluated by sEMG ($p = 0.003$) and digital palpation ($p = 0.001$), accompanied by a decrease in urinary symptoms ($p < 0.001$ for ICIQ-OAB scores e 0.036 for ICIQ UI-SF) as well as anterior pelvic organ prolapse ($p = 0.03$).
*Conclusion:* This preliminary study suggests that the applied PFMT program could be an effective way to increase PFM contractility, as well as to decrease both anterior pelvic organ prolapse and urinary symptoms, in postmenopausal women.



## 1. Introduction

Aging has an important role in urogynecological dysfunctions, especially in the development of both urinary incontinence (UI) and pelvic organ prolapse (POP). The physiological effects of the decrease in estrogen combined with the aging process increase the risk of presenting these dysfunctions in postmenopausal women [1–3]. Furthermore, with the advancing of age there is a decrease in both the diameter and quantity of the periurethral stried muscle fibers [4,5] and hence a change in muscle function [4,6].

Currently, pelvic floor muscle training (PFMT) has been indicated by the International Continence Society (ICS) as a first choice in the prevention and treatment of both stress and mixed UI.

Arnold Kegel [7] is known as the first researcher to use PFMT in the treatment of urogynecological dysfunctions. Soon after his earlier studies, many training protocols have been proposed by other researchers [8,9].

As the studies treating urinary symptoms were being conducted, a concomitant improvement of the pelvic organ prolapse was also observed, which has been the subject of recent publications [10,11].

This training is based on two essential functions of the pelvic floor muscles (PFM) – supporting the pelvic organs and

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contributing to the sphincter urethra closure's mechanism [12]. A voluntary PFM contraction promotes a squeeze and an inward lift of the PFM, resulting in urethral closure, stabilization, and a resistance to downward movement [13].

However, little is known about the effects of such training on PFM's electromyographic activity (evaluation) in postmenopausal women.

Thus, the main aim of this study was to evaluate the effects of a specific PFMT program on PFM contractility in postmenopausal women with urogynecological symptoms.

## 2. Materials and methods

### 2.1. Design

A clinical, randomized, assessor-blinded and controlled study was conducted from January to May 2013 at a Primary Physical Therapy Care Unit in Congonhal, Minas Gerais, Brazil. The women, who had attended in an Elderly Fitness Group at the same care unit, at least for six months, were invited to participate in this study. It was approved by the regional Ethics Review Board (*protocol*: *CAEE06493812.4.0000.5404*) and by the *Brazilian Clinical Trial Register* (*RBR-23NF3S*). All participants gave their informed and written consent according to the Helsinki Declaration.

This study included 46 postmenopausal women during at least 5 years, who presented some urogynecological complaints: stress, urgency or mixed urinary incontinences detected by the *International Consultation on Incontinence Questionnaire Short-Form (ICIQ UI-SF)* questionnaire; urgency either with or without urinary incontinence, urinary frequency higher than eight voids per day and noctury (which are overactive bladder symptoms) by the *International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB)* questionnaire; vaginal symptoms like pain, dryness, heaviness and/or vaginal nodules evaluated by the *International Consultation on Incontinence Questionnaire on Vaginal Symptoms (ICIQ-VS)* questionnaire.

The exclusion criteria were: women with vaginal or urinary infections; pelvic cancer; uncontrolled metabolic disorders (hypertension and diabetes); cognitive, psychiatric or neurological disorder; inability to contract the PFM; POP stage IV according to the *Pelvic Organ Prolapse Quantification System (POP-Q)* and severe heart disease, who were a total of four volunteers ($n = 4$). Specifically for the POP analyses all stage III women were excluded ($n = 3$).

The 42 volunteers included in this study were randomized by draw into two groups: Treatment Group – TG ($n = 21$) and Control Group – CG ($n = 21$). For the randomization process, each participant blindly drew a sealed envelope from a box with 42 of them, each containing a preprinted card with either CG or TG written on it and was put in one of the two groups according to the drawn card.

The study was performed by two investigators (FKA and DBVA). The treatment protocol was conducted by the main investigator (FKA) and PFM contractility evaluation was carried out by the second investigator (DBVA) who was unaware of the treatment protocol, in order to blind the analysis.

### 2.2. Primary outcomes

#### 2.2.1. Pelvic floor muscle assessment

PFM contractility evaluation was performed through digital palpation as well as surface electromyography (sEMG), seven days before then after the PFMT program, putting the subjects in supine position, with their lower limbs flexed and their feet on the stretcher [14].

PFM contractility evaluation was conducted first by digital palpation where the index and middle fingers were introduced 2–3 centimeters into the vaginal introitus, performing an abduction movement, while the patients were asked to perform a maximum contraction of the muscles, lifting inward and squeezing around the fingers. Muscle contractility was graded according to the *Modified Oxford Grading Scale* (zero to five points) [15].

Thus, during the initial evaluation, the patients were also taught how to contract their PFM correctly (they were asked to breathe normally and then lift the perineum inwards and squeeze around the vagina without any movement of the pelvis or visible co-contraction of the gluteal or hip-adductor muscles), while the appropriate contractions were confirmed by digital palpation.

PFM contractility was also registered using a sEMG equipment (*EMG System do Brasil®*), which consisted of a signal conditioner with a band pass filter with cut-off frequencies at 20–500 Hz, an amplifier gain of 1000× and a common mode rejection ratio of >120 dB. All data were processed using specific software for acquisition and analysis (*AqData®*). Moreover, a 12-bit A/D (analog to digital converter) signal converting plate was used to convert analog signals into digital ones with a 2.0 kHz anti-aliasing filter sampling frequency and an input range of 5 mV.

Surface EMG was recorded using a vaginal probe (*Physio-Med Services®*), which has two opposing metal sensors. The probe was inserted and manually positioned into the vagina, by the researcher, with the aid of *hypoallergenic gel* (*KY – Johnson's & Johnson's®*), with its metallic sensors placed laterally [14]. The reference surface electrode was positioned on the right wrist (between the radius and the styloid process of the ulna).

The sEMG evaluation protocol consisted of three maximal voluntary PFM contractions, recorded by the vaginal probe (channel 1). The PFM contraction has been previously taught to the volunteers, asking them to lift the probe in a cranial direction and observe its contraction graphs on the computer screen. Each requested contraction, was performed with a rest period of 3 min, in order to avoid muscle fatigue [14].

### 2.3. Secondary outcomes

#### 2.3.1. Assessment of urogynecological symptoms

Culturally adapted and validated versions of the questionnaires by the International Consultation on Incontinence modular questionnaire – *ICIQ* (http://www.iciq.net/) [16] were used to evaluate the presence of urinary and vaginal symptoms: *International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF)* [17]; *International Consultation on Incontinence Overactive Bladder Questionnaire (ICIQ-OAB)* [18]; and *International Consultation Questionnaire on Vaginal Symptoms (ICIQ-VS)* [19].

#### 2.3.2. Pelvic organ prolapse assessment

To investigate pelvic organ prolapse presence the *POP-Q System* was used [20].

#### 2.3.3. Satisfaction with the treatment

Additionally, a visual analog scale ranging from 0 to 10 was used to evaluate the level of satisfaction with the treatment.

### 2.4. Pelvic floor muscle training program

All women performed a Fitness Program based on global muscle stretching, endurance and functional exercises for the elderly, which was supervised by a physical educator. Just before starting the Fitness Program sessions, the women from the TG were divided into groups of seven people and performed the PFMT protocol, which consisted of 12 sessions of 30 min each, twice a week, totalizing a six week treatment, supervised by the main researcher (physiotherapist FKA).



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