

ORIGINAL RESEARCH—FSD PHARMACOTHERAPY

Sexual Function and Quality of Life of Women with Stress Urinary Incontinence: A Randomized Controlled Trial Comparing the Paula Method (Circular Muscle Exercises) to Pelvic Floor Muscle Training (PFMT) Exercises

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ABSTRACT

Aim. To compare the effectiveness of the Paula method (circular muscle exercises) vs. pelvic floor muscle training (PFMT) exercises on sexual function (SF) and quality of life (QoL) of women with stress urinary incontinence (SUI).

Methods. A randomized controlled trial (RCT) was conducted in outpatient urban community clinics serving diverse socioeconomic populations between September 2004 and July 2005. The intervention included two exercise regimens: Paula method—12 weeks of private 45 minutes sessions; PFMT—12 weeks of group (up to 10 participants) sessions of 30 minutes in length once a week, for 4 weeks plus two additional sessions, 3 weeks apart.

Main Outcome Measures. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; the Incontinence Quality of Life Questionnaire; 1-hour clinic pad test; gynecological examination; demographic/health history.

Results. Sixty-six women in the Paula group and 60 women in the PFMT group. The mean SF scores post interventions were 38.72 (5.35) in the Paula group and 38.07 (5.80) in the PFMT group. SF score improvement was found to be significant in both groups (Paula, $P = 0.01$; PFMT, $P = 0.05$), as was in the QoL scores (Paula, $P < 0.001$; PFMT, $P \leq 0.001$), with no significant difference between groups. There was a significant correlation between the mean SF score and the mean QoL score after the intervention (Paula: $r = 0.4$, $P = 0.002$; PFMT: $r = 0.4$, $P = 0.009$). A mild to moderate significant correlation was also found between the SF score and pad test results in both groups post intervention ($r = -0.3$, $P = 0.02$; $r = -0.3$, $P = 0.04$, respectively).

Conclusion. This RCT study demonstrated the effectiveness of two exercise methods on SF and QoL in women suffering from SUI. The Paula method of exercise was presented for the first time in the literature as a conservative noninvasive treatment for SUI and SF. Liebergall-Wischnitzer M, Paltiel O, Hochner Celnikier D, Lavy Y, Manor O, and Woloski Wruble AC. Sexual function and quality of life of women with stress urinary incontinence: A randomized controlled trial comparing the Paula method (circular muscle exercises) to pelvic floor muscle training (PFMT) exercises. *J Sex Med* 2012;9:1613–1623.

Key Words. Stress Urinary Incontinence; Sexual Function; Noninvasive Interventions; Pelvic Floor Muscle Training; Paula Method

This randomized controlled trial is registered on <http://www.clinicaltrials.gov>. no. NCT00197314.

Introduction

Urinary incontinence (UI) has an overall prevalence of 25% in adult women and increases with age. UI is subdivided into different types which mainly include: stress UI (SUI), urgency UI (URI), and mixed UI (MIX) [1,2]. SUI is the most frequently found type of incontinence (50%), and peaks between the ages of 45 and 49. SUI has been documented as affecting a woman's quality of life (QoL) specifically in the areas of avoidance and limiting behaviors, psychosocial behaviors, and sexual function (SF) [3–8]. In general, women with SUI report fear and embarrassment related to penetration incontinence, pain during intercourse, less ability to reach orgasm, less lubrication, and a decrease in satisfaction [6,9–11]. Besides surgical interventions, there are a wide range of conservative treatments for incontinence including lifestyle and behavioral interventions, pharmacological treatments, vaginal cones, biofeedback, and pelvic floor muscle training (PFMT) [12,13].

PFMT is recommended as a first-line treatment for all UI types [2] and was found to be effective in women with SUI in their 40s and 50s who participated in supervised programs for a minimum of a 3-month period [12]. PFMT is based on the exercising of the levator ani muscles. The pubococcygeal muscle, a part of the levator ani, is the main support for the bladder neck during the time of increased intra-abdominal pressure [14,15]. The aim of PFMT is to improve the timing of vaginal muscle contractions while strengthening them [12].

Recently, an additional conservative treatment has been reported as effective for SUI treatment. The Paula method is a circular muscle exercise protocol that works on the premise that all sphincters in the body are synchronized, with the movement of one affecting the other [16]. The Paula method theory claims that one can rehabilitate damaged muscles by contracting and relaxing specific “circular” muscles in other areas of the body. For example, according to the theory, levator ani muscle weakness resulting in SUI, can be improved by exercising circular muscles of the eye, mouth, and others [16]. The exact mechanism is unknown though speculations have been raised that one sphincter affects others due to oscillations in the spinal cord [17]. The Paula method has been used in Israel for several decades and found to be effective in three clinical trials [3,4,18].

There is a growing but limited non-randomized-controlled-trial (RCT) literature concerning SF before and after surgery [10,11] for SUI, and only a few RCTs focus on SF in women with SUI before and after noninvasive treatment [19–21]. Two of these [20,21] included postnatal women, and none have examined the Paula method in relation to SF. The objective of this study was to compare the effectiveness of the Paula method vs. the PFMT on SF and QoL of women with SUI.

Methods

This study presents original findings related to SF, from part of an RCT which examined the efficacy of two exercise interventions for women with SUI. The results regarding urinary leakage have previously been reported [4].

Study Population

Announcements and contact information were placed in local newspapers and outpatient clinic bulletin boards in three communities for women with SUI symptoms. Primary telephone screening included women who described themselves as healthy in general, aged 20–65 with a history of self-reported SUI, and the ability to understand instructions in Hebrew or English. Exclusion criteria were: pregnant or breastfeeding women as well as those within 12 weeks of delivery, 6 weeks of abortion, or 6 months of pelvic surgery. Eligible candidates were invited to a clinical appointment which included a 1-hour clinical pad test. If the pad test result was ≥ 1 g, the woman was examined by a study gynecologist. The gynecologist's examination determined final eligibility for inclusion in the study which excluded women with grade three or higher pelvic organ prolapse; women with cardiac, respiratory, psychiatric, and/or neurological illnesses that limited physical activity; previous surgery for UI; or previous pelvic radiation therapy.

Study participants were given a study number and the contact information of the research coordinator from whom they obtained their exercise group assignment. Participants were randomized to one of two research groups, Paula or PFMT instruction, and stratified by age (20–50 and 51–65) and place of residence, in order to keep those groups representation. The nurses who administered the pad test before and after the intervention were blinded to the intervention group. The research coordinator was blinded to the participants' baseline status and was only aware

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