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Pelvic floor muscle training as a treatment for genitourinary syndrome of menopause: A single-arm feasibility study

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ABSTRACT

Objectives: Treatments for genitourinary syndrome of menopause (GSM) may not be suitable for all women, may not be completely effective, and may cause adverse effects. Therefore, there is a need to explore new treatment approaches. The objectives were to evaluate the feasibility of using a pelvic floor muscle training (PFMT) program in postmenopausal women with GSM, and to investigate its effect on symptoms, signs, activities of daily living (ADL), quality of life (QoL) and sexual function.

Study design: Postmenopausal women with GSM participated in a single-arm feasibility study embedded in a randomized controlled trial (RCT) on PFMT for urinary incontinence. This substudy was composed of two pre-intervention evaluations, a 12-week PFMT program and a post-intervention evaluation.

Main outcome measures: Feasibility was defined as study completion and participation in physiotherapy sessions and in-home exercises. The effects of the PFMT program were assessed by measuring GSM symptoms ('Most Bothersome Symptom' approach, ICIQ-UI SF), GSM signs (Vaginal Health assessment scale), GSM's impact on ADL (Atrophy Symptom questionnaire), QoL and sexual function (ICIQ-VS, ICIQ-FLUTSsex) and leakage episodes.

Results: Thirty-two women participated. The study completion rate was high (91%), as was participation in treatment sessions (96%) and in-home exercises (95%). Post-intervention, there were significant reductions in GSM symptoms and signs ($p < 0.01$) as well as in its impacts on ADL, QoL and sexual function ($p < 0.05$).

Conclusions: A study including a PFMT program is feasible, and the outcomes indicate PFMT to be an effective treatment approach for postmenopausal women with GSM and urinary incontinence. This intervention should be assessed through a RCT.

1. Introduction

Genitourinary syndrome of menopause (GSM) is defined as a collection of genital and urinary symptoms and signs associated with a decrease in estrogen and other sex steroids [1]. It leads to changes to the vulva, vagina, urethra and bladder [1], causing bothersome symptoms such as vaginal dryness, pruritus, dyspareunia and urinary incontinence (UI) [2]. Most common treatments for GSM include vaginal hormonal therapy (HT) and moisturizer [2]. Vaginal HT provide estrogen to uro-vaginal tissues, which induces normal cellular maturation

Abbreviations: GSM, genitourinary syndrome of menopause; UI, urinary incontinence; HT, hormonal therapy; PFM, pelvic floor muscle training; PFM, pelvic floor muscle; ADL, activities of daily living; QoL, quality of life; RCT, randomised control trial; BMI, body mass index; PRE1, pre-intervention 1; PRE2, pre-intervention 2; POST, post-intervention; MBS, most bothersome symptom

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and restores a lactobacilli-predominant flora [3]. It is nevertheless recommended to be used with precautions for breast cancer survivors receiving aromatase inhibitors and can cause adverse effects as uterine bleeding, endometrial stimulation and breast pain [4,5]. Vaginal moisturizers are non-hormonal treatments that rehydrate the vaginal mucosa and act like secretions [6]. There are no contraindications to these treatments, but they may cause mild irritation [6]. More recently, laser technologies have been offered to women with GSM. This non-hormonal treatment is thought to induce a healing cascade to vaginal mucosa by causing micro areas of thermal necrosis to the tissues [7]. However, there is too little data regarding the efficacy and the adverse effects to recommend its use [8]. In a 2017 US survey of women with GSM, 56% of women treated with vaginal HT, systemic HT or vaginal moisturizers reported still feeling symptoms and to be "somewhat or not satisfied" with their treatment efficacy [9]. Therefore, there is a need to explore safe and effective complementary or alternative GSM treatments.

Pelvic floor muscle training (PFMT) refers to exercises for improving PFM strength, endurance, power and/or relaxation [10]. It is taught and monitored by health professionals such as physiotherapists [10]. PFMT was proven to be effective in the treatment of UI [11] and pelvic organ prolapses [12,13]. With its low-cost and minimal adverse effects, it is recommended as first-line treatment for pelvic floor dysfunctions [11]. In a recent case study from our research group, a 12-week PFMT program appeared to reduce GSM symptoms and signs in a post-menopausal woman with UI [14]. However, no clinical study has yet assessed the effects of this novel treatment approach on GSM. A feasibility study is needed prior to conducting a randomized control trial (RCT) to investigate the acceptability of vaginal assessments and of PFMT treatment within this specific study population (postmenopausal women having vaginal discomfort) as well as to explore the potential effects of this intervention on GSM.

The aims of this study were 1) to evaluate the feasibility of conducting a clinical study including vaginal assessments and a PFMT program in postmenopausal women with GSM and 2) to investigate the effects of a PFMT program on GSM symptoms, GSM signs, activities of daily living (ADL), quality of life (QoL) and sexual function.

2. Methods

2.1. Study design and population

A cohort study was carried out as a substudy of a RCT on PFMT for UI in older women [15]. The recruitment for this mother-study was done through community advertisements, newspaper ads and professional referrals. Women included were aged 55 years old and over, having stress or mixed UI at least three times a week. They were excluded if they were obese (BMI ≥ 35), had reduced mobility, chronic constipation and organ prolapses [15]. Details of all inclusion/exclusion criteria of the mother-study are presented in the study protocol [15].

For the present substudy, participants were contacted after the initial assessment of the mother-study if they reported the following GSM symptoms in the last two weeks: vaginal dryness, vaginal itching/irritation, dysuria or dyspareunia. If they agreed to participate in the substudy, an assessment with a gynecologist was scheduled to confirm the diagnosis of GSM. Women who had at least two of the following GSM signs were included: petechiae, absent rugae, decreased elasticity and friability of the vaginal wall [16]. Participants were excluded if they had vulvar dermatological diseases, had been treated with radiation for gynecological cancer, or were taking antiestrogenic medication. Moreover, the dosage of HT as well as usage of vaginal moisturizer had to be stable for at least six months before their participation in this study to ensure symptoms stability.

The present study received ethical approval from the Institutional Review Board of the Institut universitaire de gériatrie de Montréal (Canada)(approval number CER-IUGM-12-13–002) and women provided their written consent prior their participation.

For the present substudy, each woman completed two pre-intervention evaluations (PRE1 and PRE2), a 12-week PFMT program and a post-intervention evaluation (POST). PRE2 was conducted two weeks after PRE1 to document stability of some GSM symptoms and signs measurements. At the end of PRE2, participants were taught, using vaginal digital palpation, how to do a maximal PFM contraction without compensation (gluteal, adductor and abdominal muscle contraction) to ensure correct PFM contraction during the program. POST was performed at the end of the intervention.

2.2. Outcome measurements

2.2.1. Feasibility

Feasibility was defined by assessing the level of study completion, participation in physiotherapy treatment sessions and in-home exercises. Study completion was calculated as the proportion of participants completing the final assessment and at least ten of a total of twelve treatment sessions. Participation in treatment sessions was represented by the percentage of attendance at weekly sessions per participant and participation in a home exercises program by the percentage of weekly home exercises executed, as reported in each participant's exercise diary.

2.2.2. Effect of PFMT on GSM

Evaluation considered GSM symptoms and signs as well as their impact on ADL, quality of life and sexual function.

GSM symptoms were assessed with the Most Bothersome Symptom (MBS) approach and the ICIQ Urinary incontinence short form (ICIQ-UI SF). The MBS approach makes participants rate the severity of four symptoms (1-vaginal dryness, 2-vaginal itching/irritation, 3-dysuria and 4-dyspareunia) on a 4-point scale from 0 (not present) to 3 (severe). Then, women must identify a single symptom as the most bothersome [17]. The ICIQ-UI SF assesses the severity of UI with questions on frequency, amount and impact on QoL of UI, with a total score of 21 points [18].

GSM signs were evaluated using the Vaginal Health Assessment scale. The Vaginal Health Assessment scale evaluates five items of the vagina on a 4-point scale from 0 (no atrophy) to 3 (severe atrophy). Four are rated through observations of the vaginal mucosa using a pediatric speculum (1-secretions, 2-epithelial integrity, 3-epithelial surface thickness, 4-color) and one (5-pH) through hydrion pH-paper applied to the lateral vaginal wall. Total score consists of the summary of each item divided by five [19]. Finally, as UI is part of GSM symptoms, the 7-day bladder diary was also used to add information of the number of UI episodes in a week [20].

Impact of GSM on ADL, quality of life and sexual function was assessed using the Atrophy Symptom questionnaire, the ICIQ-Vaginal Symptoms (ICIQ-VS) and the ICIQ-Female Sexual Matters associated with Lower Urinary Tract Symptoms (ICIQ-FLUTSsex). The Atrophy Symptom questionnaire comprises four items assessing the impact of GSM symptoms on ADL (1-vaginal dryness, 2-vaginal soreness, 3-vulvo-vaginal irritation, 4-vaginal discharge) and one item assessing impact on sexual function (5-dyspareunia) [19]. Only women having intercourse are requested to answer the last question. For the total score, the individual items' scores rated with a 4-point scale from 0 (none) to 3 (severe) are summed and divided by five for women having intercourse or by four for those not having intercourse [19]. For the ICIQ-VS, two of the three subscales were used for this study (QoL and sexual matters) [21]. QoL subscale consists of one question rating the impact of vaginal symptoms on everyday life from 0 (not at all) to 10 (a great deal) while Sexual Matters subscale is composed of three questions about the impact of vaginal symptoms on interference with sex life, on relationship with the sexual partner and on global sex life (total score of 58). The ICIQ-FLUTSsex also investigates vaginal symptoms on sexual matters. It

is comprised of four questions about vaginal dryness, impact of UI on sex life, dyspareunia and UI during intercourse with a total score of 14 [22].

Outcome measurements (except one) included in this study showed good reliability in aging women [18,20,23,24] and most of them were shown to be valid [18,23,24]. Good sensitivity to change [18,24,25] and internal consistency [24] were also found for many of these outcome measures. While the psychometric properties of the Vaginal Health Assessment scale have not been investigated, many scientific publication have used this tool in the past to look at the effects of GSM treatment [26].

2.3. Intervention

The 12-week PFMT program was an intensive PFM physiotherapy treatment included in the mother-study. It was composed of weekly 1-hour sessions supervised by an experienced physiotherapist, and daily home-based PFM exercises [15]. Each treatment session consisted of a 15-minute educational segment and a 45-minute exercise component. The exercise component included PFM strength, endurance and coordination exercises as well as functional PFMT. Women also had to practice four home-based PFM exercises (from 9 to 30 repetitions), five days a week, for the duration of the treatment (for a total of 220 exercises in 12 weeks). The intervention protocol was divided into three phases allowing for a gradual progression in PFMT. For more details, see the mother-study protocol [15].

2.4. Statistical analysis

The statistical analyses were performed using the SPSS software, version 20. Descriptive analysis was used for study completion and for treatment sessions and home exercises participation. One-way repeated analysis of variance (ANOVA) were used to investigate the differences in GSM outcomes assessed at PRE1, PRE2 and POST, which are the MBS approach, the Atrophy symptom questionnaire and the Vaginal Health assessment scale. Paired-samples *t*-test were computed to detect statistical differences in outcomes evaluated at PRE1 and POST, which are the ICIQ-UI SF, the bladder diary, the ICIQ-VS and ICIQ-FLUTSsex. The statistical significance level of both analysis was $p < 0.05$.

3. Results

3.1. Participant baseline characteristics

Participant characteristics are detailed in the Table 1. A total of 32 women with a mean age of 68.0 ± 6.6 years old were recruited from June 2015 to July 2017. Three women dropped out of the study for personal reasons (time constraint) but their baseline data didn't differ from the other participants. Among the participants having completed the study, 20 (69%) were having sexual intercourse. Five participants (17%) had stress UI and twenty-four had urgency UI (83%). Ten participants (34%) were receiving GSM symptom treatment which remained stable in dosage and use during their participation in the study (vaginal HT alone: 6; vaginal HT and systemic HT: 1; vaginal HT and vaginal moisturizer: 1; systemic HT alone: 1; vaginal moisturizer alone: 1).

Table 1
Baseline characteristics.

Parameters	
Mean age (years ± SD)	68.0 ± 6.6
Parity (deliveries ± SD)	1.8 ± 1.1
Body mass index (mean ± SD)	26.0 ± 4.5
Sexual status (%)	
Having intercourse	20 (69%)
No intercourse	9 (31%)
Continence status (%)	
Stress urinary incontinence	5 (17%)
Urgency urinary incontinence	24 (83%)
Treatment for GSM (%)	
None	19 (65%)
Following treatment	10 (34%)
Local hormonal therapy	8 (28%)
Systemic hormonal therapy	2 (7%)
Non-hormonal vaginal moisturizer	2 (7%)

3.2. Feasibility: study completion and participation

The study was completed by 29/32 participants (91%). Women complied with the PFMT program in terms of participation in the physiotherapy treatment sessions (mean of 11.5/12; 96%), and in the home exercises program (mean of 210/220; 95%). No one reported adverse effects with vaginal assessments and the PFMT program.

3.3. Effect of PFMT program on GSM

At baseline, 24/29 participants (83%) reported suffering from vaginal dryness; 18/29 (62%) reported vaginal itching/irritation and 3/29 (10%) reported dysuria. All women who were sexually active and having intercourse (20/29 (69%)) reported dyspareunia. For the MBS, 13/29 of the women (44%) selected vaginal dryness; 6/29 (21%) vaginal itching/irritation and 10/29 (34%) dyspareunia. After the PFMT program, the severity of the MBS was improved ($p < 0.001$) (Fig. 1). Looking at raw data, 22/29 of participants (76%) reported improvement in this symptom, including four of whom had no more symptoms. None of the participants reported an increase in its severity. Of interest, 9/29 of the participants (31%) reported having more vaginal discharge after the intervention. For the UI symptoms, severity decreased by 5.24 ± 3.97 points on the ICIQ-UI SF after the intervention ($p < 0.001$).

GSM signs improved on the Vaginal Health Assessment scale total score ($p < 0.001$), particularly for vaginal secretions, vaginal epithelial thickness and vaginal color (Table 2). Moreover, frequency of weekly UI decreased by 8.48 ± 8.59 episodes in the bladder diary ($p < 0.001$) (Table 3).

As assessed with the Atrophy Symptom questionnaire, the impact of GSM symptoms on ADL decreased ($p < 0.001$) (Table 2). Looking at each item of the questionnaire, results were significant for vaginal dryness, vulvo-vaginal irritation and dyspareunia symptoms ($p < 0.05$) (Table 2). A reduction of the impact of GSM on QoL (ICIQ-VS QoL subscale ($p < 0.001$); and on sexual function (ICIQ-VS sexual matters subscale; $p = 0.001$; ICIQ-FLUTSsex; $p = 0.014$) was also observed (Table 3).

3.3.1. Participants with vaginal HT

Among the participants, eight women were using vaginal HT for GSM symptoms, which is currently the gold standard treatment. When looking at their data separately, we found a significant reduction in their MBS severity after the PFMT program ($p \leq 0.005$) (Table 4) with 7/8 of women (88%) reporting improvement of a least one level. GSM signs also improved on the Vaginal Health Assessment scale ($p \leq 0.003$). Furthermore, looking at each item separately, results were significant only for the vaginal color item ($p \leq 0.008$) and there was a tendency for improvement in vaginal secretions ($p \leq 0.063$). On the Atrophy Symptom questionnaire, the impact of GSM symptoms on ADL was reduced, but was not significant for one of the two PRE-POST-intervention comparisons (Table 4). There was a reduction of the impact of GSM on QoL and on sexual function, but results were significant only on the ICIQ-VS Sexual Matters subscale ($p = 0.029$) (Table 4).

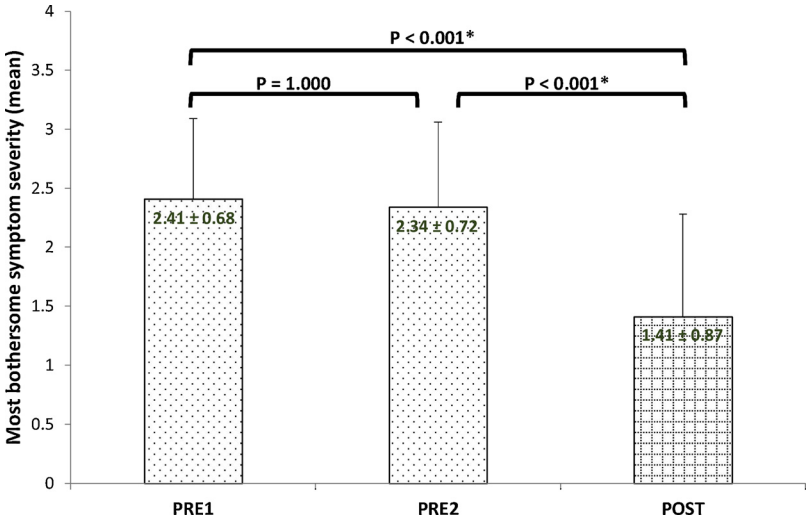

Fig. 1. Severity of the most bothersome symptom of GSM.
Legend: Mean ± SD of severity of the most bothersome symptom of GSM assessed with a scale of 0 = none, 1 = mild, 2 = moderate, 3 = severe before and after the intervention (PFMT program). PRE1, pre-intervention evaluation 1; PRE2, pre-intervention evaluation 2; POST, post-intervention evaluation 2. * Indicates level of statistically significant improvement ($p < 0.05$).

4. Discussion

This single-arm feasibility study is, to our knowledge, the first to explore the use of a PFMT program as a treatment for GSM. It showed that postmenopausal women with GSM can comply with study demands (vaginal assessments and physiotherapy treatment) as demonstrated by the high study completion rate and participation in both supervised treatment and home exercises programs. No adverse effects were reported concerning the vaginal assessments and the PFMT program. Moreover, our results suggest that a PFMT program is a promising intervention to improve GSM, showing significant reduction in GSM symptoms and signs, and in the impact of GSM on ADL, QoL and sexual function. Of interest, when separating the women using vaginal HT during the study, significant improvements were found in both GSM symptoms and signs and their impact on sexual function.

While no study has assessed PFMT alone as an intervention for GSM, one RCT investigated the addition of a combination of PFMT and electrostimulation to a vaginal HT regime in women with GSM, stress UI and recurrent urinary infections [27]. After a 6-month intervention, a higher improvement rate was found in the combined treatment (PFMT and electrostimulation added to vaginal HT) compared to the control treatment (vaginal HT alone) [27]. As in our study in which participants already taking vaginal HT showed improvement of GSM symptoms, these results support the possible added value of PFMT for women already receiving the current gold standard in GSM treatment.

Table 3
Change in participants' reported outcomes following a pelvic floor muscle training program.

	PRE1 (Mean ± SD)	POST (Mean ± SD)	p value
ICIQ-UI SF (/21)	11.41 ± 2.77	6.17 ± 4.71	< 0.001*
Bladder diary (Number of UI/week)	11.79 ± 9.59	3.31 ± 3.67	< 0.001*
ICIQ-VS QoL subscale (/10)	3.04 ± 3.34	0.79 ± 1.40	< 0.001*
ICIQ-VS Sexual Matters subscale(/58)	39.25 ± 16.71	23.67 ± 13.96	0.001*
ICIQ-FLUTSsex(/14)	6.69 ± 3.14	4.93 ± 3.50	0.014*

* Statistically significant ($p < 0.05$).

Although few studies have involved women with GSM, PFMT programs have been shown to be effective to improve vaginal symptoms and/or their impact on sexual function in other populations. For example, gynecological cancer survivors, who have similar symptoms to women with GSM because of adverse effects of treatments, have shown improved dyspareunia and sexual function after a 4-week PFMT program including PFM exercises and biofeedback sessions [28]. Some studies also looked at the effects of PFMT on sexual function in women and had positive results after programs of 6 weeks to 12 months [29,30].

Table 2
Change in GSM outcome measures following a pelvic floor muscle training program.

	PRE1 (Mean ± SD)	PRE2 (Mean ± SD)	POST (Mean ± SD)	P value		
				PRE1-PRE2	PRE1-POST	PRE2-POST
Vaginal Health Assessment scale						
Vaginal secretions (/3)	1.55 ± 0.78	1.48 ± 0.83	0.59 ± 0.78	1.000	< 0.001*	< 0.001*
Vaginal epithelial integrity (/3)	0.34 ± 0.55	0.38 ± 0.49	0.21 ± 0.49	1.000	0.635	0.172
Vaginal epithelial thickness (/3)	1.59 ± 0.57	1.55 ± 0.57	1.03 ± 0.42	1.000	< 0.001*	< 0.001*
Vaginal color (/3)	1.21 ± 0.73	1.24 ± 0.58	0.41 ± 0.57	1.000	< 0.001*	< 0.001*
Vaginal pH (/3)	2.38 ± 0.68	2.28 ± 0.84	2.07 ± 0.84	1.000	0.143	0.680
Total score (/3)	1.37 ± 0.46	1.36 ± 0.42	0.86 ± 0.42	1.000	< 0.001*	< 0.001*
Atrophy Symptom Questionnaire						
Vaginal dryness impact on ADL (/3)	1.69 ± 1.07	1.72 ± 0.84	0.97 ± 1.02	1.000	0.001*	0.001*
Vaginal soreness impact on ADL (/3)	0.10 ± 0.41	0.17 ± 0.47	0.07 ± 0.26	0.483	1.000	0.792
Vulvo-vaginal irritation impact on ADL (/3)	0.66 ± 0.86	0.68 ± 0.81	0.28 ± 0.45	1.000	0.004*	0.041*
Vaginal discharge impact on ADL (/3)	0.14 ± 0.44	0.28 ± 0.59	0.03 ± 0.19	0.130	0.553	0.050
Dyspareunia impact on sexual function (/3)	2.00 ± 0.84	1.95 ± 1.02	1.19 ± 1.12	1.000	0.004*	0.004*
Total score (/3)	0.85 ± 0.37	0.87 ± 0.38	0.45 ± 0.34	1.000	< 0.001*	< 0.001*

ADL, activities of daily living.
* Statistically significant ($p < 0.05$).

Table 4
Change in outcome measures in participant with vaginal hormonal therapy following a pelvic floor muscle training program.

	PRE1 (Mean ± SD)	PRE2 (Mean ± SD)	POST (Mean ± SD)	P value		
				PRE1-PRE2	PRE1-POST	PRE2-POST
MBS severity (/3)	2.62 ± 0.52	2.50 ± 0.53	1.50 ± 0.53	1.000	0.005*	0.003*
Vaginal Health Assessmentscale (/3)	1.12 ± 0.26	1.07 ± 0.21	0.62 ± 0.27	1.000	0.002*	0.003*
AtrophySymptom Questionnaire (/3)	0.88 ± 0.30	0.83 ± 0.33	0.39 ± 0.22	1.000	0.022*	0.065
ICIQ-VS QoL subscale (/10)	3.38 ± 3.81		1.12 ± 1.25	0.108		
ICIQ-VS sexualmatterssubscale (/58)	41.00 ± 19.31		23.60 ± 8.53	0.029*		
ICIQ-FLUTSsex (/14)	6.13 ± 2.90		4.12 ± 3.23	0.095		

* Statistically significant ($p < 0.05$).

PFMT is therefore a feasible, effective and safe treatment with no side effects, as reported in our study. It could become a treatment of interest for women for whom other GSM treatments are contraindicated or are causing adverse effects. Moreover, with the high proportion of women treated for GSM still reporting symptoms with current treatments [1], PFMT could also become a complementary therapy.

The positive effects of PFMT on GSM may be explained by different hypotheses. First, vulvo-vaginal blood flow could be improved by repeated local muscle activation. That would explain the improvement of vaginal secretions and vaginal color obtained in our study. Second, as our population was composed of women with GSM and UI, a decrease in UI episodes could reduce vulvar irritation. Finally, PFMT, in normalizing PFM tone and improving PFM coordination, could reduce vulvo-vaginal tissues' frictions during activities of daily living and sexual activities.

4.1. Strengths, limitations and further studies

Regarding the strengths of this single-arm feasibility study, diagnostics of GSM were confirmed by a gynecologist based on a standardized objective assessment on physical exam. Furthermore, PFM contractions were taught using vaginal palpation by experienced physiotherapists and the intervention involved a standardized and progressive program known to improve PFM function. To explore the effects of the intervention, we used reliable and valid outcome measures. As our study didn't include a control group, two pre-intervention assessments (PRE1 and PRE2) allowed us to verify the stability of some measurements before the intervention. Moreover, the study evaluator and physiotherapists involved in the intervention were different people.

The lack of a control group and the limited sample size in our study should be taken into account in the interpretation of our preliminary data. However, the positive results found in this study, in terms of feasibility and effect, support the need for a RCT investigating this novel treatment approach to the absence of treatment. To further generalize the results in future RCTs, populations should include women of all ages with natural postmenopausal status, those with or without UI and those having GSM symptoms with or without vaginal HT. This could accelerate the recruitment process, which took two years for this study. Moreover, the participants and the evaluator should be blinded from the intervention to prevent bias. Future RCTs should also include long-term follow-up to evaluate whether the treatment effects can be sustained over time.

5. Conclusions

A PFMT program is a feasible treatment approach and a promising treatment for postmenopausal women with GSM and UI. Participants complied with the vaginal assessments and the PFMT program, which reduced GSM symptoms and signs as well as the impact on ADL, QoL and sexual function. This intervention should be assessed in more depth through a RCT.

Contributors

Joanie Mercier contributed to protocol and project development, data collection, data analysis, and manuscript writing.

Mélanie Morin contributed to protocol and project development, and manuscript editing.

Dina Zaki contributed to project development, medical diagnosis and physical examinations, and manuscript editing.

Barbara Reichetzer contributed to project development, and manuscript editing.

Marie-Claude Lemieux contributed to project development, and manuscript editing.

Samir Khalifé contributed to project development, and manuscript editing.

Chantale Dumoulin contributed to protocol and project development, and manuscript writing.

Conflict of interest

The authors declare that they have no conflict of interest.

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Ethical approval

The present study received ethical approval from the Institutional Review Board of the Institut universitaire de gériatrie de Montréal (Canada)(approval number CER-IUGM-12-13–002) and women provided their written consent prior their participation.

Provenance and peer review

This article has undergone peer review.

Research data (data sharing and collaboration)

There are no linked research data sets for this paper. Data will be made available on request and upon IRB approval.

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