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ORIGINAL ARTICLE

Pilot Study of a Novel Online Comprehensive Pelvic Floor Program for Urinary Incontinence in Women

Katherina Y. Chen[1] · Marieke K. Jones[2] · Jacqueline M. Zillioux[1] · David E. Rapp[1]

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Abstract

Introduction and hypothesis Urinary incontinence (UI) is common in women and has a vast impact on quality of life (QOL), financial health, and work disability. Robust evidence demonstrates the efficacy of comprehensive conservative therapy (pelvic floor muscle training [PFMT], and behavioral and dietary modification) in the treatment of UI. However, numerous barriers impede access to this care, including limited specialized therapists, financial barriers, and scheduling obstacles. To address these barriers, we developed a novel comprehensive online pelvic floor program (oPFP).

Methods We performed a prospective study assessing continence and QOL outcomes in women with stress urinary incontinence (SUI), urge urinary incontinence (UUI), or mixed urinary incontinence (MUI) treated with oPFP between May 2019 and November 2022. Outcomes were assessed at baseline and following completion of the 2-month program using the validated International Consultation on Incontinence Questionnaire—Female Lower Urinary Tract Symptoms, Urgency Perception Scale (UPS), Incontinence Impact Questionnaire (IIQ-7) questionnaires, and 24-h bladder diary. Data were analyzed using linear, Poisson mixed models, or generalized estimating equations.

Results Twenty-eight women (2 SUI, 3 UUI, 23 MUI) were enrolled and 19 (2 SUI, 2 UUI, 15 MUI) completed the study. Following oPFP, participants showed significantly improved SUI domain scores (3.04 ± 0.19 vs 1.81 ± 0.23, $p < 0.001$), UPS reason score (2.52 ± 0.18 vs 2.05 ± 0.14, $p = 0.003$), IIQ-7 sum scores (5.16 ± 0.88 vs 3.07 ± 0.70, $p = 0.038$), and daily incontinence episodes (2.96 ± 0.60 vs 1.06 ± 0.29, $p < 0.001$). Mean patient-reported improvement was 5.4 ± 2.5 (ten-point Likert scale). Of respondents, 89% reported program satisfaction, ease of use, and would recommend the program to others.

Conclusion The oPFP results in significant improvements to a variety of UI and QOL measures. This program provides an important UI treatment option and gives women greater access to effective conservative therapy.

Keywords Pelvic floor therapy · Urge urinary incontinence · Stress urinary incontinence

Introduction

Urinary incontinence (UI) is one of the most common health issues in women, with prevalence rates of stress (SUI), urge (UUI), and mixed (MUI) urinary incontinence estimated to be 48%, 17%, and 34% respectively [1]. It is a condition that significantly impairs the quality of life (QOL) of affected individuals, presenting substantial psychological, social, and economic burdens [2]. Additionally, anxiety and depression are nearly twice as likely in patients with UI [3] and urgency urinary incontinence is a risk factor for falls in older patients [4].

First-line interventions for managing UI often encompass comprehensive conservative therapy—pelvic floor muscle training (PFMT), nutritional modification, and bladder training—given its efficacy and minimal risk [5]. In particular, PFMT has shown considerable effectiveness in improving urinary symptoms and enhancing QOL, thus making it an integral part of UI management strategies [6, 7]. Conservative therapies for UI are also important as they have been shown to benefit not only stress incontinence but urge incontinence and urgency as well [6].

✉ Katherina Y. Chen
Kyc3rk@uvahealth.org

[1] Department of Urology, University of Virginia, Charlottesville, VA, USA

[2] Department of Public Health Sciences, University of Virginia, Charlottesville, VA, USA

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However, despite the demonstrated efficacy of PFMT, its utilization faces significant challenges. Of the patients that agree to PFMT, less than 50% complete the treatment course [8]. The reasons underlying these poor initiation and adherence rates are multifactorial and include financial barriers (high out-of-pocket costs) and scheduling barriers (lack of transport or conflict with work schedule). Furthermore, the disparity in access to specialized therapists, particularly in rural and underserved regions, exacerbates these barriers and results in a significant proportion of UI patients not receiving optimal care and a potentially avoidable escalation to long-term drug therapy or invasive procedures.

Online platforms have been gaining traction as potential alternatives or supplements to traditional in-person care, offering greater convenience and cost-effectiveness. However, the feasibility and effectiveness of online interventions for delivering PFMT remain largely unexplored. To this end, this study sought to bridge the gap between the established effectiveness of in-person formal PFMT and the practical impediments to its delivery by developing a novel online program that delivers comprehensive conservative therapy for patients with UI (online pelvic floor program; oPFP). This study is a prospective analysis of continence and QOL outcomes in patients undergoing this program.

Materials and Methods

We performed a prospective single-arm clinical trial in women with UI. Our feasibility study was designed to evaluate the impact of the novel online pelvic floor program on continence and QOL outcomes. Inclusion criteria were defined as adult (≥ 18 years) women with SUI, UUI, or MUI. Exclusion criteria were defined as patients with a prior history of anti-incontinence surgery or those who had undergone more than one prior pharmacotherapy trial for incontinence. Participants represent a convenience sample recruited from ambulatory urology and urogynecology clinics at a single institution during visits for urinary incontinence between 2019 and 2022. The study employed the Distressed Communities Index (DCI)—a scale ranging from 0 to 100, categorized into five tiers ranging from prosperous to distressed—in conjunction with patient addresses to approximate socioeconomic status.

The oPFP is a 2-month program including dietary modification, behavioral therapy, pelvic floor anatomy and physiology education, and PFMT. The oPFP was designed with input from both urology and physical therapy providers to simulate the comprehensive approach that would be used in a pelvic floor center. A complete program calendar with related activity assignments is provided in Supplemental Fig. 1.

The online program resources include a variety of written and video tutorials. In brief, the first week consists of educational videos designed to provide patients with an understanding of pelvic floor anatomy and the physiology of urinary incontinence. Video tutorials also provide behavioral modification techniques including timed/double voiding and appropriate toileting posture. Patients are then taught a basic pelvic floor squeeze (i.e., Kegel). Over the first month, patients then complete a comprehensive pelvic floor exercise program that includes a combination of exercises including varied contraction types and durations (quick flick versus sustained) and exercise positions (supine, seated, and standing). Additional exercises focus on posture and stretching. Finally, additional physiotherapy techniques introduced include counterbracing and knack skills. The exercise sessions last approximately 20 min and are recommended every other day. Patient then transition to a second exercise module in month 2 that includes similar components of a more advanced nature.

Concurrently, patients also perform dietary modification. Written online resources guide patients through a weekly dietary modification plan with the aim of helping patients to identify and then avoid possible bladder stimulants/irritants (Supplemental Fig. 2).

Outcomes assessment was conducted at baseline and following program completion (2 months). Assessment included robust validated questionnaires assessing lower urinary tract symptoms (International Consultation on Incontinence Questionnaire—Female Lower Urinary Tract Symptoms (ICIQ-FLUTS), Urgency Perception Scale (UPS)) and QOL (Incontinence Impact Questionnaire;IIQ-7) [9–11]. Outcomes also included a 24-h bladder diary to provide quantitative information about urinary symptoms, daily pad use, and daily caffeine consumption [12]. Additional items assessed patient satisfaction, self-reported improvement, and program characteristics (e.g., ease of use). All outcome assessments were supervised by clinical research staff.

Primary and Secondary Outcomes

The primary study outcomes were the ICIQ-FLUTS SUI domain score (SDS) and the UUI domain score (UDS). This domain score ranges from 0 to 4 (0 = "Never"; 1 = "Occasionally"; 2 = "Sometimes"; 3 = "Most of the time"; 4 = "All of the time"). Secondary outcomes included daily pad use (PPD), Urge (UPS reason score), daily urinary frequency, and quality of life score (IIQ-7 sum score).

Statistical Analyses

Descriptive statistics are reported as mean ± standard deviation. SDS, UDS, and urge were only analyzed for patients with a nonzero baseline value. SDS, IIQ-7 sum, and daily

urinary frequency were analyzed using linear mixed effects models whereas UDS, daily incontinence episodes, daily pad use, and daily caffeinated beverages utilized Poisson mixed effects models. Urge (UPS reason score) was analyzed with generalized estimating equations. Both mixed effects models and generalized estimating equations allow for missing data and take into account pairing over time. Estimated marginal means were calculated on the response scale and tested for a difference on the link scale using *t* test (linear models) or *z* test (Poisson models). Results are reported as predicted mean ± standard error. Statistical significance was defined as $p < 0.05$.

Study Ethics and Conflict of Interest

Study approval was provided by the UVA Institutional Review Board (#20830). Written signed informed consent to study participation was obtained from each participant.

Principal investigator Dr Rapp (DER) is the owner of HFITNESS, LLC, and creator and owner of the website and copyright for educational materials of the reported online PFMT/pelvic floor exerciser. Conflict of interest (COI) exemption and the related management plan was approved by the UVA COI Committee (2018–17). As part of this plan, enrollment was performed by study research coordinators without DER present. All subjects were informed of DER's financial interest in HFITNESS, LLC, and were provided with ombudsperson contact information to approach if they believed that DER's financial interest interfered with the course of research. DER provided website and program tutorial at program initiation. All outcome data collection and related database entry, including validated questionnaires, was performed independently by clinical research coordinators. All descriptive and statistical analyses were performed independently by the UVA Department of Public Health Sciences. An independent faculty member not participating as a study investigator was also appointed to review project results in order to ensure data integrity.

Results

A total of 28 women were enrolled (2 SUI, 3 UUI, 23 MUI), with 9 patients lost to follow-up (0 SUI, 1 UUI, 8 MUI). Patient demographics and characteristics for all enrolled patients are listed in Table 1. Enrolled patients had a mean (± SD) age, parity, body mass index (BMI), and DCI of 54.4 ± 13.9, 2.1 ± 1.3, 30.2 ± 5.4, and 34.7 ± 23.9 respectively. Patients completing follow-up had a mean (± SD) age, parity, BMI, and DCI of 54.6 ± 15.7 years, 2.1 ± 1.2, 29.2 ± 0.4, and 36.0 ± 24.8 respectively. The DCI scores for both enrolled and completed patient cohorts ranged from 4.9 to 74.7. A minority of these women had tried prior pharmacotherapy for UI or were current smokers.

Table 1 Demographics and patient characteristics

Characteristic[a]	SUI ($n=2$)	UUI ($n=3$)	MUI ($n=23$)
Age (years)	39.0 ± 1.4	47.3 ± 24.9	56.7 ± 12.1
Parity (*n*)	3.0 ± 2.8	1.0 ± 1.0	2.1 ± 1.2
UI duration (years)	0.8 ± 0.4	2.0 ± 0.0	8.3 ± 6.3
Prior hysterectomy	1 (50%)	1 (33.3%)	9 (39.1%)
BMI (kg/m^2)	34.4 ± 2.4	31.4 ± 12.5	29.7 ± 4.4
Prior UI pharmacotherapy	0 (0%)	1 (33.3%)	5 (21.7%)
Smoking status			
Never	2 (100%)	3 (100%)	15 (65.2%)
Former	0 (0%)	0 (0%)	6 (26.1%)
Current	0 (0%)	0 (0%)	2 (8.7%)
Lost to follow-up	0 (0%)	1 (33.3%)	8 (34.8%)

UI urinary incontinence, *BMI* body mass index, *SUI* stress urinary incontinence, *UUI* urge urinary incontinence, *MUI* mixed urinary incontinence

[a]Mean ± SD or *n* (%)

Questionnaire outcomes are shown in Table 2 and Fig. 1. Upon completion of the 2-month oPFP, patients had significantly improved SDS, with a predicted mean (± se) score decrease of 1.08 ± 0.23 (3.04 ± 0.19 at baseline, 1.81 ± 0.23 post oPFP, $p < 0.001$). One out of 17 women (5.88%) reported SUI cure (SDS = 0). A nonstatistically significant improvement to UDS was also seen (2.08 ± 0.28, baseline vs 1.35 ± 0.28, 2 months; $p = 0.085$), and 1 out 17 women (5.88%) reported UUI cure (UDS = 0). The UPS reason score significantly improved from baseline (2.52 ± 0.18) to 2-month follow-up (2.05 ± 0.14, $p = 0.003$). Associated QOL improvement was seen, with a significant improvement to the IIQ-7 sum score (5.16 ± 0.88, baseline; 3.07 ± 0.70 2 months; $p = 0.038$).

Bladder diary outcomes are summarized in Table 2 and illustrated in Fig. 2. There was a significant reduction in daily incontinence episodes (2.96 ± 0.60 vs 1.06 ± 0.29, $p < 0.001$). Five patients (31.3%) reported no incontinence episodes via a bladder diary following oPFP. There was also a decrease in urinary frequency episodes (8.83 ± 0.64 vs 7.29 ± 0.68, $p = 0.02$) and a nonsignificant decrease in PPD (1.29 ± 0.38 vs 0.76 ± 0.26, $p = 0.09$). There was no difference in caffeinated beverage intake.

The mean patient-reported improvement was 5.4 ± 2.5 (ten-point Likert scale: 1—did not help at all, 10—completely cured). A vast majority (95%) of patients reported symptom improvement, with 89% expressing satisfaction with the program. All patients found the program easy to use and would recommend it to others.

Table 2 Pelvic floor muscle training and pelvic floor exercise outcomes

Characteristic[a]	Baseline[b]	2-month follow-up[b]	*p* value[c]
Questionnaire outcomes			
SUI domain (ICIQ)	3.04 ± 0.19, *n* = 25	1.81 ± 0.23, *n* = 17	< 0.001
UUI domain (ICIQ)	2.08 ± 0.28, *n* = 26	1.35 ± 0.28, *n* = 17	0.085
UPS reason score (UPS)	2.52 ± 0.18, *n* = 27	2.05 ± 0.14, *n* = 18	0.003
IIQ sum score (IIQ-7)	5.16 ± 0.88, *n* = 28	3.07 ± 0.70, *n* = 19	0.038
Patient-reported outcomes			
Patient-reported improvement (yes/no)		18 (95%), *n* = 19	
Patient-reported Satisfaction (y/n)		17 (89%), *n* = 19	
Patient-reported ease (yes/no)		18 (100%), *n* = 18	
Patient-reported recommend (yes/no)		19 (100%), *n* = 19	
Patient found educational (yes/no)		18 (100%), *n* = 18	
Bladder diary			
Daily incontinence episodes (*n*)	2.96 ± 0.60, *n* = 19	1.06 ± 0.29, *n* = 16	< 0.001
Daily pad use (*n*)	1.29 ± 0.38, *n* = 19	0.76 ± 0.26, *n* = 16	0.094
Daily caffeinated beverages (*n*)	1.06 ± 0.26, *n* = 16	1.00 ± 0.26, *n* = 15	0.864
Daily urinary frequency (*n*)	8.83 ± 0.64, *n* = 19	7.29 ± 0.68, *n* = 16	0.024

SUI stress urinary incontinence, *ICIQ* International Consultation on Incontinence Questionnaire, *UUI* urge urinary incontinence, *UPS* Urgency Perception Scale, *IIQ* Incontinence Impact Questionnaire

[a]SUI, UUI, and UPS reason score are only reported for women with a nonzero baseline value

[b]For continuous variables: predicted mean ± SE, number of nonmissing observations. For categorical variables: *n* (% of nonmissing observations), number of nonmissing observations

[c]SUI, IIQ-7, daily urinary frequency: linear mixed effects models. UUI, daily incontinence episodes, daily pad use, daily caffeinated beverages: Poisson mixed effects models. UPS reason score: generalized estimating equations

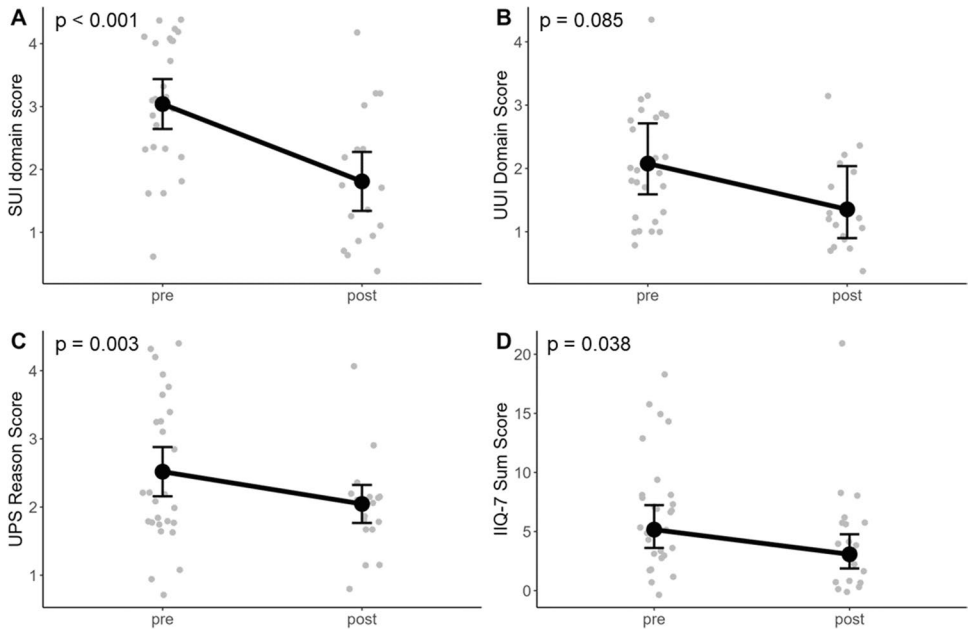

Fig. 1 International Consultation on Incontinence Questionnaire—Female Lower Urinary Tract Symptoms, Urgency Perception Scale (*UPS*), and Incontinence Impact Questionnaire (*IIQ-7*) scores before and after online pelvic floor program intervention. *SUI* stress urinary incontinence, *UUI* urge urinary incontinence

Discussion

Our pilot study demonstrates the efficacy of a novel and comprehensive online program for the treatment of UI in women. After completion of the comprehensive 2-month oPFP, patients experienced significant improvement in SUI and UUI symptoms, as measured by the validated ICIQ-FLUTS questionnaire. Bladder diary also demonstrated a significant reduction in daily incontinence episodes.

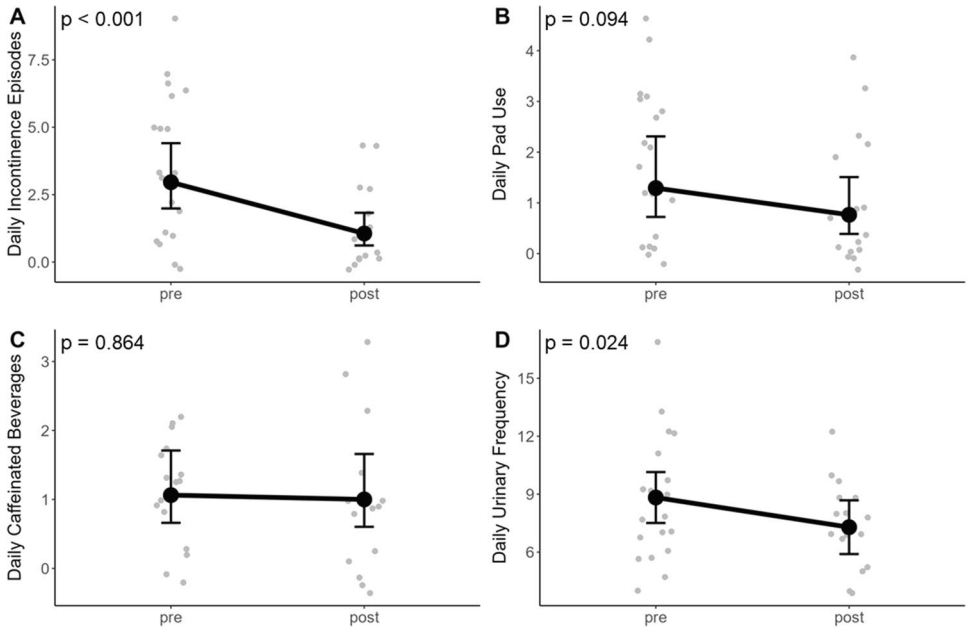

Fig. 2 Change in daily incontinence episodes, daily pad use, daily caffeinated beverage consumptions, and daily urinary frequency after online pelvic floor program intervention (24-h bladder diary)

A minority of patients completing oPFP reported cure (complete absence of incontinence), with a mean patient-reported improvement of 5.4 (ten-point scale). This finding is consistent with a wide body of literature supporting that PFMT is most commonly associated with significant improvement, although cure is less frequent [13, 14]. Despite this, a prior study suggests that the majority of women experiencing symptom improvement but not cure might nonetheless be satisfied [15], with another study showing that PFMT for SUI avoids surgery in half of patients at 1-year follow-up [16]. In our cohort, completion of oPFP was associated with a significant improvement in QOL and the vast majority of women reported program satisfaction, highlighting the significance of UI improvement to a woman's health and well-being.

Importantly, the improvement and cure rates observed in our study are consistent with reported literature assessing outcomes using in-person PFMT. Both Williams et al. and Kondo et al. treated women suffering from SUI or MUI with intensive supervised PFMT and found a 5% and 17% cure rate respectively [17, 18]. Our findings are also notable given prior research demonstrating that online electronic health education programs are not always associated with the efficacy demonstrated via in-person alternatives [19, 20]. Our pilot study demonstrates successful translation of an effective in-person PFMT program to an online format and thus supports a larger comparative investigation of oPFP.

The oPFP was developed to facilitate both ease of user interface and treatment success. One strength of the study is its successful enrollment of participants across a broad spectrum of socioeconomic statuses, which allows this study to illustrate the program's wide-ranging accessibility. Our assessment also included outcomes important to understanding program feasibility, demonstrating that all patients were able to access and use online program education and materials, with all respondents reporting ease of use. No patients reported the inability to access online materials or adverse events related to PFMT.

To promote treatment success, our program was designed to mirror the care that would be obtained through the combined, in-person treatment by both urology and physical therapy providers. Accordingly, our program incorporates not only PFMT but also comprehensive pelvic floor education, dietary modification, behavioral therapy, and education on pelvic floor anatomy and physiology. Numerous studies demonstrate that the addition of behavioral and nutritional modification therapies is an effective strategy in the treatment of UI [6, 7], and that patients who are well-educated about their health conditions engage more actively in their care, which can lead to improved health outcomes [21, 22]. Finally, our PFMT exercises include a robust variety of not only isometric pelvic contractions with functional loading but also stretching and posture components to promote pelvic floor stability. Combined, our program incorporates all components proposed to be essential for a comprehensive electronic pelvic health program [23].

Although widespread research has detailed the efficacy of in-person PFMT for UI, relatively little investigation has focused on the development or testing of electronic PFMT programs [6, 24]. Ho et al. reported that, out of 139 available mobile apps that offer PFMT, only one had been evaluated with a randomized clinical trial, underscoring the need for further assessment of such digital interventions in managing UI [25]. That mobile application was the Tät II mobile

application, which offers PFMT, bladder training, psychoeducation, lifestyle advice, an exercise log, and personalized advice. Although it was proven effective in improving UUI and MUI symptoms, it primarily employs text and visual imagery [26]. Similarly, there are limited options available via online access. We identified one RCT assessing the efficacy of an internet program specifically for SUI, comprising cognitive behavioral therapy, PFMT, behavioral and lifestyle education [27]. The study found no significant difference in SUI outcomes when comparing patients undergoing internet-based therapy versus therapy delivered via postal service. Our program is distinguished from this program as well as the aforementioned mobile application in its additional inclusion of dietary modification, pelvic floor anatomy, and physiology education, as well as content delivery using video aids, given evidence suggesting that videos featuring individuals performing exercises are more effective in presenting health information and modifying patient behavior than verbal instruction or instruction utilizing graphic aids [28].

As outlined previously, multiple barriers impede patient access to formal PFPT. Foremost, there is a limited number of physiotherapists with pelvic floor specialization and the patient demand far exceeds this provider pool [29]. When available, insurance coverage barriers or required co-pays often create financial hardships that prevent access. Scheduling barriers are also significant, as formal PFPT often requires numerous visits that can conflict with work or create transportation barriers for specific patients [29]. Our results indicate that oPFP may be an effective solution to these barriers.

Initiatives such as ours that increase access and standardize conservative therapy delivery are also critical for a value-based health care model. Systematic review has described implementation strategies for value-based urological care, highlighting a need for integrated practice units that focus on standardized care organized around specific medical conditions and the use of technology to enable this care [30]. The significance of UI specifically is underscored by inclusion of UI assessment as an eligible quality indicator for the Merit-based Incentive Payment System under CMS. Further, successful completion of conservative therapies is commonly necessary prior to surgical therapies under insurance coverage policies. Combined with the previously described barriers to care access, these data highlight the importance of innovative solutions to deliver conservative therapy for UI.

Study limitations include small patient number and heterogeneity. Our study was also impacted by a significant loss to follow-up. Much of this was related to the COVID pandemic, which began after study initiation. Consistent with institutional directive, all studies involving in-person visits such as ours were paused for a lengthy period of time. Both our enrollment and tutorial visits, as well as questionnaire completion at follow-up, were performed in person and this study pause resulted in both loss to follow-up of enrolled patients and a significant break prior to restarting enrollment. Despite these limitations, our study demonstrated significant improvements in patient-reported outcomes and represents meaningful data from a real-world population. In addition, our data are strengthened by the use of multiple validated outcome measures and support a future larger randomized controlled trial investigating oPFP versus in-person PFMT and pelvic floor education.

Conclusion

The results demonstrate that oPFP is an effective treatment option for women who suffer from MUI and may alleviate the existing barriers to treatment adherence to improve patient outcomes. This innovative approach may bridge the gap between the established effectiveness of PFMT and the practical impediments to its delivery and adherence, aligning health care with the growing digital era.

Supplementary information The online version contains supplementary material available at https://doi.org/10.1007/s00192-023-05695-y

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Authors' contributions K.Y. Chen: data analysis, manuscript writing/editing; M.K. Jones: data analysis, manuscript writing/editing; J.M. Zillioux: manuscript writing/editing; D.E. Rapp: project development, data collection, data analysis, manuscript writing/editing.

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Data availability The data that support the findings of this study are available from the corresponding author, KYC, upon reasonable request.

Declarations

Financial disclaimers David E. Rapp is the owner of HFITNESS, LLC, and creator and owner of the website and copyright for educational materials of the reported online pelvic floor muscle training/pelvic floor program. Jacqueline M. Zillioux has received payment from Medtronic for research.

Conflicts of interest None.

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