PM R 12 (2020) 55-63

www.pmrjournal.org

Original Research

Pfilates and Hypopressives for the Treatment of Urinary Incontinence After Radical Prostatectomy: Results of a Feasibility Randomized Controlled Trial

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Abstract

Background: Urinary incontinence (UI) is an important side effect of radical prostatectomy (RP). Coactivation of surrounding muscles via novel techniques for pelvic floor rehabilitation known as Pfilates and Hypopressives has not been compared to pelvic floor muscle exercises (PFMXs) for UI.
Objective: To assess the feasibility and efficacy of isolated PFMXs with and without the addition of Pfilates and Hypopressives on UI recovery following RP.
Design: Randomized controlled trial.
Setting: Participants were recruited from a community and tertiary cancer center in Toronto, Canada.
Participants: A total of 226 patients undergoing RP were assessed for eligibility. One hundred twenty-two patients were eligible and 50 consented to participate; 37 participants completed the trial.
Methods: Participants were randomized to either isolated PFMX (control) or PFMX plus Pfilates and Hypopressives (advanced pelvic floor exercises; APFX) groups. PFMX participants (n = 25) received instructions for isolated pelvic floor contractions starting with 30 contractions per day during weeks 1 to 2 up to 180 per day for weeks 7 to 26. The APFX group (n = 25) received a comparable volume of exercises.
Main Outcome Measurements: Feasibility was assessed by rates of recruitment, adverse events, and study-arm compliance. Information about UI and quality of life was collected 1 week before surgery and at 2, 6, 12, and 26 weeks after surgery.
Results: The recruitment rate was 41%, adherence to the PFMXs and APFXs was >70%, and there were no reported adverse events. Between-group differences were observed in the frequency of self-reported 24-hour urinary leakage (rate ratio 0.45, 95% confidence interval [CI] 0.2-0.98) and during waking hours (rate ratio 0.43, 95% CI 0.20-0.91) at 26 weeks after surgery favoring APFX.
Conclusions: Pfilates and Hypopressives are feasible in men undergoing RP, and preliminary data suggest a potential benefit in aiding recovery of urinary control. Larger studies with longer follow-up are warranted.
Level of Evidence: II.

Introduction

Radical prostatectomy (RP) is an effective curative strategy for localized prostate cancer (PCa)[1] but results in urinary incontinence (UI). UI has been shown to affect almost all patients immediately after RP, peaks at 6 months (79.5%),[2,3] and nearly 70% of patients experience some leakage 2 years postoperatively.[3] The burden

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https://dx.doi.org/10.1002/pmrj.12157

of UI challenges patients' social and personal identities—a bothersome symptom of treatment that interferes with social roles, including partner relationships, sexual life, and energy levels.[4] Long-term effects of UI present a major barrier to social interests, physical recreation, and self-efficacy for activities of daily living.[5] Subsequently, UI has been identified as the most predictive variable for decreased health-related quality of life (HRQOL) during the early post-RP period and has been closely linked to dissatisfaction with surgical treatment.[6] Recovery of urinary control is a major priority given the prevalence of RP in the management of PCa and the associated psychosocial and functional adversity caused by UI.

First-line management for post-RP UI often consists of pelvic floor muscle exercises (PFMXs) that include voluntary muscle contractions to counteract the increases in intraabdominal pressure that cause stress UI.[7] Research on PFMX for UI after RP suggests a small to moderate benefit[8,9]; however, a limitation to the potential benefit is that PFMXs frequently do not include training of the surrounding abdominal muscles[9] that have recently shown to facilitate optimal pelvic floor contractions.[10,11] The synergistic activation of the pelvic floor muscle and transverse abdominis has been demonstrated in electromyography (EMG) studies.[12] The likelihood of poor pelvic floor tone (autonomic contraction), and consequently risk of UI, is apparent when the ability of the transverse abdominis to maintain a contraction is impaired.[13,14] This is consistent with research showing that relaxing the abdominal wall during PFMXs results in only 25% of the maximal voluntary contraction of the pelvic floor.[11] Furthermore, improved coordination of the diaphragm with abdominal and pelvic floor muscles with training may be related to reduced stress UI via more efficient forced expiratory patterns.[11,15]

Conventional PFMX interventions in research have not targeted coactivation of regional muscles, possibly resulting in suboptimal pelvic floor muscle rehabilitation. Novel strategies have emerged that incorporate regional muscles aimed at enhancing pelvic floor muscle adaptation. "Pfilates" (Pelvic Floor Pilates) incorporates the fundamental elements of Pilates (core strength, stability, flexibility, muscle control, posture, and breathing) combined with isolated pelvic floor activation. Hypopressive exercises emphasize engaging the deep abdominal muscles, with conscious coordination of the diaphragm.[16] Given the absence of comparative trials examining conventional and comprehensive PFMXs, our study's primary objective was to assess the feasibility of conducting a full-scale randomized controlled trial (RCT) comparing these approaches to resolving UI while deriving preliminary estimates of their effects in men with PCa who are undergoing RP.

Methods

A detailed trial protocol is published elsewhere[17] and briefly summarized in subsequent text of this article. This study was a two-arm feasibility RCT. Following approval from a research ethics board in Toronto, Ontario, Canada and trial registration (NCT02233608), we sought to recruit 88 participants at the time of treatment consent if they were: (1) diagnosed with PCa undergoing RP; (2) 40 to 80 years of age; (3) proficient in English; (4) without a neurological disease, autoimmune/connective tissue disorder; chronic obstructive or restrictive pulmonary disease, history of inguinal herniation, or uncontrolled hypertension; (5) had no preexisting UI; and (6) had no formal pelvic floor training experience. The recruitment targets were intended to yield a analyzable sample of 70 participants (35 per group) accounting for an anticipated attrition rate of 20% to provide an adequate interpretation with an estimated treatment effect to plan for a full-scale trial.[18,19]

Participants were randomized 1:1 to PFMX or PFMX plus Pfilates and Hypopressives (advanced PFMX, hereafter referred to as APFX) following baseline measures (~1 week preoperatively). Allocation concealment was conducted using sequentially numbered sealed opaque envelopes that were opened after the baseline assessment. A trained kinesiologist explained and demonstrated the pelvic floor training regimens pertaining to each group and instructed participants to initiate them after postoperative urinary catheter removal until 26 weeks postoperatively or until UI was completely resolved. The kinesiologist communicated weekly with all study participants by telephone or email to provide support and quantify program compliance, facilitate appropriate progression, and address any barriers to program engagement.

Study Arms

PFMX (ie, control) participants received instructions to isolate and maximally contract the pelvic floor muscles with escalating repetition volume every 2 weeks, starting at 30 repetitions per day during weeks 1 to 2 up to 180 per day for weeks 7 to 26. APFX participants engaged in similar isolated exercises as per PFMX plus Hypopressives and Pfilates (Figure 1). Detailed exercise instructions can be found in the published protocol.[17] The total weekly volume of contractions in the APFX group (including Hypopressives and Pfilates) was comparable to the PFMX-only group, and the intensity of the exercises progressed every 2 weeks and was maintained until week 26 (see Table S1 for detailed intervention parameters). To reduce the risk of significant rise in blood pressure, participants were instructed to perform three deep breaths before each Hypopressive pose, as acute reduction in blood pressure has been shown with slow, controlled deep breathing.[20]

Outcomes

Feasibility Assessment

Phase III trial feasibility was examined via recruitment rate, attrition rate, adverse events, and participant

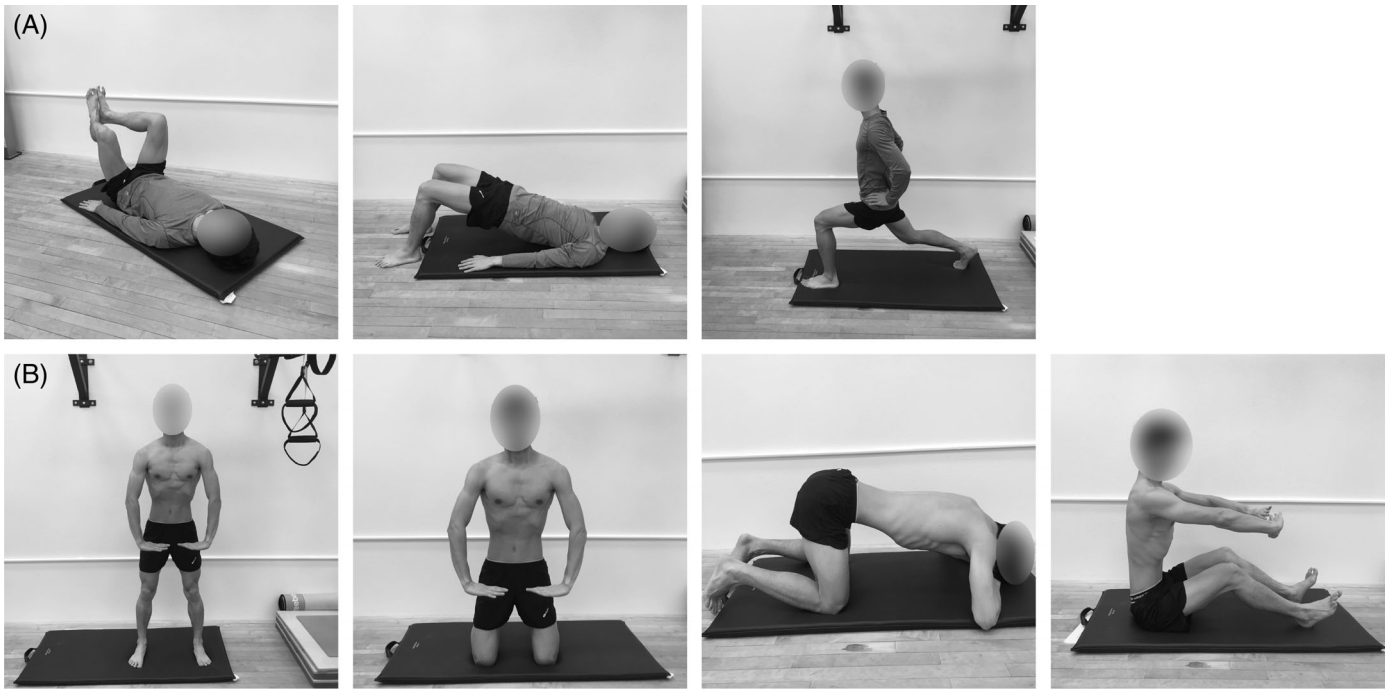

Figure 1. (A) Pfilates poses. *Left to right:* butterfly, bridge, lunge. (B) Hypopressive poses. *Left to right:* Standing, kneel, downward kneel, seated.

compliance with the assigned study arm. Success was defined as >30% recruitment rate, no reported serious adverse events, <30% attrition rate, and >70% adherence rate.

Estimates of Efficacy

All outcomes were measured at baseline (~1-week pre-RP), and at 2, 6, 12, and 26 weeks post-RP. UI was measured with the 24-hour pad test. Severity of incontinence was indicated by the total increase in weight of all pads. Continence status was further dichotomized and defined by less than 4.4 g of urine loss in 24 hours, or the use of one or fewer urinary pads per day.[2] A 3-day bladder diary was also used to subjectively quantify the frequency of urinary voids. Participants were asked to record the time they wake and slept to differentiate between diurnal and nocturnal voids. The Modified Oxford Scale[21] for pelvic floor strength was also a planned efficacy measure for the recovery of pelvic floor muscle function. However, due to the temporary departure of a qualified team member for pelvic floor evaluation, the Modified Oxford Scale was not possible for all participants, thus excluded from estimates of potential efficacy.

HRQOL was measured using the Functional Assessment of Cancer Therapy-Prostate (or FACT-P) and the Patient-Oriented Prostate Utility Scale (PORPUS). A single item for urinary leakage was taken from the PORPUS to evaluate participants' self-reported urinary function, where UI status was dichotomized for participants responding "occasionally leak urine or lose bladder control, interferes with a few activities" or worse as incontinent. Lower urinary tract symptoms and erectile function were assessed using the American Urological Association's International Prostate Symptom Score (IPSS) and International Index of Erectile Function-5 (IIEF-5) scale, respectively.

Statistical Analysis

Participant demographics and disease characteristics were summarized using descriptive statistics and the appropriate parametric and nonparametric tests to assess for effective randomization. Linear and logistic mixed-effects regression models were used to estimate the adjusted sample mean scores of scalar and dichotomized dependent variables, respectively. The frequency of urinary episodes as described in the bladder diary was analyzed with a mixed model under the Poisson distribution. Fixed effects in the model included: age, body mass index, cancer stage, and surgical approach. Physical activity level (via Godin Leisure-Time Exercise questionnaire[22]) was also captured as a covariate; this, however, was excluded in the statistical modeling given that the intervention was a targeted therapy (ie, pelvic floor exercise) rather than whole body resistance/aerobic exercise. Group and time point were modeled as an interaction and individual participants were included as the random effect. The maximum likelihood estimation was used for the mixed models and analyzed under the intention-to-treat principle. Post hoc pairwise comparisons between time points were conducted for each intervention group as well as for differences between groups at each time point. Pairwise comparisons were adjusted

using Tukey's honest significant difference test. All analyses were done using R version 3.4.4. Alpha was set to .05.

Results

Study recruitment occurred between August 2015 and March 2017, and a Consolidated Standards of Reporting Trials (CONSORT) diagram is presented in Figure 2 to depict participant flow through the trial. The recruitment period was discontinued before achieving sample size targets due to resource expiration, given fewer eligible patients than expected, primarily owing to a history of hernia (40%) or participation in a competing trial (20%). Overall, 122 patients were eligible of the 226 patients who were screened (54%). Of the eligible patients, 72 (59%) declined participation; primarily due to travel and distance-related barriers to attending study assessments (44%). From the 50 enrolled in the study, 13 dropped out (withdrawal reasons are detailed in Figure 2). In total, 37/50 (74%) participants were retained to trial completion. Table 1 describes the demographic and disease-specific profile of the enrolled participants that were statistically equivalent between groups (Table 1). Both groups met intervention adherence targets of 70%, with PFMX having higher overall adherence to the prescribed exercises (PFMX 91.1 $\pm$ 10.9%; APFX: 82.7 $\pm$ 11.2%; P = .03). No trial-related adverse events occurred. All trial feasibility data are summarized in Table 2. Of note, the feasibility of conducting a digital rectal examination (DRE) for pelvic floor strength and stability using the Modified Oxford Scale[21] requires specialized training and is a restricted act to some health care professions. During our study, DREs for this purpose were conducted on 25 participants (with 16, 12, and 3 follow-up assessments at 6 , 12 , and 26 weeks, respectively), and a significant majority demonstrated high function at baseline (19 = 5/5, 5 = 4/5, and 1 = 3/5). All DREs were conducted without adverse events; however, the protocol was modified from the originally published version,[17] where DREs were not performed at 2-weeks post-RP so as not to unnecessarily perturb the internal surgical site.

Between-group differences in urine loss via the 24-hour pad test and the adjusted proportions of

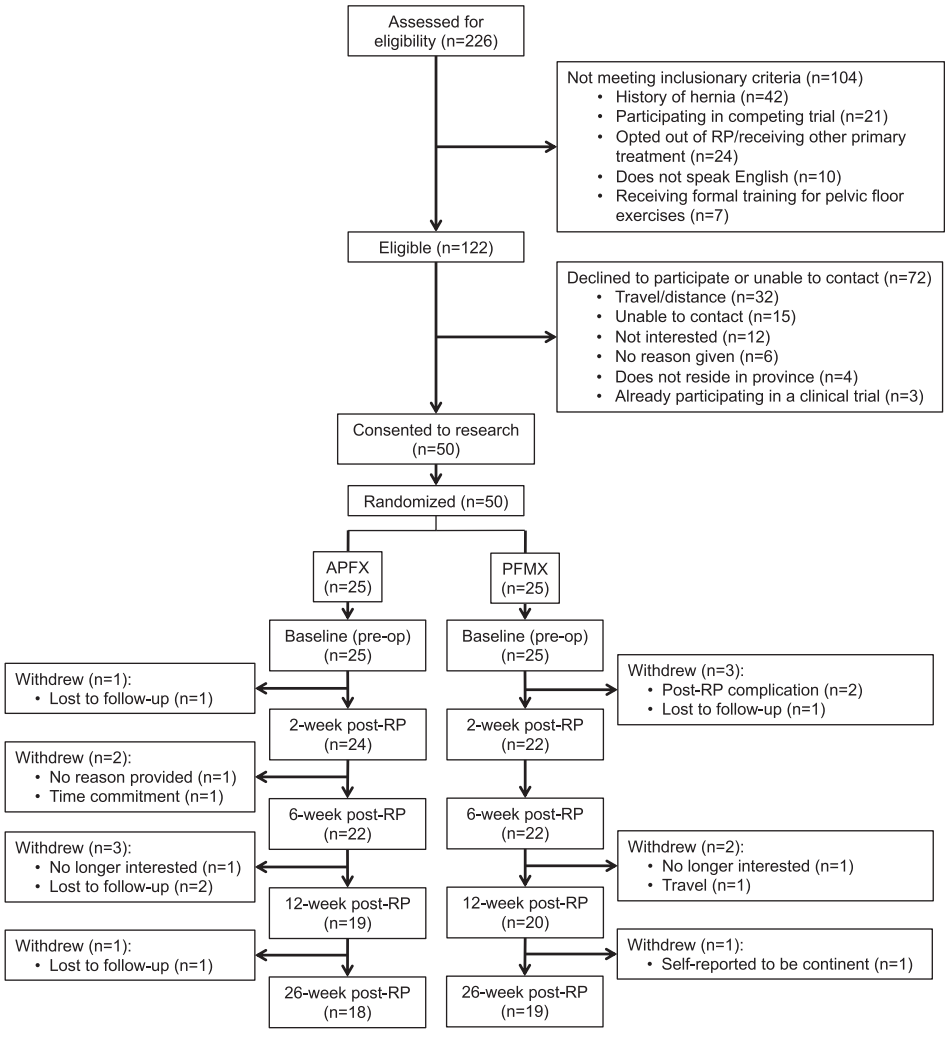

Figure 2. CONSORT diagram.

Table 1
Participant baseline demographic and disease characteristics

	PFMX (n = 25)	APFX (n = 25)	
Demographic Characteristics	Mean ± SD		*P* value*
Age, y	61.3 ± 7.3	63.0 ± 8.5	.455
BMI, kg/m^2	28.2 ± 4.4	26.87 ± 3.7	.262
Body fat, %	26.0 ± 5.9	23.5 ± 6.1	.138
	Frequency [%]		*P* value†
Ethnicity			
White	18 [72]	23 [92]	.071
Black	6 [24]	1 [4.0]	
Arabic	0	1 [4.0]	
South Asian	1 [4]	0	
Marital			
Married	21 [84.0]	24 [96.0]	.110
Divorced	2 [8.0]	0	
Widowed	2 [8.0]	0	
Single	0	1 [4.0]	
Education			
Finished university/college	12 [48.0]	16 [64.0]	.150
Some university/college	7 [28.0]	5 [20.0]	
Finished high school	2 [8.0]	2 [8.0]	
Some high school	4 [16.0]	0	
Grade school or less	0	2 [8.0]	
Work Status			
Full-time	16 [64.0]	8 [32.0]	.073
Retired	8 [32.0]	14 [56.0]	
Part-time	1 [4.0]	1 [4.0]	
Disability	0	2 [8.0]	
Household income			
Greater than $75 000	13 [52]	12 [48.0]	.273
$40 000 to $75 000	5 [20]	7 [28.0]	
$20 000 to $39 000	2 [8]	5 [20.0]	
Less than $20 000	0	0	
Prefer not to answer	5 [20]	1 [20.0]	
Baseline Disease Characteristics	Mean ± SD		*P* value*
PSA [ng/ml]	11.2 ± 9.9	7.6 ± 3.0	.087
	Frequency [%]		*P* value†
Gleason			
6	4 [16]	4 [16]	.883
7	16 [64]	18 [72]	
8	3 [12]	1 [4]	
9	2 [8]	2 [8]	
T-Stage			
T1c	7 [28]	10 [40]	.883
T2a	10 [40]	5 [20]	
T2c	6 [24]	4 [16]	
T3a	1 [4]	4 [16]	
Missing	1 [4]	2 [8]	
Surgery type			
Open	4 [16]	8 [32]	.321
Robotic-assisted	21 [84]	17 [68]	
Nerve-sparing			
Bilateral	19 [76]	22 [88]	.660
Unilateral	3 [12]	2 [8]	
Non-nerve-sparing	2 [8]	0	
Unknown	1 [4]	1 [4]	

APFX = advanced pelvic floor muscle exercise; BMI = body mass index; PFMX = pelvic floor muscle exercise; PSA = prostate specific antigen.
* *P* value for *t*-test.
† *P* value for Fisher exact test.

Table 2
Feasibility table

Outcome	PFMX	APFX	Total
Recruitment Rate [%; target ≥30%]	--	--	41.0 [50/122]
Attrition Rate [to 26-wk post-operative assessment; target ≤30%]	24 [6/25]	28 [7/25]	26 [13/50]
Adherence Rate [% meeting minimum target exercise volume; target ≥70%]			
2-6 wk	92.3	85.9	89.1
6-12 wk	90.0	76.3	83.5
12-26 wk	86.5	69.1	78.3
Total Adherence	91.1	82.7	87.1
Trial-related Adverse Events [target = 0]	0	0	0

continence status according to aforementioned thresholds are described in Table 3. There were no observed between-group differences in UI via net weight of pads and no difference between APFX and PFMX in terms of a priori UI rates across time points. However, both groups improved UI as per the 24-hour pad test from 2 to 26 weeks post-RP (PFMX -203.2 ± 29.2 g, $P < .001$; APFX -242.3 ± 29.0 g, $P < .001$; data not shown). The adjusted estimated events and between-group difference reported from the bladder diary are presented in Table 4. At 26 weeks, the APFX group demonstrated less total leakage and day leakage via the bladder diary. Total leakage events were 2.07 ± 0.57 and 0.94 ± 0.28 in PFMX and APFX, respectively (rate ratio 0.45; 95% confidence interval [CI] 0.21-0.98). Leakage events during waking hours were 2.37 ± 0.64 and 1.02 ± 0.3 in PFMX and APFX, respectively (rate ratio 0.43; 95% CI 0.20-0.91). No other significant group differences in the number of void events in the bladder diary were observed.

HRQOL scores from FACT-P and PORPUS scores were not statistically different between groups at any time point (Table 5). However, the FACT-G subscore was clinically significant between groups in favor of APFX 26 weeks post-RP (5.26 ± 3.31, $P = .11$). No other significant differences were observed across FACT-P subdomains. Prostate-specific symptoms as reported by the IPSS showed increase in severity 2 weeks following RP in both groups compared to baseline. Erectile function measured by IIEF-5 showed significant declines in both groups and did not return to baseline over the course of the study. Differences between groups were not statistically significant at any time point.

Discussion

To our knowledge, no studies have compared conventional PFMXs and multipronged pelvic floor muscle training that elicits supportive muscles in urinary function and HRQOL outcomes following RP. Markers of feasibility exceeded predictions and thresholds of pragmatism for

Table 3
Adjusted probability for incontinence status and OR between APFX and PFMX at each post-RP time point

Measure	Time point (wk)	Mean Difference ± SE APFX-PFMX	95% CI
Urine loss [g]	2	1.6 ± 33.6	−65.2, 68.5
	6	−19.8 ± 35.6	−90.5, 50.8
	12	−47.3 ± 37.2	−121.0, 26.5
	26	−37.5 ± 38.1	−113.0, 38.0

Incontinence Status	Time point (wk)	Adjusted Probability ± SE PFMX	APFX	APFX-PFMX OR [95% CI]
Urine loss	2	1.00 ± 0.00	1.00 ± 0.00	0.41 [0.00, inf]
	6	1.00 ± 0.01	0.99 ± 0.01	0.28 [0.00, 64.26]
	12	0.97 ± 0.05	0.94 ± 0.08	0.51 [0.01, 33.33]
	26	0.54 ± 0.32	0.35 ± 0.29	0.44 [0.01, 15.21]
Pad number [1 > pads/d]	2	1.00 ± 0.00	1.00 ± 0.00	0.70 [0.00, inf]
	6	0.98 ± 0.03	0.96 ± 0.06	0.43 [0.00, 67.61]
	12	0.88 ± 0.18	0.69 ± 0.34	0.30 [0.00, 30.54]
	26	0.39 ± 0.37	0.07 ± 0.11	0.12 [0.00, 9.75]
Single item PORPUS	2	0.98 ± 0.02	0.97 ± 0.04	0.48 [0.01, 17.68]
	6	0.87 ± 0.10	0.88 ± 0.10	1.08 [0.08, 13.97]
	12	0.72 ± 0.17	0.44 ± 0.19	0.30 [0.03, 2.99]
	26	0.34 ± 0.18	0.22 ± 0.14	0.55 [0.06, 5.33]

APFX = Advanced Pelvic Floor Exercise; PFMX = Pelvic Floor Muscle Exercise; PORPUS = Patient-Oriented Prostate Utility Score; CI = confidence interval; SE = standard error; OR = odds ratio.

Table 4
Adjusted counts for the 3-day bladder diary outcomes and rate ratio between APFX and PFMX at each post-RP time point

Measure	Time point (wk)	Group PFMX	APFX	APFX-PFMX Rate Ratio [95% CI]
Total voids [24-h]	2	12.4 ± 0.9	12.46 ± 0.86	1.01 [0.83, 1.22]
	6	12.31 ± 1.01	12.31 ± 0.94	1.00 [0.81, 1.24]
	12	10.71 ± 1.14	10.38 ± 0.92	0.97 [0.74, 1.27]
	26	8.32 ± 1.21	8.49 ± 0.96	1.02 [0.70, 1.48]
Day time voids	2	10.78 ± 0.8	10.05 ± 0.81	1.07 [0.87, 1.32]
	6	10.71 ± 0.88	10.55 ± 0.93	1.02 [0.80, 1.28]
	12	9.92 ± 1.1	9.20 ± 0.87	0.93 [0.70, 1.23]
	26	7.53 ± 1.15	7.40 ± 0.9	0.98 [0.66, 1.47]
Night time voids	2	2.11 ± 0.39	2.00 ± 0.34	0.94 [0.58, 1.52]
	6	1.81 ± 0.41	1.48 ± 0.32	0.82 [0.44, 1.49]
	12	0.92 ± 0.34	1.29 ± 0.31	1.39 [0.59, 3.32]
	26	1.11 ± 0.47	0.94 ± 0.3	0.84 [0.30, 2.41]
Total leaks [24-h]	2	5.41 ± 1.04	5.21 ± 0.93	0.96 [0.61, 1.52]
	6	4.03 ± 0.84	3.61 ± 0.7	0.89 [0.54, 1.48]
	12	3.36 ± 0.78	1.96 ± 0.44	0.58 [0.33, 1.04]
	26	2.07 ± 0.57	0.94 ± 0.28	0.45 [0.22, 0.98]*
Day leak	2	4.94 ± 0.91	5.05 ± 0.85	1.02 [0.66, 1.57]
	6	3.83 ± 0.77	3.34 ± 0.63	0.87 [0.54, 1.42]
	12	2.89 ± 0.67	1.69 ± 0.38	0.58 [0.32, 1.05]
	26	2.37 ± 0.64	1.02 ± 0.3	0.43 [0.20, 0.91]*
Night leak	2	0.34 ± 0.16	0.21 ± 0.1	0.61 [0.22, 6.55]
	6	0.23 ± 0.12	0.18 ± 0.09	0.78 [0.22, 2.77]
	12	0.24 ± 0.14	0.14 ± 0.08	0.58 [0.15, 2.25]
	26	0.03 ± 0.03	0.03 ± 0.03	1.12 [0.08, 15.49]

APFX = Advanced Pelvic Floor Exercise; PFMX = Pelvic Floor Muscle Exercise; CI = confidence interval.
*$P < .05$.

Table 5
Mean group differences for patient-reported outcomes

Measure	Time point (wk)	Mean Difference ± SE APFX-PFMX	95% CI
FWB	Preop	−0.02 ± 0.79	−1.59, 1.55
	2	−0.65 ± 0.85	−2.34, 1.03
	6	1.44 ± 0.96	−0.45, 3.34
	12	2.09 ± 1.1	−0.08, 4.26
	26	1.67 ± 1.33	−0.96, 4.3
PWB	Preop	0.08 ± 0.82	−1.56, 1.71
	2	−0.58 ± 0.88	−2.33, 1.17
	6	0.2 ± 0.98	−1.73, 2.14
	12	0.81 ± 1.1	−1.36, 2.98
	26	0.86 ± 1.3	−1.72, 3.43
EWB	Preop	0.00 ± 0.59	−1.17, 1.17
	2	−0.05 ± 0.63	−1.30, 1.20
	6	0.99 ± 0.7	−0.39, 2.38
	12	0.85 ± 0.79	−0.73, 2.42
	26	0.33 ± 0.95	−1.54, 2.21
SWB	Preop	0.36 ± 0.51	−0.66, 1.38
	2	1.44 ± 0.55	0.34, 2.54
	6	0.53 ± 0.65	−0.75, 1.82
	12	0.43 ± 0.74	−1.04, 1.9
	26	0.24 ± 1.17	−2.07, 2.54
PCS	Preop	1.03 ± 1.08	−1.11, 3.16
	2	−0.6 ± 1.19	−2.95, 1.76
	6	0.45 ± 1.33	−2.19, 3.09
	12	−0.06 ± 1.54	−3.1, 2.98
	26	−1.88 ± 1.88	−5.6, 1.84
FACT-P	Preop	1.34 ± 2.78	−4.17, 6.85
	2	−0.69 ± 3.00	−6.64, 5.27
	6	3.35 ± 3.34	−3.27, 9.96
	12	4.32 ± 3.8	−3.2, 11.83
	26	2.69 ± 4.56	−6.31, 11.7
FACT-G	Preop	0.45 ± 2.08	−3.68, 4.58
	2	0.2 ± 2.23	−4.21, 4.62
	6	3.26 ± 2.46	−1.62, 8.14
	12	4.77 ± 2.78	−0.73, 10.28
	26	5.26 ± 3.31	−1.29, 11.8
PORPUS	Preop	0.75 ± 2.19	−3.6, 5.1
	2	−1.08 ± 2.38	−5.79, 3.63
	6	1.93 ± 2.66	−3.33, 7.2
	12	−0.48 ± 3.02	−6.44, 5.49
	26	2.83 ± 3.61	−4.31, 9.96
IPSS	Preop	0.08 ± 1.67	−3.21, 3.38
	2	−1.96 ± 1.81	−5.53, 1.62
	6	2.61 ± 2.04	−1.42, 6.65
	12	−2.26 ± 2.35	−6.91, 2.39
	26	0.3 ± 2.87	−5.39, 5.98
IIEF-5	Preop	1.88 ± 1.48	−1.05, 4.82
	2	0.76 ± 1.64	−2.47, 4.00
	6	−2.92 ± 1.86	−6.58, 0.75
	12	−0.28 ± 2.15	−4.54, 3.98
	26	1.53 ± 2.65	−3.72, 6.77

APFX = Advanced Pelvic Floor Exercise; EWB = emotional well-being; FACT-G = Functional Assessment of Cancer Therapy-General; FACT-P = Functional Assessment of Cancer Therapy-Prostate; FWB = functional well-being; IIEF-5 = International Index of Erectile Function; IPSS = International Prostate Symptom Score; PCS = prostate cancer subscale; PFMX = Pelvic Floor Muscle Exercise; PORPUS = Patient-Oriented Prostate Utility Score; PWB = physical well-being; SWB = social well-being.

a larger trial. Despite recruitment success, there were challenges in recruitment that included competing trials of the same population at the study site (NCT02640131

and NCT02036684); this will likely remain a challenge given heavy interest in surgical outcomes in this population. Moreover, RPs have reached a 7-year low in Canada[23] with more men with localized low-risk PCa electing active surveillance.[24] Another major barrier to participation was distance and travel, which were often cited as reasons for nonparticipation (44%). Similar to other trials, patients travel from outside the city and travel time and cost associated with travel are major barriers to participation. From a trial-risk perspective there were no adverse events associated with the intervention and the high retention rate suggests that the intervention protocols were safe and tolerable. Although concerns regarding increased blood pressure associated with Hypopressives are warranted, there were no reported episodes of light-headedness or other related symptoms. Moreover, this study showed that the abdominal engagement in APFXs was well tolerated despite recent abdominal surgery. Participants were able to maintain and perform the exercises as described, similar to general recommendations for PFMXs.

A major issue with pelvic floor training is patient compliance and its sole reliance on patient comprehension of appropriate exercise technique and motivation to diligently perform the exercises. Thus, outcomes for PFMX trials are highly contingent upon adherence with the prescribed exercise routine. In our study, we found that PFMX participants were statistically more adherent than APFX participants to the prescribed exercise. Although this difference was statistically significant, the clinical relevance in the difference in adherence rate may be inconsequential. Regardless, our adherence rates are encouraging for these novel training techniques where previous studies that have reported PFMX adherence rates ranged from 50% to 70%.[25,26]

One strength of our study is that we assessed urinary function in numerous ways. The 24-hour pad test is likely the most objective method of assessing post-RP UI. Previous studies have reported post-RP urinary leakage ranging from 291 to 440 g, 1 to 2 weeks after catheter removal.[27-29] Our results yielded comparable a level of urine loss at 2 weeks post-RP, with 270 g in both groups. Previous reports have indicated that the severity of UI is at its worst within 2 months post-RP,[30] after which, most patients improve.[31] Accordingly, both APFX and PFMX showed statistically significant improvements within groups from 2 to 26 weeks post-RP. Previous trials examining PFMXs after RP have reported similar mean urine loss at 12 and 26 weeks post-RP (82-141 g). This is further supported by continence rates defined by the 24-hour pad test. No participants were continent at 2 weeks post-RP; by 12 weeks, 21% and 15% in APFX and PFMX, respectively, were classified as continent. Previous trials that have investigated the recovery of continence after pelvic floor muscle retraining and PFMX post-RP have reported continence rates of 37% to 72% at 12 weeks[28,29,32,33] and 78% to 90% at 26 weeks.[3,34] These previous reports of continence were higher than our current study at similar time points. However, it should be mentioned that the definition of UI varies between studies and that classification of UI based on total urine loss can range from 1.3 to 8 g.

Our study showed no between-group differences in overall HRQOL. FACT-P total score showed that both interventions returned to baseline levels by 26 weeks. However, PORPUS scores at 26 weeks were below baseline levels, but the improvements observed were clinically significant in both groups. The discrepancy between the two HRQOL measures could be accounted for by the heavy focus on common prostate cancer symptoms and its treatments in the PORPUS. The FACT-P measure include physical, social, functional, and emotional domains as well as prostate specific concerns. As such, when examining the HRQOL scores without the prostate-specific concerns as the FACT-G score, we find that there is a clinical significance between the groups at 26 weeks in favor of APFX. This may suggest that APFX is more likely to aid recovery of general HRQOL sooner than PFMX, absent urinary outcomes, which is typically seen to recover up to 1 to 2 years post-RP. This may also indicate that patients performing APFXs are likely to regain confidence and perform daily activities despite the urinary impairments.

Our study should be interpreted cautiously for several reasons. First, due to resource limitations, our sample size was limited to 37 participants in the analysis rather than the targeted 70, which compromises the precision of our treatment-effect estimate. However, our sample size does align with recommendations that support appropriate interpretation of trial feasibility to permit assumptions about capacity for full-scale trial delivery (eg, recruitment and attrition rate, adherence, and tolerability).[18,19] Second, generalization may be hampered because PFMX may not be considered usual care in other settings; however, it was used as the control condition in our study. Third, as previously reported, post-RP urinary continence recovery has shown to continue 12 to 24 months post-RP, whereas our follow-up was limited to 26 weeks post-RP. This period may not reflect the potential impact of APFX in long-term recovery; however, 26 weeks does represent a nadir in urinary function post-RP described in the previous literature.[2] Fourth, due to the temporary departure of a physiotherapist trained in pelvic floor assessment, and the absence of an adequate replacement, we were unable to complete pelvic floor strength testing for most of our patients. Finally, the outcome assessor was not blinded to study group assignment.

Conclusion

We evaluated the feasibility of conducting an RCT of traditional PFMX versus APFX for the recovery of UI after RP. Although targets for feasibility were met, we note that recruitment may be compromised in a major, urban

cancer center setting due to competing trials and challenges to complying with facility-based study activity. Preliminary findings show promise for APFX in expediting urinary control following RP; however, potential benefits of APFX compared to PFMX must be studied in larger samples. Given the growing research suggesting synergy of the pelvic floor muscles with the abdominal muscles and diaphragm in managing UI, more research is warranted to further elucidate the relationship between these muscles and how coactivation may yield differential benefits for this problematic symptom following RP in men with PCa.

Acknowledgment

The authors would like to thank Lianne McCabe for her support and contributions to this trial. We would also like to acknowledge Prostate Cancer Canada for graciously supporting this trial as part of the Movember Discovery Grant (grant number D2014-20).

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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This study was funded by the Movember Discovery Grant from Prostate Cancer Canada (grant number D2014-20).

Submitted for publication October 26, 2018; accepted February 22, 2019.