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Is a behavioral treatment for urinary incontinence beneficial to prostate cancer survivors as a follow-up care?

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Abstract

Purpose—The American Cancer Society (ACS) recommends a follow-up care plan for urinary incontinence of prostate cancer survivors that includes pelvic floor muscle exercise (PFME). We examined potential impacts and access barriers of this recommendation with consideration of patients who normally do not seek such care.

Methods—We compared 267 participants of a clinical trial that tested a PFME-based treatment of urinary incontinence and 69 nonparticipants who declined the trial. All subjects were assessed at baseline, 3, and 6 months on leakage frequency, disease-specific quality of life (QOL), and physical well-being. The nonparticipants were interviewed to examine reasons for intervention refusal.

Results—The participating and nonparticipating groups did not differ in most baseline demographics and clinical variables except that the nonparticipants had lower baseline prostate-specific antigen ($P \leq 0.01$), lower education levels, and higher likelihood of receiving surgery alone (both $P \leq 0.05$). Nonparticipants exhibited significantly more frequent daily leakage, poorer

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Compliance with ethical standards There are no financial disclosures from the authors. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

urinary function and bother, and severer urinary problems at 3 and 6 months, as well as worse physical well-being at 6 months, relative to baseline, than the participants. The primary reason for refusal was economical, such as lacking transportation and time for participation.

Conclusions—Urinary function and QOL can worsen without appropriate follow-up care. It is important to make a PFME-based follow-up care program available to all incontinent prostate cancer survivors as recommended by ACS guidelines.

Implications for cancer survivors—Seeking PFME-based treatment is crucial for long-term urinary health outcomes even if present leakage is minor or financial challenge is a concern.

Keywords

Prostate cancer; Urinary incontinence; Pelvic floor muscle exercise; Survivorship; Quality of life

The American Cancer Society (ACS) prostate cancer survivorship care guidelines recommend that pelvic floor rehabilitation be a part of the follow-up care plan for prostate cancer survivors suffering from urinary incontinence [1], that is, “the complaint of any involuntary leakage of urine” [2]. There are nearly 3 million prostate cancer survivors living in the USA [3], and many experience long-term urinary incontinence, thus needing follow-up care [4, 5]. Pelvic floor muscle exercise (PFME) as a behavioral treatment of prostatectomy incontinence has been well-studied, but according to Cochrane Incontinence Group’s review, these studies have yielded inconclusive findings [6]. Given the ACS acknowledgement of limited empirical support for its guidelines [1] and the fact that pelvic floor rehabilitation is not regularly used in current practice, evidence that is conducive to evaluate the recommended behavioral approach is imperative. Furthermore, the existing studies sampled motivated individuals that were willing to participate in research. When incontinent prostate cancer patients that are nonconsenting and not participating in research are considered, the PFME effect remains unknown. Because the ACS recommends follow-up care for all prostate cancer survivors with urinary incontinence, data including incontinent patients who normally do not seek such a behavioral treatment are critical for the evaluation of pelvic floor rehabilitation as a follow-up care.

The ACS guidelines have legitimized insurance coverage with a physician referral for pelvic floor muscle rehabilitation and hence may have reduced a financial burden for patients who need this care. Despite available PFME treatment at a reduced cost, the patient’s decision on taking the treatment may be contingent on other factors, such as evaluation of PFME outcomes, resources for supporting continuing care, and other economic (e.g., limited insurance coverage from Medicare) or family burdens [7]. It is possible that those not seeking the treatment bear a disproportionate cost burden due to disadvantageous socioeconomic conditions (e.g., fewer resources or greater need for health care) [7]. Nonetheless, not taking the treatment may put the patients at an increasing risk of worsening incontinence and quality of life (QOL). Factors that influence a patient’s decision on taking the PFME-based treatment need to be investigated in order to highlight potential treatment barriers and possible solutions to enhancing treatment compliance.

It is informative to know more about patients that opt out of PFME treatment so that we can better evaluate and implement the follow-up care plan according to the ACS guideline recommendations. Recently, we completed a study to test a PFME-based behavioral intervention for persistent urinary incontinence in prostate cancer survivors [8]. Additionally, we received supplemental funding to enroll and assess a cohort of patients who were eligible for the PFME-based intervention, but declined study participation. The findings about the treatment effect on the intervention participants have been reported elsewhere [8], but the treatment effect in respect to the intervention nonparticipating patients has yet to be examined. Thus, we analyzed our data to address the following questions: (1) Is the PFME-based behavioral treatment more effective in improving continence and QOL when comparing intervention participants to nonparticipants? (2) What are the reasons, particularly economic ones, that caused the nonparticipants to refuse a PFME-based behavioral treatment for urinary incontinence? This analysis was conducted to shed light on the ACS-recommended follow-up care plan for prostate cancer patients that remain incontinent long after cancer treatment.

Methods

Study design

The data reported in this study were collected from a randomized, controlled longitudinal clinical trial (R01CA127493) and a supplemental study of the nonparticipants of the trial. The studies were conducted at three major medical centers in Northeast Ohio between 2009 and 2013 after obtaining approvals from local institutional review boards. Subject eligibility included a diagnosis of early stage prostate cancer, completion of cancer treatment (surgery or radiotherapy) at least 6 months prior, and presence of incontinence symptoms. The exclusion criteria included receiving hormonal treatment, having urinary tract infection or retention, and exhibiting cognitive impairment.

The study interventions aimed to maintain daily PFME and symptom management through behavioral modifications. The interventions had two components as follows: (1) a 60-min biofeedback session of PFME training taught by a certified biofeedback technician who was experienced in teaching PFME; and (2) six biweekly sessions of problem-solving therapy over 3 months, in which three licensed professionals (two health psychologists and a nurse specialist) individually taught symptom management skills and monitored PFME practice through either a support group (three to five subjects) or a telephone one-to-one contact, using an intervention manual.

The 279 eligible participants that consented to the intervention study were randomized at 1:1:1 ratio to 3 groups as follows: (1) biofeedback PFME plus a support group (BF + Group), (2) biofeedback PFME plus telephone (BF + Phone), and (3) usual care (UC). The BF + Group and BF + Phone participants received the study interventions, whereas the UC participants continued receiving usual care without receiving any training session. Additionally, 69 eligible patients that declined participation in the PFME-based intervention study but agreed to provide feedback were recruited consecutively as nonparticipating (NP) subjects. The nonparticipating and UC subjects received print materials unrelated to the study interventions periodically through mail to minimize a potential attention bias.

Research assistants who collected data were kept blind to the intervention participants' treatment group assignment. All subjects were assessed 3 times, at baseline (T_1), 3 months (T_2, postintervention), and 6 months (T_3, follow-up) at their homes or a hospital office. The details of the study design were published elsewhere [8].

Measurement

All subjects were assessed on six outcome variables of urinary incontinence and QOL. The daily frequency of urinary leakage was recorded by the subjects in a urinary diary for 3 days, and the average daily frequency was calculated [9]. The validity and reliability of the Urinary Diary in recording the number of wet episodes have been established for women [10, 11] and well-demonstrated for men [9, 12]. The disease-specific QOL was measured on four variables by self-report. Urinary function was assessed by the University of California-Los Angeles Prostate Cancer Index (UCLA-PCI) urinary function subscale and on a 6-point item of symptom bother, with a higher score indicating better condition. The UCLA-PCI has been widely used to measure disease-specific QOL in prostate cancer patients with excellent reliability, construct validity, and responsiveness [13]. The severity of incontinence was rated on a visual analog scale (VAS) for the past 7 days and 4 weeks, respectively, with "incontinence as bad as it could be" at 10 versus "no incontinence" at 0. This single-item self-report measure has shown to be more sensitive to mild urinary incontinence than objective measures [14]. Lastly, the Physical Component Summary (PCS) score of the SF-36v2™ Health Survey was used to assess overall physical well-being, with a higher score indicating better physical health. The SF-36 has high validity and reliability, is sensitive to change, and is widely used in outpatient populations [15]. Demographic, socioeconomic, and medical variables (e.g., cancer stage, treatment type, body mass index [BMI], and comorbidity) were collected at the baseline interview and verified against the medical chart.

A semi-structured interview was conducted with the intervention nonparticipants at the end of the study. The following questions were asked during the interview: (1) "What are the major issues or concerns that led you to the decision not to participate in the clinical trial?" and (2) "Which reason concerned you the most when making the decision not to participate?" Those that had any economic issue or concern (e.g., transportation, illness, and lack of time due to work) were asked to rate the amount of time and effort anticipated for study participation, degree of concerns, and cost for the estimated time and effort on a five-point Likert scale, with "5" indicating "very much" and "1" indicating "none."

Statistical analysis

Chi-square tests were conducted to compare the participants and nonparticipants of the intervention study on baseline characteristics. Linear mixed-effects models [16] were performed to evaluate group effects on the mean change of the six outcome measures over time. Covariates of age, race, marital status, education, household income, employment, religion, BMI, cancer stage, treatment status, prostate-specific antigen (PSA) score, Gleason score, Charlson comorbidity index score, and the use of medication were controlled for in all models. SAS version 9.3 software was used for all analyses [17]. All P values were two-sided, and P values < 0.05 were considered statistically significant. Further, the intervention nonparticipants' responses to the two open-ended questions about why they did not

participate in the PFME-based intervention study were examined, and the identified reasons were coded into two nominal variables, one per question. Frequencies were used to examine the reasons for not participating and the anticipated time or effort, concerns, and cost of the intervention study participation.

Results

The study sample consisted of 336 subjects, including 267 participants and 69 nonparticipants of the intervention study that provided needed data. The baseline sociodemographic and clinical characteristics are listed in Table 1. The study subjects had a mean age of 65 years; a majority were White and married (>60 %), and had an annual household income ≤ $50,000 (about 60 %); more than a third were still working. Most subjects had stage II prostate cancer and received surgery. The levels of BMI and comorbidity were high. The two groups were not significantly different in most baseline variables except that the intervention nonparticipants had less education (53 vs. 35 % ≤ high school graduates; $P = 0.028$), lower PSA scores (mean = 0.28 vs. 0.70; $P = 0.002$) and were more likely to have received surgery alone (71 vs. 51 %; $P = 0.019$), suggesting a better disease status at baseline compared to the intervention participants.

Figure 1 shows the unadjusted raw data of 6 outcome variables at each assessment (T_1, T_2, and T_3) by group. There were significant group differences at the baseline (T_1), as the nonparticipating group reported significantly better urinary function on the urinary function subscale of UCLA-PCI, less bother (UCLA-PCI), and less severe urinary problems on the VAS in the past month and past week ($P \leq 0.001$ for all), respectively, than the participating group. No group difference was observed on these measures at 3- and/or 6-month time points (T_2 and T_3).

Table 2 presents the results from linear mixed-effect models with adjustment of sociodemographic and clinical covariates. Compared to the intervention nonparticipants, the participants had significantly fewer daily leakage episodes ($P \leq 0.02$, $P \leq 0.01$), better urinary function ($P \leq 0.01$, $P \leq 0.001$), less bother ($P \leq 0.02$, $P \leq 0.001$), and less severe urinary problems over the past week ($P \leq 0.04$, $P \leq 0.001$) at 3 and 6 months than at baseline after adjusting for baseline group differences on these variables and covariates. Similarly, they also exhibited less severe urinary problems over the past month ($P = 0.003$) and better physical well-being ($P \leq 0.001$) at 6 months. The results indicate that the participating group had downward trends of urinary incontinence symptoms with upward trends of QOL (quality of life) measures, while the nonparticipating group had an opposite trend on all measures, suggesting worsening incontinence symptoms and QOL.

Table 3 presents the intervention nonparticipants' reasons for declining the PFME-based intervention and their reported concerns. Of 68 nonparticipating respondents, 40 % ($n = 27$) reported one reason and 52 % ($n = 35$) reported two or three reasons for declining. Two thirds (66 %) reported "too far to drive" to the study site and one third (32 %) reported "have no time due to work." When asked about the primary reason for declining to participate, they identified transportation (31 %), including the reasons "too far to drive," "have no car," and "unable to drive." Another main reason was the lack of time due to work or family needs

(18 %). Fifteen percent of the intervention nonparticipants did not consider treating incontinence a priority. Forty-two intervention nonparticipants responded to the questions about the amount of time, level of effort, and cost for participation. Of them, 45 % said that the participation would require “very much” or “a lot” of time or effort, 57 % had “very many” or “a lot” of concern about it, and 52 % had “very many” or “a lot” of concern about the cost. They estimated that each study encounter would average 2.5 h and $80 out of pocket for paying travel expenses or wage loss.

Discussion

Our data showed opposite trajectories of the participating and nonparticipating groups. At baseline, the intervention nonparticipants had better disease status (i.e., lower PSA and fewer treatments) and continence (i.e., better urinary function, less bother and urinary problems) in comparison to the intervention participants. Yet they exhibited significantly more frequent daily leakage, poorer urinary function and bother, and severer urinary problems at the end of the interventions (T_2) and follow-up (T_3). Their overall physical health measured on SF-36 was also significantly worsening at T_3. These results could be explained by a combination of improvement among the intervention participants and regression among the nonparticipants over time. This suggests that urinary function and QOL worsen over time when prostate cancer patients do not expect or are not able to have follow-up care after initial cancer treatment. More important, the results present evidence that a PFME-based treatment can reverse the deterioration of urinary function. Offering follow-up care during the survivorship period is essential for stopping or slowing regression of urinary function and QOL in this patient population.

The intervention nonparticipants had better urinary and health status at baseline, but also a lower level of education than the intervention participants, suggesting the possibilities that the nonparticipants felt less urgency to treat incontinence, and also less understanding of the study and its potential benefit. Both these factors can weigh on patients’ decisions to not participate in a treatment for incontinence that requires the input of their own resources (i.e., time, travel). Despite a reasoned choice by the nonparticipant patients, the study findings show that their initial urinary health advantage can disappear over time without appropriate follow-up care. We also reported that when the cost was taken into consideration, our study interventions were more cost-effective for the intervention participants than the nonparticipants [18], meaning that the investment in the study intervention yielded better return for patients and their health care providers. Therefore, for patients that have minor leakage and are reluctant to pursue further treatment of incontinence, it is important that they be aware of the risk of a negative trajectory of urinary continence and the value of PFME treatment. Patient education is crucial for facilitating participation and adherence with treatment recommendations.

The main reasons for patients to decline the intervention focused on the access issue: the lack of transportation and time. Our intervention study required a maximum of 10 encounters for assessment and intervention procedures that took place in either homes or hospitals where the patients received their cancer treatments. The 3-month intervention duration and frequency of hospital visits (maximally 7 to 10 times) resemble what a pelvic

floor rehabilitation program entails if it were to be an evidence-based practice [19]. When a physician referral is present, patients may feel more compelled to take a treatment, but major concerns that they harbor for the PFME-based treatment as revealed in this study remain to be addressed. For many patients, the proximity of the care-provision location to a patient's home is a primary concern. Referral to pelvic floor rehabilitation providers in a patient's own community can ease this concern. For patients that have little time for follow-up care or cannot keep up with multiple appointments over time, health care providers may need to consider other methods of care delivery. For example, home visits by urologic nurses and using technology or electronically collected data for communication and monitoring purposes may reduce the need for hospital or clinic visits. Patient long-term adherence to PFME is crucial for enhancing positive treatment outcomes, and evidence has shown that peer social support is effective [8]. A patient-centered PFME-based behavioral treatment, which is less dependent on hospitals but more on the patients themselves, would be an excellent alternative to a hospital-based treatment approach. Using a web-based patient support group may also be worth exploring.

A major limitation of our study stems from dissimilarities between the study intervention and a formal pelvic floor rehabilitation program. It is likely that patients are more compliant with a physician recommendation for treatment than a research protocol. When they are referred to a PFME treatment by a physician, their reasons for refusal may decline and expectations about the treatment outcome may increase. Patient retention and treatment completion may become a concern. The impact of this motivational factor on treatment adherence could not be addressed in this study due to a lack of relevant data, but remains to be studied. Moreover, existing literature indicates that embarrassment and shame of urinary incontinence affect many individuals' willingness to share health information and seek treatment [20, 21]. Although 82 % of eligible patients consented to our intervention study [8], we did not investigate the role of stigma in the nonparticipants' decision-making. The potential impact of stigma on patients' decisions to seek or not seek treatments for urinary incontinence remains to be studied. During our study, the research staff was blind to the intervention participants' treatment status but not blind to the nonparticipants' status; this might affect data quality. Another limitation of this study is that our sample from Northeast Ohio may not represent a broad patient population in the USA.

In conclusion, our study demonstrated the need and value of a PFME-based behavioral treatment as follow-up care for prostate cancer survivors. Health care providers should pay special attention to those patients that experience minor incontinence or have limited resources, as they may be less willing to pursue follow-up care, which may in turn lead to worsening urinary function and QOL. Patient education is essential for enhancing patient adherence to the ACS prostate cancer survivorship care guidelines. Further research is needed in this area, especially in the examination of innovative ways to deliver the PFME behavioral treatment that can help prostate cancer survivors overcome barriers and proactively seek health care for better urinary function and quality of life.

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Appendix:: American Cancer Society guidelines for assessment and management of physical and psychosocial long-term and late effects—urinary dysfunction

1. Discuss urinary function (e.g., urinary stream, difficulty emptying the bladder) and incontinence with all survivors.
2. Consider timed voiding, prescribing anticholinergic medications (e.g., oxybutynin) to address issues such as nocturia, frequency, or urgency. Consider alpha blockers (e.g., tamsulosin) for slow stream.
3. Refer survivors with postprostatectomy incontinence to a physical therapist for pelvic floor rehabilitation; at a minimum, instruct survivors about Kegel exercises.
4. Refer men with persistent leakage or other urinary symptoms to a urologist for further evaluation (e.g., urodynamic testing, cystoscopy) and discussion of treatment options including surgical placement of a male urethral sling or artificial urinary sphincter for incontinence.

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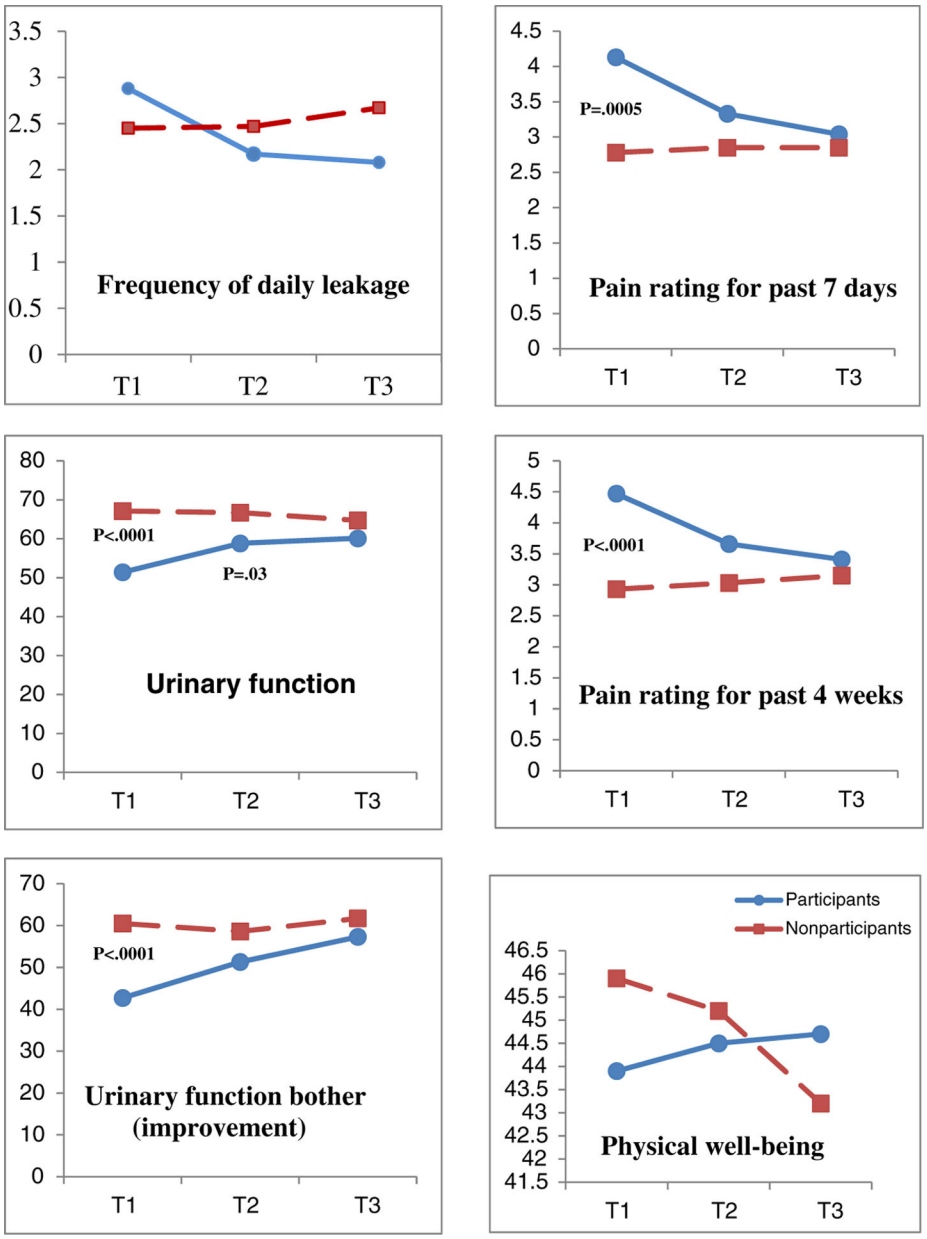

Fig. 1.
Urinary incontinence and quality of life outcomes by time and group

Table 1

Patient characteristics at baseline (mean or %)

	Nonparticipant	Participant	*P* value
n	69	267	
Sociodemographics			
Age	64.9	64.8	0.91
Race			
White	72.4	63.6	0.36
Black	26.3	34.9	
Other race	1.3	1.5	
Education			
8th grade or less	2.6	2.9	0.028
Some high school	5.3	6.1	
High school graduate/G.E.D.	44.7	25.5	
Some college/associate's degree	25.0	29.4	
College graduate	14.5	17.6	
Graduate or professional school	7.9	18.6	
Household income			
Under $15,000	11.4	14.0	0.91
$15,000—$24,999	22.9	18.8	
$ 25,000—$49,999	24.3	27.5	
$ 50,000—$100,000	25.7	24.0	
Over $100,000	15.7	15.7	
Marital status			
Married	61.8	64.9	0.72
Single	15.8	12.5	
Widowed	1.3	3.6	
Separated	5.3	2.9	
Divorced	15.8	15.8	
Religion			
Christian	86.8	84.1	0.85

	Nonparticipant	Participant	*P* value
Jewish	2.6	2.2	
Others	6.6	7.2	
None	4.0	6.5	
Employment			
Full-time employed	21.1	30.5	0.37
Part-time employed	15.8	13.3	
Unemployed	6.6	3.4	
Retired	46.1	37.6	
Cannot work—disabled	9.2	13.3	
Other	1.3	1.8	
Clinical characteristics			
BMI	28.6	29.0	0.57
Cancer stage			
Stage 1	39.5	27.3	0.22
Stage 2	56.6	67.6	
Stage 3	4.0	4.7	
Surgery (Y/N)	71.1	56.1	0.019
Radiation (Y/N)	42.1	50.0	0.22
Chemotherapy (Y/N)	1.3	0.4	0.33
PSA score	0.28	0.70	0.002
Gleason score	6.96	6.76	0.21
Charlson comorbidity score	0.84	0.78	0.68
Medication			
Anticholinergic	93.4	94.3	0.79
Alpha blocker	72.4	78.9	0.23
Diuretic	79.0	75.5	0.53

Table 2

Changes of urinary incontinence and quality of life outcomes by group (adjusted results)

	Adj. mean diff.	95 % CI	*P*
Leakage frequency			
At 3 months	−1.13	−2.06, −0.20	0.017
At 6 months	−1.20	−2.15,−0.24	0.014
Urinary function			
At 3 months	6.94	1.98, 11,89	0.006
At 6 months	11.23	6.23, 16.22	<0.001
Urinary function bother			
At 3 months	9.35	1.42, 17.29	0.021
At 6 months	13.05	5.05, 21.04	0.001
VAS rating of past 7 days			
At 3 months	−0.84	−1.64, −0.05	0.037
At 6 months	−1.34	−2.15, −0.54	0.001
VAS rating of past 4 weeks			
At 3 months	−0.77	−1.63, 0.09	0.078
At 6 months	−1.34	−2.21, −0.47	0.003
Physical well-being			
At 3 months	0.85	−1.43, 3.13	0.47
At 6 months	3.78	1.49, 6.08	0.001

Linear mixed models with NP as the reference group controlling for baseline age, race, education, household income, marital status, employment, religion, BMI, cancer stage, surgery, radiation, chemotherapy, PSA, Gleason, Charlson comorbidity scores, and medications (anticholinergics, alpha blockers, and diuretics)

NP nonparticipating, *CI* confidence interval

Table 3

Reasons for declining PFME-based intervention participation

Reasons for refusal (subjects can have multiple answers)	***N* = 68%**	**%**
Too far to drive	45	66.2
Have no time due to work	22	32.4
Treating UI is not a priority	14	20.6
Have no car	10	14.7
Too busy—assisting needy family members	9	13.2
Cannot drive	6	8.8
Other reasons	21	30.9
Primary reason for refusal	***N* = 68%**	**%**
Transportation (e.g., too far to drive, had no car, or cannot drive)	21	31
Have no time (e.g., had no time due to work or family needs)	12	18
Treating urinary incontinence is not a priority	10	15
Other (e.g., too sick, Kegel is not helpful, tired of talking about cancer or incontinence, study has too many questions)	25	28
How much time or effort is needed for participation	***N* = 42%**	**%**
Very much or a lot	19	45.3
Some	11	26.2
A fair amount to a little	12	28.6
How many concerns about putting in this time or effort	***N* = 42%**	**%**
Very many or a lot	24	57.1
Some	9	21.4
A few to none	9	21.5
How many concerns about the cost of this time or effort	*N* = 42%	%
Very many or a lot	22	52.4
Some	4	9.5
A few to none	16	38.1