

Improved cancer coping from a web-based intervention for prostate cancer survivors: A randomized controlled trial

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Abstract

Objectives: Prostate cancer (PCa) survivors report poor physical functioning alongside negative psychological outcomes as they cope with treatment side effects and practical concerns after treatment completion. This study evaluated PROGRESS, a web-based intervention designed to improve adaptive coping among PCa survivors.

Methods: Localized PCa patients ($N = 431$) within one year of treatment completion were randomized to receive educational booklets or PROGRESS + educational booklets. Surveys completed at baseline, 1-, 3-, and 6-months assessed patient characteristics; functional quality of life and coping (*primary outcomes*); and psychosocial outcomes (e.g., self-efficacy, marital communication; *secondary outcomes*). Intent-to-treat and as-treated analyses were completed to assess change in outcomes from baseline to 6 months using linear mixed effects regression models.

Results: In the intent-to-treat analyses, participants randomized to the intervention group had improved diversion coping (i.e., healthy redirection of worrying thoughts about their cancer), but more difficulties in marital communication ($ps < 0.05$). However, PROGRESS usage was low among those randomized to the intervention group (38.7%). The as-treated analyses found PROGRESS users reported fewer practical concerns but had worse positive coping compared to PROGRESS non-users ($ps < 0.05$).

Conclusions: The findings suggest PROGRESS may improve certain aspects of adaptive coping among PCa survivors that use the website, but does not adequately address the remaining coping and psychosocial domains. Additional research is needed to better understand the gaps in intervention delivery contributing to low engagement and poor improvement across all domains of functional quality of life and adaptive coping.

KEYWORDS

eHealth, prostate cancer, quality of life, randomized controlled trial, survivorship, urologic oncology

1 | INTRODUCTION

Prostate cancer (PCa) is the most common cancer among men in the U.S. and most PCa diagnoses are at a local or regional stage with a 5-year relative survival rate near 100%.¹ Subsequently, there is a growing number of PCa survivors in the U.S.² While localized PCa patients have the option of active surveillance, most have undergone active treatment (e.g., surgery, radiation).³ Despite the favorable survival rate, active treatment often results in urinary, sexual, and bowel dysfunction reducing functional quality of life.^{4,5} While treatment side effects may improve over time,⁴ establishing reasonable expectancies is critical for PCa patients' transition into survivorship. Additionally, many survivors experience a significant psychological impact from their cancer experience,⁶ often linked to uncertainty, cancer recurrence, and regret.⁵ Survivors also report difficulties adjusting to life post-treatment (e.g., financial difficulties, healthcare access, communication difficulties with family).⁵

Supportive interventions should comprehensively focus on PCa survivors' functional, psychological, and adjustment needs. However, existing interventions typically focus on one need⁷⁻¹⁵ and are resource-intensive, limiting their scalability.¹⁶⁻¹⁸ As more cancer survivors are seeking health information online,¹⁹ web-based interventions have demonstrated improved patient-reported outcomes.¹² However, most web-based interventions are either underpowered, not evaluated in a randomized controlled design,^{12,15} or are not adaptable to the specific needs of cancer survivors over the survivorship trajectory.²⁰

To comprehensively address PCa survivors' functional, psychological, and adjustment needs, our team developed and evaluated a "Prostate Cancer Online Guide & Resource for Electronic Survivorship" (PROGRESS),²¹ a web-based intervention designed to improve post-treatment needs. We hypothesized that PROGRESS would improve functional quality of life and adaptive coping (*primary outcomes*) compared to enhanced usual care. We also hypothesized PROGRESS would improve self-efficacy for re-entry and symptom control, practical concerns (i.e., managing practical aspects of their lives), and interactions with providers and significant others (*secondary outcomes*) compared to enhanced usual care. To examine how outcomes differ by intervention use,¹⁵ an as-treated analysis was completed in addition to an intent-to-treat analysis.

2 | METHODS

2.1 | Study design and participants

PCa patients within 1 year of treatment completion were recruited between 2013 and 2016 at four Mid-Atlantic cancer centers. Research staff identified eligible patients scheduled for follow-up appointments through medical chart review. Patients were eligible if they (a) received a diagnosis of localized PCa with no regional lymph node or distant metastasis (stages T1-T3c), (b) were within

one year of treatment completion and have completed all primary treatment, (c) had access to a computer with Internet access, (d) were 18 years of age or older, (e) were able to communicate in English, and (f) were able to give consent. Patients were introduced to the study before their appointment and if interested, provided written informed consent and completed the baseline survey. Using a 1:1 randomized control trial design, participants were block randomized by site using REDCap to enhanced usual care or the intervention. The computer-generated randomization table was created by an independent researcher. Participants received a \$20 gift card at the completion of each survey. The study protocol was approved by each site's Institutional Review Board and is registered at clinicaltrials.gov (NCT02224482).

3 | INTERVENTION CONDITIONS

3.1 | PROGRESS

PROGRESS was guided by the Cognitive Social Health Information Processing (C-SHIP) model²² and designed to provide a comprehensive resource for PCa survivors.²¹ The website addressed challenges faced by PCa survivors (e.g., physical function, emotional well-being, interpersonal concerns; Table S1). PROGRESS included written information, videos from providers and survivors, and tools to help participants identify values, goals, and support complementary behaviors. Each participant had a unique login ID and password and was instructed to log into the website as needed. Logins and usage was tracked via Google Analytics. Intervention participants also received the same booklets as enhanced usual care.

3.2 | Enhanced usual care

Participants randomized to enhanced usual care (control group) received two print brochures from the National Cancer Institute via mail: *Facing Forward: Life after Cancer Treatment* and *What You Need to Know about Prostate Cancer*. The *Facing Forward* brochure includes sections on (a) follow-up medical care; (b) managing physical changes, body changes and intimacy; (c) feelings, (d) social and work relationships; and (e) reflection. The *What You Need to Know about Prostate Cancer* booklet provided general information about PCa diagnosis and treatment. Neither print materials contained features offered in PROGRESS (e.g., coping strategies, skills and training exercises, self-tailoring, video presentations).

3.3 | Data collection

Participants completed surveys at baseline and at one, three, and six months. Surveys were completed via paper-and-pencil, online using REDCap, or via telephone based on participant preference. Participants completing the survey via paper-and-pencil were mailed the

survey with a preaddressed and stamped envelope. The survey was then entered into REDCap by research staff. For online survey completion, participants were emailed a unique survey link to REDCap. Research staff directly entered responses into REDCap during phone interviews.

4 | MEASURES

4.1 | Demographics and medical variables

Self-reported demographic information was obtained on the baseline survey (e.g., age, race/ethnicity, household income). Medical variables obtained by patient self-report included PSA at diagnosis; treatment received (surgery, radiation, hormone therapy); comorbidities²³; and health literacy.²⁴ PSA at diagnosis and treatment received were confirmed with medical records.

4.2 | PROGRESS usage

Intervention participants were considered to have used PROGRESS if they clicked through the home page at least once as identified by Google Analytics. Participants were classified as non-users if they did not log in or logged in but did not click through to any other page beyond the home page.

4.3 | Primary outcome variables

The outcome variables used in the study were informed by the C-SHIP model and the PROGRESS intervention development preliminary testing with the target population.²¹ Cancer coping was assessed using the Cancer Coping Questionnaire,²⁵ a 14-item scale that comprehensively measures cancer patients' coping ability ($\alpha = 0.879$) on a 4-point scale (1 = *not at all* to 4 = *very often*) with greater scores indicating greater coping ability. The four subscales and an additional interpersonal coping scale were also included. The 5-item coping subscale assessed general coping techniques (e.g., slow breathing; $\alpha = 0.780$). The 3-item positive subscale assessed respondents' outlook on their future ($\alpha = 0.559$). The 3-item diversion subscale assessed respondents' ability to appropriately divert their thoughts from cancer ($\alpha = 0.712$). The 3-item planning subscale assessed respondents' ability to make short-term plans ($\alpha = 0.756$). An additional 7-item interpersonal coping scale assessed respondents' ability to discuss their cancer diagnosis with their partner ($\alpha = 0.915$).

Functional quality of life was assessed using the four Expanded Prostate Cancer Index Composite scales²⁶ scored on a range of 0 to 100 with greater scores indicating greater functional quality of life. The 4-item urinary incontinence scale assessed respondents' leaking and urinary control in the past four weeks ($\alpha = 0.883$). The 4-item urinary irritation scale assessed respondents' urinary irritation or obstruction in the past four weeks ($\alpha = 0.688$). A six item scale

assessed respondents' bowel function in the past four weeks ($\alpha = 0.818$). Finally, a six item scale assessed respondents' sexual function in past four weeks ($\alpha = 0.914$).

4.4 | Secondary outcome variables

The self-efficacy for re-entry scale is a 14-item author-constructed 11-point scale (0 = *not at all confident* to 10 = *completely confident*; $\alpha = 0.915$) that assessed respondents' self-efficacy to manage their relationships, stress, medical care, and side effects in their first year post-treatment as they "re-enter" their various roles (e.g., spouse, employee, friend).²⁷ The 13-item self-efficacy for symptom control scale is a validated scale assessed respondents' perceived confidence to manage their care post-treatment on a 4-point scale (1 = *strongly disagree* to 4 = *strongly agree*; $\alpha = 0.925$).²⁸ This scale has been previously used among individuals with a history of PCa to assess their post-treatment symptoms after receiving surgery or radiation,^{29,30} as well as individuals with other chronic illnesses.³¹⁻³³ Greater scores on both self-efficacy scales indicate greater self-efficacy. An adapted 12-item practical concerns scale assessed respondents' concern about managing practical aspects of their lives including finances, employment, and healthy lifestyle activities on a 5-point scale (1 = *strongly disagree* to 5 = *strongly agree*; $\alpha = 0.919$).³⁴ Greater scores indicate greater concern. Two measures were used to assess communication and focused on interactions with medical providers and partners to reduce participant burden. The 5-item medical interactions scale assessed respondents' difficulty communicating with medical staff on a 5-point scale (0 = *not much* to 4 = *very much*; $\alpha = 0.758$) and the 5-item marital interactions scale assessed respondents' difficulty communicating with their partner ($\alpha = 0.739$).³⁵ Greater scores indicate greater difficulty communicating.

4.5 | Data analysis

We tested whether the randomization achieved balance for important covariates and baseline outcome measures using Chi-squared tests and *t*-tests, as appropriate. We also assessed whether baseline covariates were predictive of dropout or website use; significant variables were included as covariates in subsequent models. For each outcome, the primary result of interest was change from baseline averaged across post-intervention follow-up times (e.g., coping adjustment over time). We fit linear mixed effects regression models for change in outcome, with subject-specific random intercepts and fixed effects for treatment condition, time of follow-up, and the baseline value of the given outcome measure. Significance was assessed via likelihood ratio tests, with $p < 0.05$ considered to be statistically significant. Primary analyses used an intent-to-treat approach, and we also conducted as-treated analyses, where the participant must have accessed PROGRESS to be considered treated. In additional multivariable regression models, we assessed whether

treatment effects differed across follow-up times for the primary outcomes by including an interaction term between an indicator for 6-month follow-up and treatment condition, using an *F*-test to assess whether any changes were statistically significant. The study was designed to expect 240 participants per group ($N = 480$) at 6-month follow-up after attrition. Conservatively, the nominal Type-1 error rate was set to 1% and allowed for robust power to detect a modest effect size of 0.10 in all cases. Analyses were conducted in R (R Foundation for Statistical Computing).

5 | RESULTS

5.1 | Participant recruitment and demographics

A total of 431 patients were enrolled and randomized to the intervention group ($n = 217$) or enhanced usual care ($n = 214$; Figure 1). There were no significant differences in demographic characteristics between participants in each group (Table 1). Of the 217 participants randomized to PROGRESS, 84 participants (38.7%) logged into and used PROGRESS (i.e., PROGRESS users). Therefore, we completed an as-treated analysis to compare study outcomes among users and non-users of PROGRESS. PROGRESS users were significantly older than PROGRESS non-users ($p < 0.05$). Participants with greater income, completed radiation, and less urinary incontinence were more likely to be lost to follow-up at 6 months ($ps < 0.05$). There were no significant differences in primary or secondary outcomes at baseline or 6-month follow-up between groups for the intent-to-treat or as-treated analyses (Table 2).

5.2 | Intent-to-treat analyses

Participants randomized to the intervention group reported a significantly greater increase in diversion coping ($F = 7.914, p < 0.01$; Table 3). Additionally, while participants in both groups (i.e., randomized to intervention and control groups) saw a decrease in interpersonal coping from baseline to six months, participants randomized to the intervention group had a smaller decrease in interpersonal coping over time compared to participants receiving enhanced usual care ($F = 6.201, p < 0.05$). Conversely, participants randomized to the intervention group reported worse marital interactions than participants in enhanced usual care ($F = 4.585, p < 0.05$). There were improvements for participants in both the intervention and control groups in urinary incontinence ($F = 36.196, p < 0.001$), urinary irritation ($F = 25.716, p < 0.001$), and sexual function ($F = 5.008, p < 0.05$) over time. However, there was a decrease in positive coping ($F = 11.613, p < 0.001$) and increase in practical concerns ($F = 131.582, p < 0.001$) for participants in both the intervention and control groups over time. There were no significant differences between those randomized to the intervention group or control group across follow-up times for the primary outcomes ($ps > 0.05$; Table S2).

5.3 | As-treated analyses

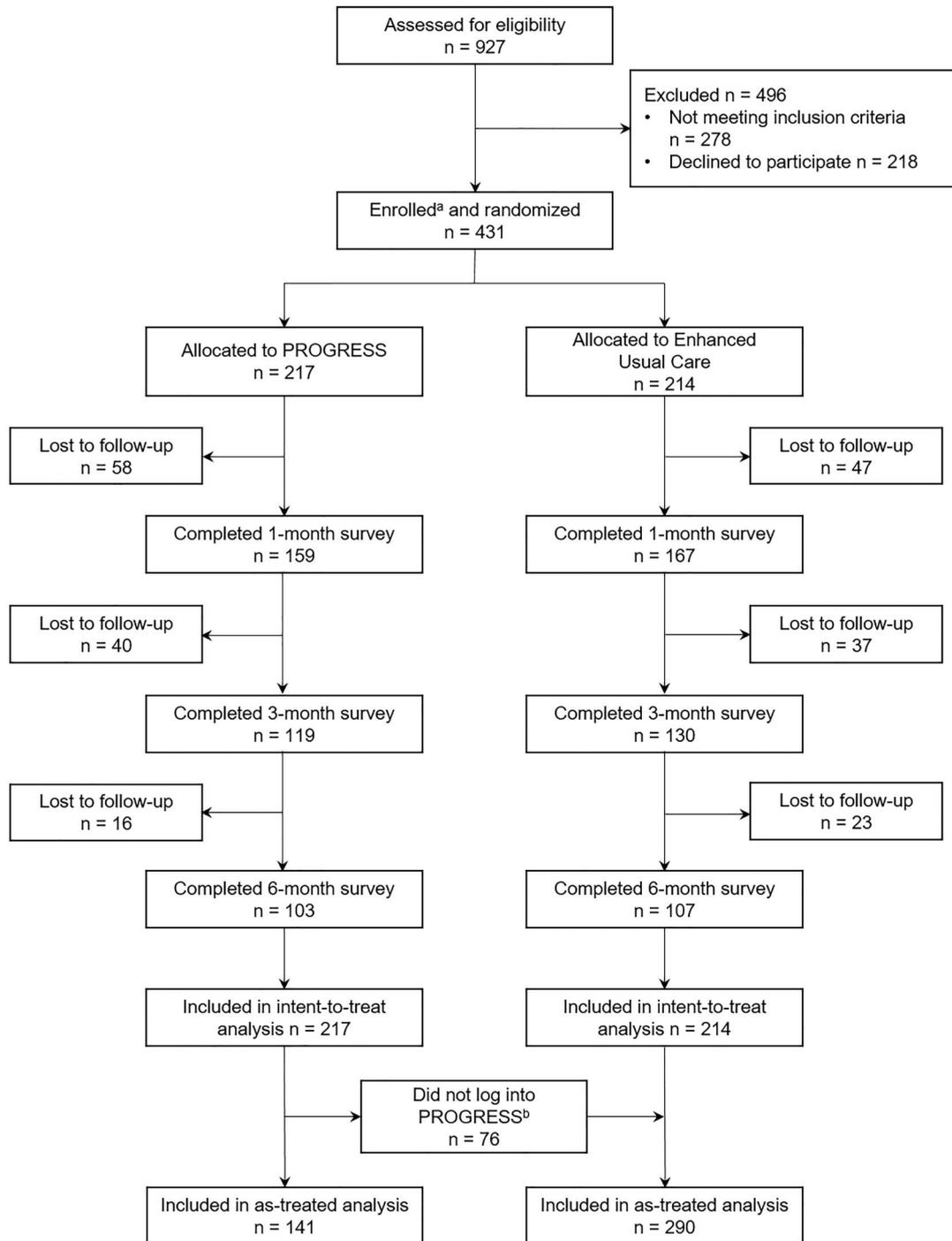
PROGRESS users (i.e., clicked through the home page at least once) reported a significant decrease in practical concerns compared to PROGRESS non-users ($F = 7.370, p < 0.01$; Table S3). However, PROGRESS users had worse positive coping compared to PROGRESS non-users ($F = 73.195, p < 0.01$). Both PROGRESS users and non-users reported an increase in general coping techniques (e.g., slow breathing; $F = 4.544, p < 0.05$), urinary incontinence functioning ($F = 35.513, p < 0.001$), and practical concerns ($F = 128.740, p < 0.001$) over time. However, there was a decrease in positive coping for both PROGRESS users and non-users over time ($F = 11.253, p < 0.001$). There were no significant differences between PROGRESS users and non-users across follow-up times for the primary outcomes ($ps > 0.05$; Table S4).

6 | DISCUSSION

PROGRESS is a theoretically guided web-based intervention to help localized PCa survivors cope with functional, psychological, and adjustment difficulties. As hypothesized, participants randomized to the intervention group had improved diversion coping (i.e., healthy redirection of worrying thoughts) but unexpectedly had more difficulties in marital communication. Within the as-treated analysis, PROGRESS users reported fewer practical concerns as we expected. However, PROGRESS users had worse positive coping compared to PROGRESS non-users.

Diversion coping includes positive reframing of survivors' symptoms and side-effects and the adoption of healthy behaviors to channel frustrations. This coping mechanism has found success in multiple studies targeting PCa patients and survivors.³⁶ As expected, the intent-to-treat analysis found participants randomized to the intervention group had greater diversion coping compared to participants randomized to enhanced usual care. However, the change from baseline to six months was minimal (0.08 point increase on a 4 point scale) and may not be meaningfully significant. Additionally, this effect was not sustained in the as-treated analysis suggesting this significant finding may have been spurious.

While participants randomized to the intervention group had a smaller decrease in interpersonal coping compared to participants receiving enhanced usual care, participants randomized to the intervention group reported more difficult marital interactions. The interpersonal coping items ask if participants have talked with their partner about the impact of cancer on their lives. Conversely, the marital interactions scale asked about participants' perceived difficulties talking to their partner about financial arrangements or desired intimacy, or if their partner spends too much time taking care of the patient. Extant literature has found PCa patients often restrict communication with their partners and avoid intimacy³⁶ and most men prefer to not disclose health issues with their spouse.³⁷ Similarly, intimacy may be a mediator to relationship communication and distress.³⁸ However, participants randomized to the intervention



^aParticipants were enrolled if they completed the consent process and the baseline survey.

^bIntervention participants that did not log into PROGRESS were grouped with control participants for the as-treated analysis.

FIGURE 1 CONSORT flow diagram of randomized controlled trial evaluating PROGRESS

group only reported a 0.06 change in perceived marital interactions on a 5 point scale. Similar to diversion coping, this difference may not be meaningfully significant and have been a spurious significant finding. Future research should examine these marital outcomes to better understand their relationship to each other (i.e., interpersonal coping and marital communication) among individuals who have received treatment for PCa.

PROGRESS users (i.e., clicked through the home page at least once) in the as-treated analysis reported fewer practical concerns, suggesting the website may have helped participants cope with the tangible aspects of their survivorship (e.g., financial concerns, social activities). However, PROGRESS users had worse positive coping than PROGRESS non-users. Positive coping includes making definite plans for the future, reminding themselves of what things they still

TABLE 1 Demographics of PROGRESS participants (N = 431)

Characteristic	Intent-to-treat			As-treated		
	PROGRESS (n = 217) N (%) or M (SD)	Enhanced usual Care (n = 214) N (%) or M (SD)	p-value	Used PROGRESS (n = 84)N (%) or M (SD)	Did not use PROGRESS (n = 347) N (%) or M (SD)	p-value
Age	63.8 (6.67)	63.3 (7.51)	0.447	65.37 (7.03)	63.08 (7.05)	0.008
Race			0.709			
White	163 (75.8)	148 (69.8)		68 (81.9)	243 (70.6)	0.085
Black/African American	41 (19.1)	52 (24.5)		10 (12.1)	83 (24.1)	
Other	11 (5.1)	12 (5.7)		5 (6.0)	18 (5.2)	
Hispanic	9 (4.34)	8 (4.3)	0.982	2 (2.5)	15 (4.8)	0.282
Married or living with partner	175 (80.6)	172 (80.8)	0.321	72 (85.7)	275 (79.5)	0.381
Education			0.685			0.695
≤ High school diploma	49 (22.8)	51 (24.1)		16 (19.1)	84 (24.5)	
Some college	63 (29.3)	64 (30.2)		26 (31.0)	101 (29.5)	
4 year degree	55 (25.6)	46 (21.7)		22 (26.2)	79 (23.0)	
Graduate degree	48 (22.3)	51 (24.1)		20 (23.8)	79 (23.0)	
Household income			0.177			0.104
≤ \$30,000	20 (9.9)	29 (14.3)		5 (6.2)	44 (13.5)	
\$30,001 – 60,000	39 (19.2)	43 (21.2)		20 (24.7)	62 (19.1)	
\$60,001 – 75,000	29 (14.3)	22 (10.8)		7 (8.6)	44 (13.5)	
≥ \$75,001	115 (56.7)	109 (53.7)		49 (60.5)	175 (53.9)	
Treatment completed						
Surgery	112 (51.6)	119 (55.6)	0.406	45 (53.6)	186 (53.6)	0.546
Radiation	69 (31.8)	74 (34.6)	0.540	32 (38.1)	111 (32.0)	0.174
PSA at diagnosis	14.0 (49.0)	8.6 (10.7)	0.168	12.2 (39.8)	8.2 (8.6)	0.408
Comorbidities			0.892			0.845
0	167 (78.0)	160 (76.2)		66 (79.5)	261 (76.5)	
1	28 (13.1)	29 (30.8)		10 (12.0)	47 (13.8)	
≤2	19 (8.9)	21 (10.0)		7 (8.4)	33 (9.7)	
Health literacy ^a	13.1 (2.2)	13.1 (2.4)	0.837	13.5 (1.9)	13.0 (2.4)	0.042

Note: Any percentages not totaling 100% are due to rounding.

^aHealth literacy maximum score is 15 with greater scores indicating greater health literacy.

have in life despite cancer. Using PROGRESS resulted in continued exposure to the past cancer experience. Although the website was designed to be supportive, helpful, and foster positive coping behavior, it requires additional skills to manage information that reminds one of the existential cancer experience. This limits, in turn, survivor's positive thoughts. O'Malley and colleagues observed survivors who wanted more information to guide their follow-up care reported greater worries about the future and fears about disease recurrence compared to those who did not want additional information.³⁹ Additional research is needed to identify the relationship between PROGRESS

usage and positive coping to better support PCa patients during this difficult transition time.

7 | STUDY LIMITATIONS

Limitations to the current study include recruitment of patients from academic cancer centers who may differ in their socio-demographic and medical variables and have greater access to resources than those treated at smaller regional hospitals or

TABLE 2 Primary and secondary outcomes at baseline and 6-month follow-up of PROGRESS

Variable	Intent-to-treat				As-treated			
	Baseline		6 months		Baseline		6 months	
	PROGRESS M (SD)	Enhanced usual care M (SD)	PROGRESS M (SD)	Enhanced usual care M (SD)	Used PROGRESS M (SD)	Did not use PROGRESS M (SD)	Used PROGRESS M (SD)	Did not use PROGRESS M (SD)
Primary outcomes								
Cancer coping total score	2.22 (0.64)	2.22 (0.67)	2.22 (0.63)	2.17 (0.64)	2.16 (0.71)	2.24 (0.67)	2.14 (0.60)	2.22 (0.65)
General coping techniques	1.88 (0.70)	1.88 (0.70)	1.93 (0.73)	1.91 (0.73)	1.78 (0.65)	1.90 (0.71)	1.84 (0.74)	1.95 (0.72)
Diversion	2.00 (0.81)	2.03 (0.84)	2.08 (0.81)	2.04 (0.78)	1.90 (0.82)	2.04 (0.83)	1.94 (0.75)	2.10 (0.81)
Planning	2.51 (0.96)	2.50 (0.91)	2.52 (0.85)	2.43 (0.87)	2.41 (0.98)	2.53 (0.92)	2.42 (0.86)	2.49 (0.86)
Positive outlook	2.74 (0.78)	2.70 (0.85)	2.52 (0.64)	2.50 (0.64)	2.80 (0.75)	2.70 (0.83)	2.52 (0.62)	2.51 (0.64)
Interpersonal	1.94 (0.78)	2.06 (0.88)	1.80 (0.76)	1.88 (0.80)	1.89 (0.74)	2.03 (0.85)	1.81 (0.82)	1.85 (0.77)
Urinary incontinence	63.43 (29.67)	62.57 (30.14)	78.54 (22.30)	76.72 (23.16)	66.83 (30.99)	62.04 (29.55)	79.46 (22.98)	76.88 (22.63)
Urinary irritation	78.51 (19.02)	79.49 (19.37)	87.44 (15.14)	88.82 (12.70)	79.71 (17.91)	78.81 (19.50)	86.29 (15.95)	88.88 (13.02)
Bowel dysfunction	88.66 (15.81)	89.76 (14.41)	92.62 (13.30)	91.41 (13.08)	90.26 (13.55)	88.94 (15.51)	92.21 (12.72)	91.92 (13.39)
Sexual dysfunction	32.14 (29.24)	31.44 (29.68)	34.19 (29.38)	36.39 (28.42)	34.15 (30.35)	31.21 (29.20)	35.64 (31.24)	35.16 (27.94)
Secondary outcomes								
Self-efficacy for re-entry	8.75 (1.11)	8.82 (1.11)	8.54 (1.15)	8.48 (1.19)	8.82 (0.98)	8.77 (1.14)	8.62 (1.18)	8.47 (1.16)
Self-efficacy for symptom control	3.33 (0.48)	3.32 (0.51)	3.36 (0.44)	3.32 (0.52)	3.39 (0.42)	3.31 (0.51)	3.38 (0.44)	3.32 (0.49)
Practical concerns	2.41 (0.99)	2.45 (1.01)	1.58 (0.86)	1.68 (0.92)	2.36 (0.97)	2.45 (1.00)	1.45 (0.80)	1.70 (0.91)
Medical interactions	2.70 (3.28)	2.39 (3.07)	2.09 (2.20)	1.96 (2.72)	2.23 (2.50)	2.63 (3.32)	1.72 (1.82)	2.14 (2.68)
Marital interactions	3.40 (3.92)	3.42 (3.97)	3.34 (3.93)	3.18 (4.18)	3.14 (3.34)	3.48 (4.07)	2.87 (4.09)	3.41 (4.05)

Note: No significant differences between groups at baseline or 6-month follow-up.

private clinics. Additionally, as this was a web-based intervention, patients that did not have Internet access were ineligible, limiting our potential reach to certain populations. Further, only 38.7% of participants randomized to PROGRESS logged in and used the website. Age and health literacy were the only two demographic variables significantly different across those who did and did not use the website. While older men were significantly more likely to be PROGRESS users, consistent with other web-based interventions,⁴⁰ the mean age difference between the two groups is marginal (65.37 vs. 63.08). Participants with greater health literacy were more likely to be PROGRESS users, suggesting health literacy may be a barrier to website use. Finally, many survivors show a preference for print-based materials to be delivered alongside web-based materials.⁴¹ The study findings were limited in their assessment of why participants did not use PROGRESS, including lack of follow-up to ask participants why they did not use the website. Despite preliminary evidence of PROGRESS' feasibility,²¹ this warrants further investigation into why and which participants may or may not use a web-based support tool. Further, the

feasibility assessment prior to this randomized controlled trial was limited to usability testing and did not evaluate participant website use outside of the laboratory environment. This in turn did not provide data that would have allowed us to hypothesize website usage rates including metrics such as click rates and time on website. During PROGRESS development, usability testing revealed that participants wanted improved content organization, additional instructions for using the website, and targeted information for their specific treatment received—all improvements were incorporated into the website design and underwent another round of participant review.²¹ However, it is likely that our usability testing did not identify all website access and design features that led to reduced participant use. Finally, due to technical difficulties, our website tracking was also limited to participant clicking off the home page onto another page and did not include metrics such as time spent on website and number of pages clicked. Therefore, we were unable to assess how much those who were coded as "using" PROGRESS were actually clicking through the website and using the website. Future research should ensure the study design

TABLE 3 Multivariable regression of outcome variables at 6-month follow-up for intent-to-treat analyses

	Group ^a			Time		
	B	SE	F-value	B	SE	F-value
Primary outcomes						
Cancer coping total	0.082	0.047	2.111	-0.003	0.007	0.185
General coping techniques	0.069	0.056	0.861	0.017	0.008	4.424*
Diversion	0.183	0.067	7.914**	0.005	0.010	0.172
Planning	0.050	0.067	0.090	-0.006	0.012	0.340
Positive outlook	-0.004	0.051	0.673	-0.037	0.011	11.613***
Interpersonal	0.086	0.063	6.201*	0.000	0.008	0.011
Urinary incontinence	1.614	1.614	1.634	1.296	0.216	36.196***
Urinary irritation	-1.436	1.120	1.225	0.904	0.174	25.716***
Bowel dysfunction	-0.014	0.973	0.356	0.149	0.144	0.819
Sexual dysfunction	-1.147	1.747	0.076	0.464	0.120	5.008*
Secondary outcomes						
Self-efficacy for re-entry	-0.083	0.088	0.116	0.012	0.012	0.896
Self-efficacy for symptom control	0.033	0.037	0.407	0.010	0.006	2.577
Practical concerns	0.055	0.068	0.780	-0.139	0.012	131.582***
Medical interactions	0.232	0.204	0.172	-0.053	0.031	2.651
Marital interactions	0.716	0.317	4.585*	0.043	0.048	0.735

Note: Analyses controlled for age, income, and treatment. Outcome variables assess change over time from baseline to 6-month follow-up. Reported significance for F-value. Sample size of participants randomized to PROGRESS = 217 and randomized to enhanced usual care = 214.

^aReference group: Enhanced usual care.

*** $p < 0.001$; ** $p < 0.01$; * $p < 0.05$.

includes adequate objective website tracking metrics and website usage self-report items for complete evaluation of web-based intervention use and nonuse.

8 | CLINICAL IMPLICATIONS

With a growing number of PCa survivors,² interventions are needed to support these individuals as they continue across the survivorship trajectory. Additionally, as drastically shown during the COVID-19 pandemic, effective web-based health services are needed to ensure continuity of care when in-person services are abruptly halted. However, the present study's findings demonstrate the need for additional research to identify methods to increase participant engagement in PROGRESS and enhance skills building. When developing web-based interventions, we suggest researchers use well-designed feasibility studies beyond usability data to identify issues with engagement to address any issues before the randomized controlled trial. Further, as researchers and practitioners implement web-based tools in clinical practice, careful attention is needed to confirm only those interventions with demonstrated success in engagement and patient-reported outcomes are adopted.

9 | CONCLUSIONS

Overall, the intent-to-treat analysis identified improved diversion coping, but greater difficulties in marital communication. The as-treated analysis found fewer practical concerns but poorer positive coping among PROGRESS users. The as-treated findings suggest PROGRESS may be addressing certain psychosocial factors (i.e., practical concerns), but may not provide the necessary skills building or other relevant information for survivors to adequately improve patient-reported outcomes. Compounded with low engagement, these results have relevance in the development of future interventions for cancer survivors, serving as a model for evaluating interventions designed to improve physical functioning and adaptive coping. Specifically, these findings demonstrate the importance of identifying and addressing factors related to low engagement as well as the development of intervention content that include skill building exercises to increase participant self-efficacy and improve quality of life.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ETHICS STATEMENT

All participants completed the informed consent process as approved by each site's Institutional Review Board (Fox Chase Cancer Center: #11-825, Rutgers Cancer Institute of New Jersey: #0220110092, Northwell Health: 14-672, Mt. Sinai: #11-01136) including review of the consent documents with a research staff member and receipt of signed consent on the informed consent and HIPAA forms.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

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

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