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FULL LENGTH MANUSCRIPT

Low Social Well-Being in Advanced and Metastatic Prostate Cancer: Effects of a Randomized Controlled Trial of Cognitive Behavioral Stress Management

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Abstract

Background Social well-being impacts cancer patients' health-related quality of life (HRQOL) and coping style. This secondary analysis was conducted to examine whether advanced prostate cancer survivors who had experienced low social well-being would benefit from a web-based cognitive behavioral stress management (CBSM) intervention.

Method APC survivors ($N = 192$) who had received androgen deprivation therapy (ADT) were randomized to a 10-week CBSM or a health promotion (HP) control condition. A subsample of participants ($n = 61$) with low pre-intervention SWB (measured by social support from and relationship satisfaction with family and friends) was included in the study. Multilevel models compared participants' PC-specific quality of life (sexual, hormonal, urinary), affect-based psychosocial burden (cancer-related anxiety and distress), and coping strategies at baseline, 6 months, and 12 months. Covariates were included in all models as appropriate.

Results Participants randomized to the CBSM condition showed significantly greater improvements in fear of cancer recurrence and cancer-related intrusive thoughts than those in the HP control condition. A significant condition by time interaction was also found, indicating that CBSM improved participants' PC-related fear in both short- (6 months) and long-term (12 months). However, the CBSM intervention did not significantly impact APC-related symptom burden. Only for the urinary domain, clinically meaningful changes (CBSM vs HP) were observed. In addition, all participants, regardless of condition, reported less coping (e.g., emotion-, problem- and avoidance-focused) over time.

Conclusion As predicted, the CBSM intervention improved several affect-based psychosocial outcomes for APC survivors with low baseline SWB.

Keywords Advanced prostate cancer · Psychosocial · Cognitive behavioral therapy · Stress management · Social well-being · Health-related quality of life

Introduction

Prostate cancer (PC) is a significant health burden and is a major cause of cancer-related death in men worldwide [1]. PC, and particularly advanced and metastatic disease (APC), is associated with a wide range of chronic and debilitating symptoms and treatment-related side effects including sexual dysfunction, urinary incontinence and urgency, and hormonal-related symptom burden [2–4]. Androgen deprivation therapy (ADT) is predominantly used for APC. Its objective is to reduce the levels of androgens—the hormones responsible for stimulating PC cell growth [5]. While ADT is not considered a curative treatment, it has been well-documented to offer clinical benefits. It effectively enables many men with APC to live free from the symptoms

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of metastases for extended periods, thus improving their quality of life [6]. Nevertheless, ADT has been linked to various adverse psychological effects. Research indicates that men undergoing ADT face an elevated risk of health-related fear and anxiety [7, 8], distress [9], and threats to masculine identity [10, 11], which can present significant challenges to their health-related quality of life (HRQOL) and overall well-being.

Given multiple physical and psychosocial challenges, there is increasing research on how psychosocial interventions may be used to mitigate the distress associated with PC. One of the promising interventions is cognitive behavioral stress management (CBSM). CBSM integrates aspects of cognitive behavioral therapy (CBT) (e.g., cognitive restructuring, behavioral, and interpersonal skills) with relaxation skills training (e.g., deep breathing) to manage stress, improve health-related quality of life (HRQOL), and reduce symptoms [12]. We have seen a growing literature suggesting that CBSM is linked to psychological benefits (i.e., emotional well-being) and improved sexual and immune functioning in men with localized prostate cancer [13–15]. Nonetheless, randomized controlled trials testing the efficacy of CBSM among patients with advanced cancer are lacking. In fact, clinicians rely heavily on studies in men with localized disease for practice recommendations [16].

Our team recently examined the efficacy of a 10-week web-based CBSM intervention program adapted for men with advanced prostate cancer [17]. They reported that the CBSM intervention did not significantly impact several domains of HRQOL and APC-related symptom burden. The authors reasoned that the null effects can be attributed to a ceiling effect in measurements of observed baseline levels of HRQOL. More specifically, the initial study cohort was found to have higher mean scores on the FACT-G social well-being ($M = 20.8$) than the established norms for the general population ($M = 19.1$) [18]. Although the difference in the FACT-G social well-being scale between the initial study cohort and the general population may or may not reach statistical significance, it is evident that the initial study cohort demonstrated equally as well, or even better than, the general population in this regard. Given this context, we reason that it is important to determine whether the CBSM intervention offers advantageous for a specific subgroup of patient participants characterized by lower baseline social well-being within the initial study cohort.

Social well-being (SWB) refers to the social aspects of health-related quality of life (HRQOL). In the broader literature, its two indicators, namely, social support and relationship satisfaction, have been increasingly associated with chronic disease progression and survival [19], including cancer [20]. Precious research has shown that social support positively predicts better general health and improved physical functioning [21–23]. Furthermore, prior findings have indicated that social support and relationship satisfaction promote psychological well-being [24, 25]. Some studies found that perceiving high levels of social support directly improved emotional adjustment and cancer-related distress [26]. Other research suggested that SWB indirectly affected cancer patients' emotional well-being via coping strategies chosen [27], with a more pronounced effect for those who adopted positive coping styles. For instance, the use of active coping and positive reframing strategies has been consistently found to be associated with better quality of life [28].

Yet, we note that the interactions between social well-being and psychosocial intervention for APC survivorship have rarely been studied. This gap raises important questions about the effectiveness of existing CBSM intervention, particularly for a patient population with low SWB when considering social support as an integral component of the CBSM intervention. This patient population is likely to benefit the most from the CBSM intervention, as CBSM incorporates social interaction, facilitates the optimization of an effective social network, and provides skills to enhance both social and communication support. Additionally, it is worth noting that the initial study cohort consisted of older males at their 60 s. Relevant research has indicated that this APC patient population characterized by older age (> 65 years) is particularly vulnerable to ADT treatment toxicities and often experience a reduction in their access to social resources [1, 29]. This may help explain why the older patient participants with low SWB could benefit from the CBSM intervention. Therefore, we aimed to identify a subgroup of older patient participants with low levels of SWB to further investigate the efficacy of the CBSM intervention on their health-related quality of life (HRQOL).

Present Study

The primary purpose of this secondary analysis was to determine whether CBSM leads to better symptom-related quality of life and psychosocial outcomes among a subgroup of APC patients with low pre-intervention SWB, as measured by social support from and relationship satisfaction with family and friends. Specifically, we hypothesized that participants randomly assigned to the CBSM condition would significantly improve PC-specific symptom burden in sexual, urinary, and hormonal domains as compared to those in the HP control condition. Those domains represent major challenges within this specific APC patient population. In addition, given that the CBSM intervention targets APC patients' stress management [17], we hypothesized that participants who received CBSM would show significantly greater improvements in cancer-related anxiety and cancer-specific distress than those who received HP.

A secondary purpose of the study was to explore whether CBSM promotes coping strategies that are emotion-, problem-, and avoidance-focused. Accordingly, CBSM targets APC patients' coping skills (e.g., cognitive reconstructing, anger management) in response to ADT-related physical (pain, fatigue) and psychological stressors (bodily feminization). Indeed, APC patients have been found to adopt various strategies to cope with the unique nature and special severity of the psychosocial challenges that they face [30]. Therefore, we test the hypothesis that participants who received CBSM will significantly engage more in coping, particular the problem-focused strategies that consist of active coping, positive reframing, and planning when compared to participants in the HP condition, as discussed previously [27].

Methods

The present study is a secondary analysis of a randomized controlled trial that examined the efficacy of a web-based intervention for improving HRQOL and reducing symptom burden in men with APC receiving androgen deprivation therapy (ADT). The study population, details about recruitment, descriptions of study conditions, and primary results can be found in the previous publication [17].

Participants In the initial study, one hundred and ninety-two participants were recruited. The eligibility criteria included men who were at least 50 years old, fluent in English at the sixth-grade level or higher, initially diagnosed with stage III or IV prostate cancer, had received androgen deprivation therapy (ADT), and experienced an ADT-related symptom within the 12 months prior to study enrollment. Participants were excluded if they (1) had undergone treatment for any other cancer within the past 5 years, (2) reported inpatient psychiatric treatment for mental illness within the past 6 months, (3) reported active substance or alcohol dependence issues, (4) were diagnosed with an immunocompromising condition, (5) had an anticipated life expectancy < 12 months, or (6) received a score < 20 on the mini–mental state examination at the time of screening. The vast majority of the initial study cohort (81%) completed at least six of the ten weekly sessions, with an average attendance of more than seven sessions.

Procedure The study protocol was approved by the Institutional Review Board, and the protocol is available in more detail at ClinicalTrials.gov (NCT03149185). After providing informed consent, participants were randomly assigned to one of the two study conditions: CSBM intervention or health promotion (HP) control. They were not blinded to their assigned conditions; however, they were kept unaware of what was the experimental vs. attention control condition. Participants in the HP control condition received general health information and health information specific to APC, and they were not exposed to any of the CBSM intervention procedures. At baseline (T1), 6 months post-baseline (T2), and 12 months post-baseline (T3), all participants attended in-person appointments during which they completed a battery of psychosocial assessments. Both conditions were group-based and delivered via a HIPAA-compliant, web-based platform over a 10-week period. Assessment completion rates were > 50% at both week 1 and week 10 of the intervention period.

CBSM Intervention The CBSM intervention integrates cognitive behavioral stress and self-management skills with relaxation practice training to improve HRQOL and reduce symptoms (see Table 1). In particular, the CBSM skills specific to building self-efficacy comprised of cognitive restructuring and reappraisal and active and problem-focused coping strategies and communication skills. The CBSM

Table 1 Description of intervention components

	Cognitive behavioral stress management		Health promotion
	Relaxation	Stress management	Topic
Week 1	Deep breathing	Health- and stress-related education	Living with APC
Week 2	Deep breathing	Stress & awareness	Maintaining a healthy lifestyle
Week 3	Progressive muscle relaxation	Cognitive distortions & automatic thoughts	Physical & social changes
Week 4	Progressive muscle relaxation	Cognitive restructuring	Physical & social activity
Week 5	Deep breathing & progressive muscle relaxation	Effective coping skills	Health diet
Week 6	Deep breathing & progressive muscle relaxation	Sexuality & intimacy	Cognition & memory
Week 7	Imagery	Social support	Family relations & intimacy
Week 8	Imagery	Anger management	Health-related quality of life & life satisfaction
Week 9	Mindfulness meditation	Assertiveness	Information overload
Week 10	Mindfulness meditation	Acceptance & program review	Review & summary

intervention was adapted for men with advanced prostate cancer to provide disease-relevant knowledge and skills. The intervention was implemented through weekly didactic presentations and in-session demonstration exercises (via web-based conferencing platform) as well as through at-home practice. Each weekly session lasted approximately 90 min. Sessions began with practicing a relaxation technique (30 min). Followed was discussion and practice of stress management techniques (60 min). Group facilitators were therapists with master's or doctoral degrees who had completed in-person training to become proficient in the manualized treatments. Each session was video recorded and reviewed weekly by licensed clinical psychologists who had been trained for CBSM.

Prostate Cancer-Specific Quality of Life

Prostate Cancer-Specific Symptom Burden The 50-item Expanded Prostate Cancer Index Composite (EPIC) was used to evaluate specific symptom burden related to prostate cancer [31]. Participants were asked to rate on a 4- to 5-point Likert scale that measures their functioning (symptom severity, e.g., "Over the past four weeks, how often have you leaked urine?") and bother (the degree to which symptoms are problematic, e.g., "How big a problem in the last four weeks, bleeding with urination?") as reflected by four domains of urinary, sexual, hormonal, and bowel. Response scores were linearly transformed to a 0–100 scale and computed to yield a mean score for each subscale, with higher scores indicating less symptom burden. The present analysis included the three functioning scores (hormonal, sexual and urinary) and two additional symptom scores (urinary incontinence and urinary irritation). These subscales have demonstrated strong internal consistency: hormonal ($\alpha = 0.71$), and sexual ($\alpha = 0.89$), and acceptable internal consistency: urinary ($\alpha = 0.67$).

Cancer-Related Distress and Coping Strategies

Cancer-Related Anxiety The 18-item Memorial Anxiety Scale for Prostate Cancer (MAX-PC) was used to measure anxiety specific to prostate cancer [32]. It consists of three subscales assessing general anxiety related to prostate cancer (e.g., "I thought about prostate cancer even though I didn't mean to"), fear of cancer recurrence (e.g., "My fear of having my cancer getting worse gets in the way of my enjoying life"), and anxiety specific to prostate specific antigen (PSA) testing (e.g., "Even though it's a good idea, I found that getting a PSA test scared me"). The items were rated on a four-point Likert scale ranging from "0 = not at all" to "3 = often." A total response score was calculated for each subscale, with higher scores representing greater anxiety. The measure has previously been shown excellent internal consistency: PC anxiety $\alpha = 0.93$, and fear of recurrence $\alpha = 0.87$, and poor internal consistency: PSA anxiety $\alpha = 0.58$.

Cancer-Specific Distress The 22-item Impact of Event Scale-Revised (IES-R) was used to assess cancer-related distress [33]. All distress-related symptoms are clustered into three categories: intrusion, avoidance, and hyperarousal. Participants were asked to rate how frequently each symptom was distressing for them during the past 7 days (e.g., "I felt irritable and angry"), on a 5-point Likert scale ranging from "0 = not at all" to "4 = extremely." For each subscale, the average of the response scores was computed, with higher scores reflecting greater distress. The IES-R has demonstrated high internal consistency: intrusions ($\alpha = 0.85$), avoidance ($\alpha = 0.82$), and hyperarousal ($\alpha = 0.81$).

Coping Strategies The Brief COPE questionnaire was designed to measure the frequency of different coping strategies used for a stressful life event [34]. Participants were asked to rate on a response scale (e.g., "I've been saying things to let my unpleasant feelings escape") ranging from "1 = I haven't been doing this at all" to "4 = I've been doing this a lot," with higher scores indicating frequent use of a particular coping strategy. We chose this questionnaire because coping strategies can be explored in a situational rather than a trait format. The Brief COPE comprised fourteen subscales, each evidenced high or satisfactory reliability. For the present analysis, we used the three-factor coping structure that consists of emotion-focused coping (venting, self-acceptance, humor, religion), problem-focused coping (active coping, planning, positive reframing), and avoidance coping (denial, behavioral disengagement, self-distraction, substance use). We further computed an additional summary score for the negative coping (denial, venting, substance use).

Data Analysis

Preliminary Analysis for Low SWB Group Selection

This subsample was determined by scoring from the Functional Assessment of Cancer Therapy-General (FACT-G) social/family well-being (SWB) subscale, which includes 7 items (e.g., "I get emotional support from my friends"; "My family accepts my illness"; "I am satisfied with family communications"). Response scores range from 0 (not at all) to 4 (very much), with higher scores indicating greater social well-being in terms of support from family, friends and partners, and satisfaction with those relationships. The FACT-G is a psychometrically strong measure of health-related quality of life that is commonly used with

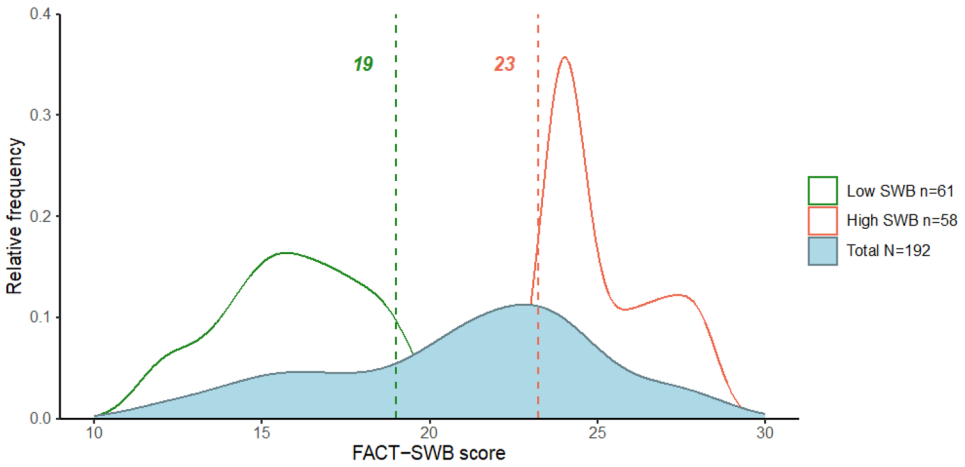

Fig. 1 Probability density plot of the SWB scores measured at baseline: all patient participants (blue), the low SWB group (green) with SWB scores below the 30th percentile, and high SWB group (red) with SWB score above the 70th percentile. Vertical dashed lines in green and red mark the 30th and 70th percentiles, respectively

oncologic samples. In particular, the SWB subscale demonstrated good internal consistency ($\alpha = 0.76$). By closely examining the baseline SWB score distribution across all patient participants ($N = 192$), we identified three groups (see Fig. 1). Notably, a distinctive pattern was observed exclusively within the low SWB group, comprising participants who fell below the baseline SWB score approximate 30th percentile ($n = 61$). First, this low SWB group exhibited significantly lower SWB scores at baseline when compared to both the mid- and high-SWB groups (see Fig. 2). Second, only the low SWB group demonstrated an improvement in SWB over time ($p = 4.7e-0.7$) (see Fig. 1), whereas the other two groups maintained their SWB scores, as depicted in the boxplots. It appeared that having a low SWB score allowed patient participants in the low SWB group to make improvements.

For the analysis, we included a total of 61 participants who scored below the 30th percentile, with 34 in the CBSM condition and 27 in the HP condition. A description of sociodemographic and medical-related information for this subsample by condition (CBSM vs. HP) is presented in Table 2. Their mean age was approximately 69 years. Twenty-three were Caucasians, and twenty-eight identified as African American. Most participants were not working (62.3%), and over 50% had a college or more advanced degree. All participants received androgen deprivation therapy, with the great majority (93.44%) having undergone ADT 6-month prior to the intervention. Fewer had radiotherapy (21.31%) or chemotherapy (3.38%) during the same 6-month period.

To examine whether participants with low SWB at baseline demonstrate greater CBSM effects, we conducted multilevel models (MLMs) on prostate cancer-specific symptom burden (i.e., sexual, urinary, hormonal) and relevant affect-based psychosocial outcomes (i.e., cancer-related anxiety and cancer-specific distress). We further

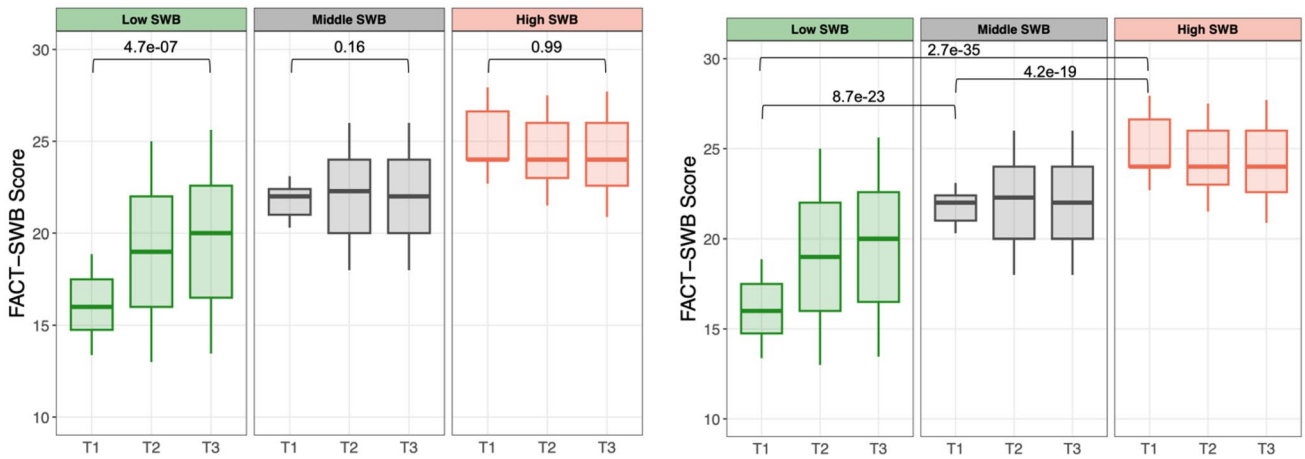

Fig. 2 Boxplots of SWB score across low SWB (green), mid SWB (gray), and high SWB (red) subgroups at baseline (T1), 6 months (T2), and 12 months (T3). The left panel shows statistical differences between T3 and T1 within each subgroup; the right panel displays statistical differences between subgroups at T1

Table 2 Demographic and clinical characteristics for SWB groups by condition

		Low SWB group		High SWB group	
	Total	**CBSM**	**HP**	**CBSM**	**HP**
Age, years, mean (SD)	68.71 (8.78)	68.32 (9.86)	67.38 (9.88)	71.38 (7.61)	68.44 (8.19)
Charlson comorbidity index, mean (SE)	1.38 (0.1)	1.7 (0.26)	1.96 (0.39)	1.67 (0.26)	0.91 (0.18)
BMI (SD)	28.79 (5.1)	30.82 (6.47)	28.15 (5.63)	29.62 (5.07)	27.89 (4.96)
Years since diagnosis, mean (SD)	4.69 (5.27)	4.65 (6.42)	5.68 (4.9)	5.08 (4.62)	4.71 (6.26)
Ethnicity, *n* (%)					
White	114 (59.07)	14 (41.18)	9 (33.33)	19 (73.08)	20 (62.5)
Black	69 (35.75)	14 (41.18)	14 (51.85)	6 (23.08)	11 (34.38)
Other	10 (5.18)	1 (2.94)	4 (14.81)	1 (3.85)	1 (3.12)
Employment, *n* (%)					
Full time and part time	75 (38.86)	14 (41.18)	9 (33.33)	6 (23.08)	15 (46.88)
Unemployed	118 (61.14)	20 (58.82)	18 (66.67)	20 (76.92)	17 (53.12)
Married or equivalent, *n* (%)	128 (66.67)	18 (52.94)	9 (33.33)	22 (84.61)	20 (62.50)
Family annual income ≥ 35,000, *n* (%)	107 (55.44)	19 (55.88)	10 (37.04)	15 (57.69)	17 (53.12)
Education					
High school diploma or less	60 (31.09)	13 (38.24)	12 (44.44)	5 (19.23)	10 (31.25)
College or more advanced degree	129 (66.84)	20 (58.82)	14 (51.85)	21 (80.77)	22 (68.75)
Hypertension, yes, *n* (%)	110 (56.99)	20 (58.82)	19 (70.37)	15 (57.69)	14 (43.75)
Androgen deprivation therapy, *n* (%)					
6 months prior to baseline	184 (95.34)	32 (94.12)	25 (92.59)	26 (100)	30 (93.75)
Radiotherapy, *n* (%)					
6 months prior to baseline	39 (20.21)	8 (23.53)	5 (18.52)	7 (26.92)	5 (15.62)
Chemotherapy, *n* (%)					
6 months prior to baseline	6 (3.11)	1 (2.94)	1 (3.7)	2 (7.69)	1 (3.12)
Radical retropubic prostatectomy, *n* (%)	98 (50.78)	9 (26.47)	12 (44.44)	15 (57.69)	17 (53.12)

CBSM cognitive behavioral stress management group, *HP* health promotion group, *SD* standard deviation

employed the MLMs analysis to explore whether the intervention affects coping strategies. We chose a multilevel modeling approach, given that it is an appreciated tool for predicting missing data (due to illness, drop out and death) rather than simply removing them. Also, it allows greater flexibility for modeling individual patterns of change over time [35]. Therefore, MLMs with restricted maximum likelihood estimation was applied. For the structure of the models, patients with low SWB (level 1) are nested in study condition (level 2) and time (crossed at level 2). All models included a cross-level two-way interaction term (condition by time).

Across all analyses, MLMs were adjusted for sociodemographic and cancer-related covariates. Continuous covariates including age, comorbidity index, body mass index, and years since diagnosis were grand mean centered prior to analysis. Categorical covariates including race, employment status, income, education, hypertension, and cancer treatment history were dummy coded prior to analysis. Details regarding the coding of the covariates are presented in Table 2.

Results

Intervention Effects on Prostate Cancer (PC)-Specific Quality of Life (QOL)

Table 3 summarizes the results of the EPIC subscales across the three domains. Participants in the CBSM condition reported overall improvements (higher mean scores) in hormonal function, urinary function, urinary incontinence, and urinary irritation over time. In contrast, participants in the HP condition showed a general decreasing trend in urinary domain. This pattern was more apparent in Fig. 3, which plots those CBSM versus HP differences directly by comparing their mean urinary scores at all time points. The between-condition differences in mean urinary function scores were low at baseline (MD = 3.04), and higher at 6 months (MD = 10.44), and much higher at 12 months (MD = 12.57). The similar pattern was also found for urinary incontinence and urinary irritation. The between-condition differences in mean urinary incontinence scores were 3.83 at baseline, 14.82 at 6 months,

Table 3 Descriptive statistics for outcome measures by condition (CBSM vs. HP) across time

	Baseline		Six months		12 months	
	CBSM	HP	CBSM	HP	CBSM	HP
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
FACT-G SWB	14.85 (0.54)	15.44 (0.69)	18.42 (0.81)	18.28 (0.97)	18.44 (0.88)	20.14 (0.74)
EPIC hormonal function	60.91 (3.09)	64.26 (3.9)	71.35 (2.99)	69.17 (3.98)	70.24 (3.17)	67.37 (3.59)
EPIC sexual function	9.06 (2.24)	15.61 (3.94)	8.22 (2.35)	15.64 (4.58)	10.97 (2.8)	15.67 (4.71)
EPIC urinary function	83.63 (2.27)	80.59 (4.03)	87.65 (2.36)	77.21 (3.84)	87.43 (2.75)	74.86 (4.49)
EPIC urinary incontinence	75.24 (3.43)	71.41 (6.03)	81.44 (3.7)	66.62 (5.1)	79.39 (4.32)	63.62 (5.85)
EPIC urinary irritation	81.3 (2.51)	81.08 (2.88)	86.77 (2.02)	82.95 (2.45)	88.54 (1.72)	81.55 (3.83)
MAX-PC total	18.55 (2.42)	8.48 (1.44)	10.88 (1.6)	9.17 (1.42)	11.9 (1.74)	8.21 (1.23)
MAX-PC anxiety	9.76 (1.77)	5.56 (1.15)	7.01 (1.37)	4.84 (1.12)	6.17 (1.32)	4.15 (1.02)
MAX-PC fear	6.17 (0.53)	3.05 (0.43)	4.83 (0.42)	3.83 (0.41)	4.85 (0.51)	4.05 (0.37)
MAX-PC PSA	1.12 (0.34)	0.63 (0.23)	0.7 (0.21)	0.76 (0.27)	0.5 (0.19)	0.42 (0.17)
IES-R total	16.43 (2.51)	10.4 (1.92)	12.76 (2.09)	10.34 (1.68)	15.83 (2.38)	8.78 (1.44)
IES-R intrusions	0.73 (0.13)	0.47 (0.11)	0.56 (0.11)	0.43 (0.09)	0.62 (0.12)	0.36 (0.08)
IES-R avoidance	0.92 (0.14)	0.52 (0.11)	0.73 (0.15)	0.57 (0.1)	1 (0.17)	0.57 (0.12)
IES-R hyperarousal	0.54 (0.11)	0.41 (0.11)	0.4 (0.08)	0.43 (0.09)	0.47 (0.11)	0.22 (0.06)
Coping avoidance	11.35 (0.64)	11.15 (0.64)	9.5 (1.02)	10.7 (0.9)	8.68 (1.11)	9.04 (1.15)
Coping emotion	18.97 (1.03)	18.52 (1.21)	16.21 (1.64)	18.19 (1.43)	13.94 (1.73)	15.74 (1.97)
Coping problem	14.35 (0.93)	14.04 (1.15)	9.94 (1.29)	13.89 (1.28)	9.35 (1.29)	11.48 (1.54)
Coping negative	8.32 (0.6)	8.07 (0.55)	6.85 (0.74)	7.22 (0.63)	6.5 (0.87)	6.67 (0.89)

FACT-G SWB Functional Assessment of Cancer Therapy – Social Well-Being, *EPIC* Expanded Prostate Cancer Index, *MAX-PC* Memorial Anxiety Scale for Prostate Cancer, *IES-R* Impact of Events Scale – Revised, *Coping* Brief COPE Questionnaire, *SE* standard error

and 15.77 at 12 months and in mean urinary irritation scores were 0.22 at baseline, 3.82 at 6 months, and 6.99 at 12 months.

The multilevel models (MLM) revealed no statistically significant effect for the condition by time interaction, main effect of condition, or main effect of time for the three QOL domains: hormonal, sexual, and urinary. These results are summarized in Table 4. By conducting contrasts tests within the multilevel analysis, we further investigated within-condition differences in EPIC subscale scores over time. Participants in the CBSM condition were found to have higher levels of hormonal function (fewer symptoms of hormone deprivation) between baseline and 6 months ($t(33) = 2.17$, $p = 0.032$); and a marginally significant improvement in urinary irritation from baseline to 12 months. There were no significant changes across all three EPIC domains within the HP condition.

Intervention Effects on Cancer-Related Distress

Cancer-Related Anxiety

Descriptive statistics for MAX-PC subscale scores are shown in Table 3. At baseline, participants in the CBSM condition reported higher levels of anxiety related to PC (M[SE] = 9.76 [1.77]), fear of PC recurrence (M[SE] = 6.17 [0.53]) and anxiety specific to PSA (M[SE] = 1.12 [0.34]) than those in the HP condition: M[SE] = 5.56 [1.15] for PC

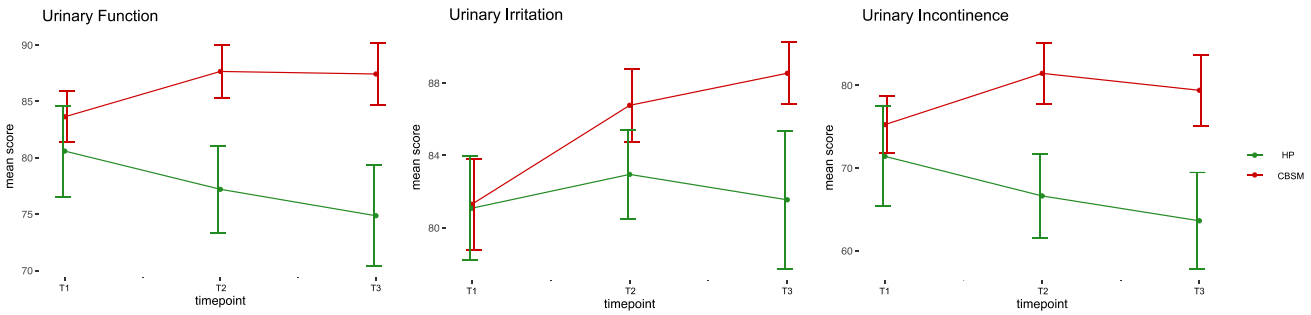

Fig. 3 Effects of intervention on urinary domains, by condition and time

Table 4 Results for the multilevel modeling: the effects of intervention on PC-specific symptom burden

	EIPC hormfx Coef (SE)	EPIC sexfx Coef (SE)	EPIC urinfx Coef (SE)	EPIC urinirr Coef (SE)	EPIC urininc Coef (SE)
Intercept	67.69 (19.38)**	−6.37 (18.09)	89.84 (17.42)**	99.87 (16.91)**	99.37 (23.9)**
Condition					
CBSM vs. HP	0.07 (4.9)	−4.24 (4.54)	1.49 (4.44)	−1.45 (4.23)	0.71 (6.07)
Time					
T3–T1	2.02 (5.64)	−0.8 (5.1)	−7.31 (5.02)	0.26 (4.74)	−6.62 (6.74)
T2–T1	6.4 (5.22)	1.24 (4.89)	−3.27 (4.74)	2.08 (4.5)	−4.32 (6.51)
Cond*time					
Cond*T3–T1	4.76 (7.38)	1.94 (6.72)	10.61 (6.49)	6.92 (6.18)	9.86 (8.8)
Cond*T2–T1	3.25 (6.85)	−0.98 (6.49)	6.72 (6.18)	3.43 (5.91)	9.46 (8.49)
Age	0.39 (0.19)*	−0.43 (0.17)*	−0.04 (0.17)	0.12 (0.16)	0.08 (0.23)
Comorbidity	−4.9 (0.98)**	−2.46 (0.92)**	−2.89 (0.86)**	−1.94 (0.83)*	−5.49 (1.19)**
BMI	−0.99 (0.3)**	−0.13 (0.28)	0.22 (0.26)	0.06 (0.25)	0.19 (0.35)
YrsDiagnosis	−0.66 (0.41)	−0.17 (0.38)	0.46 (0.36)	−0.05 (0.35)	0.29 (0.49)
Race	−5.47 (4.21)	9.47 (3.89)*	1.64 (3.76)	3.45 (3.66)	−5.28 (5.15)
MaritalStatus	7.43 (3.51)*	5.12 (3.3)	6.09 (3.17)	3.33 (3.04)	11.05 (4.35)*
Employment	7.27 (3.87)	7.73 (3.52)*	−1.31 (3.31)	−3.91 (3.22)	1.39 (4.53)
Income	4.42 (3.32)	7.08 (3.29)*	−6.62 (3)*	−2.71 (2.84)	−13.11 (4.12)**
Education	5.55 (3.89)	−8.51 (3.53)*	−10.54 (3.43)**	−5.82 (3.17)	−12.01 (4.63)*
Hypertension	−0.46 (3.41)	3.31 (3.31)	−5.57 (2.96)	−2.7 (2.85)	−6.54 (4.06)
ADT	21.35 (5.88)**	18.32 (5.42)**	8.79 (5.23)	10.42 (5.09)*	14.06 (7.18)
RT	−0.15 (3.99)	2.54 (3.78)	−3.79 (3.57)	0.91 (3.38)	−7.84 (4.85)
Chemo	−6.3 (18.15)	1.84 (16.79)	−13.85 (16.22)	−15.92 (15.81)	−29.89 (22.25)
RRP	−10.73 (3.66)**	2.94 (3.33)	19.12 (3.29)**	−0.96 (3.09)	26.92 (4.41)**

CBSM cognitive behavioral stress management, *HP* health promotion, *EPIC* Expanded Prostate Cancer Index, *BMI* body mass index, *YrsDiagnosis* years since diagnosis, *ADT* androgen deprivation therapy, *RT* radiotherapy, *Chemo* chemotherapy, *RRP* radical retropubic prostatectomy, *Coef* coefficient, *SE* standard error

*$p < 0.05$; $p < 0.01$

anxiety, M[SE] = 3.05 [0.43] for fear, and M[SE] = 0.63 [0.23] for PSA anxiety. However, the between-condition gaps reduced over time. Participants in the CBSM condition showed improvements across all three subscales at 6 months, and these improvements maintained at 12 months.

Statistically significant main effect of condition (F[1, 95] = 7.83, $p = 0.006$) and condition by time interaction (F[2, 95] = 4.04, $p = 0.021$) were found for the fear of cancer recurrence subscale. To interpret the results, we first examined the significant two-way interaction. As compared to those in the HP condition, participants in the CBSM condition demonstrated significantly greater reductions in their fear of cancer recurrence at 6-month ($b = -2.45$, $p = 0.039$) and at 12-month ($b = -3.37$, $p = 0.009$) follow-up (see Table 5). It appears that the CBSM intervention is effective in both short- and long-term. Furthermore, the significant main effect of condition indicated that the CBSM intervention improved participants' overall levels of fear of PC recurrence ($b = 3.51$, $p < 0.001$). However, there were no main effects of time or condition by time interaction on PC- and PSA-related anxiety subscales.

Cancer-Specific Distress

The mean IES-R subscale scores are presented in Table 3. Participants in the CBSM condition showed improvements in all three subscales of intrusion, avoidance, and hyperarousal at 6-month follow-up. There was no condition by time interaction. Significant main effects of condition were found for intrusion subscale (F[1, 112] = 6.87, $p = 0.01$). Participants assigned to the CBSM condition significantly reduced their distress specific to intrusive thoughts ($b = 0.39$, $p = 0.042$) than participants in the HP condition (see Table 5). However, no significant CBSM intervention effect was observed for distress specific to avoidance (F[1, 112] = 2.42, $p = 0.12$) and hyperarousal (F[1, 112] = 2.12, $p = 0.147$) .

Intervention Effects on Coping Strategies

As shown in Table 3, descriptive results show that all participants, regardless of condition, tended to use all

Table 5 Results for the multilevel modeling: the effects of intervention on cancer-related distress

	FACT-G SWB Coef (SE)	MAX-PC anxiety Coef (SE)	MAX-PC fear Coef (SE)	MAX-PC PSA Coef (SE)	MAX-PC total Coef (SE)	IES-R intrusions Coef (SE)	IES-R avoidance Coef (SE)	IES-R hyperarousal Coef (SE)	IES-R total Coef (SE)
Intercept	19.53 (4.56)**	9.97 (8.9)	0.08 (3.28)	1.24 (1.73)	11.34 (12.51)	0 0.01(0.76)	2.31 (0.88)*	0.07 (0.65)	18.81 (14.3)
Condition									
CBSM vs. HP	−0.85 (1.14)	4.61 (2.23)*	3.51 (0.87)**	0.4 (0.43)	8.88 (3.32)**	0.39 (0.19)*	0.33 (0.22)	0.22 (0.16)	7.08 (3.58)*
Time									
T3–T1	4.83 (1.28)**	−0.84 (2.56)	2.22 (0.97)*	−0.24 (0.51)	1.04 (3.7)	−0.12 (0.22)	0.17 (0.25)	−0.17 (0.19)	−0.63 (4.11)
T2–T1	3.28 (1.21)**	−0.75 (2.37)	1.43 (0.91)	0.19 (0.46)	1.1 (3.47)	−0.07 (0.2)	0.01 (0.23)	0.02 (0.17)	−0.37 (3.81)
Cond*time									
Cond*T3–T1	−1.39 (1.67)	−3.44 (3.32)	−3.37 (1.26)**	−0.46 (0.65)	−7.42 (4.8)	−0.05 (0.28)	−0.14 (0.33)	0.04 (0.24)	−1.23 (5.3)
Cond*T2–T1	0.21 (1.59)	−2.64 (3.11)	−2.45 (1.17)*	−0.67 (0.6)	−7.9 (4.47)	−0.15 (0.26)	−0.19 (0.31)	−0.22 (0.23)	−3.97 (4.99)
Age	−0.06 (0.04)	−0.23 (0.08)**	−0.09 (0.03)**	−0.01 (0.02)	−0.38 (0.13)**	−0.02 (0.01)*	−0.02 (0.01)*	−0.01 (0.01)	−0.37 (0.13)**
Comorbidity	0.6 (0.23)**	0.6 (0.44)	0.14 (0.17)	−0.05 (0.09)	0.75 (0.63)	0.09 (0.04)*	0.06 (0.04)	0.08 (0.03)*	1.71 (0.71)*
BMI	−0.07 (0.07)	0.06 (0.14)	−0.02 (0.05)	−0.01 (0.03)	0.05 (0.19)	−0.01 (0.01)	0.01 (0.01)	−0.01 (0.01)	−0.08 (0.22)
YrsDiagnosis	0.05 (0.09)	−0.53 (0.18)**	0.02 (0.07)	−0.13 (0.04)**	−0.59 (0.26)*	−0.01 (0.02)	−0.04 (0.02)*	−0.02 (0.01)	−0.49 (0.29)
Race	−0.48 (0.99)	0.87 (1.93)	−0.06 (0.72)	0.52 (0.37)	1.66 (2.73)	0.11 (0.16)	0.25 (0.19)	−0.08 (0.14)	2.37 (3.09)
MaritalStatus	−0.92 (0.82)	−1.28 (1.61)	−1.13 (0.59)	−0.01 (0.31)	−3.21 (2.25)	−0.01 (0.14)	−0.14 (0.16)	0.02 (0.12)	−1.08 (2.58)
Employment	0.87 (0.87)	1.13 (1.71)	0.54 (0.67)	0.06 (0.33)	1.72 (2.56)	0.01 (0.15)	0.04 (0.17)	0.04 (0.13)	0.7 (2.74)
Income	−1.2 (0.77)	0.07 (1.5)	0.39 (0.58)	0.18 (0.29)	0.18 (2.21)	0.21 (0.13)	−0.35 (0.15)*	0.11 (0.11)	−0.36 (2.4)
Education	−0.77 (0.86)	−1.78 (1.7)	−0.61 (0.69)	−0.47 (0.33)	−3.49 (2.62)	−0.07 (0.14)	−0.18 (0.17)	−0.05 (0.12)	−2.27 (2.7)
Hypertension	−0.53 (0.77)	−1.35 (1.51)	−0.71 (0.58)	0.12 (0.29)	−2.77 (2.2)	−0.02 (0.13)	−0.19 (0.15)	0 (0.11)	−1.65 (2.41)
ADT	0.51 (1.37)	−1.31 (2.68)	0.25 (0.95)	0.18 (0.52)	−0.58 (3.64)	−0.05 (0.23)	−0.4 (0.27)	0.07 (0.2)	−3.15 (4.3)
RT	−1.19 (0.91)	6.46 (1.78)**	1.8 (0.68)**	0.63 (0.35)	8.14 (2.6)**	0.22 (0.15)	0.23 (0.18)	0.12 (0.13)	4.34 (2.87)
Chemo	−1.29 (4.27)	−7.12 (8.32)	1.25 (3)	−0.99 (1.62)	−5.83 (11.43)	0.26 (0.71)*	−1.82 (0.82)	0.23 (0.61)	−10.99 (13.36)
RRP	−1.14 (0.83)	−3.12 (1.63)	0.39 (0.6)	−0.48 (0.32)	−2.2 (2.29)	−0.26 (0.14)	0.08 (0.16)	−0.09 (0.12)	−1.88 (2.62)

CBSM cognitive behavioral stress management, *HP* health promotion, *FACT-G SWB* Functional Assessment of Cancer Therapy – Social Well-Being, *MAX-PC* Memorial Anxiety Scale for Prostate Cancer, *IES-R* Impact of Events Scale – Revised, *BMI* body mass index, *YrsDiagnosis* years since diagnosis, *ADT* androgen deprivation therapy, *RT* radiotherapy, *Chemo* chemotherapy, *RRP* radical retropubic prostatectomy, *Coef* coefficient, *SE* standard error

*$p < 0.05$; **$p < 0.01$

four types of coping strategies less frequently over time. Participants in the HP condition reported a relatively slowly progressive decline in all copings from baseline to 6 months.

MLM analysis revealed no significant main effects of condition or condition by time interaction across all four coping strategies (see Table 6). The changes in the mean scores of these scoping strategies did not differ significantly between the CBSM and HP conditions. Nonetheless, we found a significant main effect of time ($F[2, 133] = 6.82$, $p = 0.002$) for the problem-focused coping subscale. Participants reported using problem-focused coping strategies less frequently from baseline to 12 months ($b = -3.85$, $p = 0.056$).

Discussion

Primary Findings

In the present study, we tested whether older advanced prostate cancer survivors with low baseline SWB would benefit from a 10-week web-based CBSM intervention. In contrast to the initial study cohort, our findings suggest that CBSM leads to improvements in certain types of cancer-related anxiety and cancer-specific distress for this vulnerable subgroup of APC survivors. As expected, participants randomized to the CBSM condition showed significantly decreased levels of fear of cancer recurrence and cancer-related intrusive thoughts, as compared to participants in the HP control

Table 6 Results for the multilevel modeling: the effects of intervention on coping strategies

	Coping avoidance Coef (SE)	Coping emotion Coef (SE)	Coping problem Coef (SE)	Coping negative Coef (SE)
Intercept	12.04 (4.12)**	14.63 (6.46)*	17.43 (5.31)**	9.51 (3.24)**
Condition				
CBSM vs. HP	1.09 (1.46)	2.68 (2.29)	1.11 (1.88)	0.8 (1.15)
Time				
T3–T1	−2.3 (1.55)	−3.4 (2.43)	−3.85 (1.99)	−1.5 (1.22)
T2–T1	−1.15 (1.55)	−0.35 (2.43)	−0.4 (1.99)	−1.2 (1.22)
Cond*time				
Cond*T3–T1	−1.15 (1.99)	−2.89 (3.11)	−1.73 (2.56)	−0.76 (1.56)
Cond*T2–T1	−1.01 (1.99)	−3.2 (3.11)	−4.28 (2.56)	−0.41 (1.56)
Age	−0.04 (0.05)	0.03 (0.08)	−0.08 (0.07)	−0.03 (0.04)
Comorbidity	−0.13 (0.27)	−0.38 (0.42)	−0.42 (0.34)	0.01 (0.21)
BMI	−0.08 (0.08)	0.04 (0.12)	−0.13 (0.1)	−0.08 (0.06)
YrsDiagnosis	−0.2 (0.12)	−0.08 (0.18)	−0.12 (0.15)	−0.21 (0.09)*
Race	−0.82 (1.18)	−1.62 (1.85)	2.16 (1.52)	−0.68 (0.93)
MaritalStatus	2.1 (0.93)*	3.97 (1.46)**	2.29 (1.2)	1.4 (0.73)
Employment	1.25 (1.06)	2.2 (1.66)	−0.77 (1.37)	1.26 (0.83)
Income	−0.46 (0.93)	2.13 (1.46)	0.66 (1.2)	−0.46 (0.73)
Education	−1.02 (1.05)	−2.7 (1.64)	−3.35 (1.35)*	−0.41 (0.82)
Hypertension	0.28 (0.96)	1.43 (1.5)	−0.17 (1.23)	0.57 (0.75)
ADT	0.49 (1.76)	3.77 (2.76)	1.19 (2.27)	1.35 (1.39)
RT	−0.23 (1.09)	−3.71 (1.71)*	−0.81 (1.4)	−0.64 (0.86)
Chemo	0.31 (3.61)	5.97 (5.66)	−0.96 (4.65)	−0.27 (2.84)
RRP	−2.84 (1.03)**	−4.03 (1.62)*	−4.06 (1.33)**	−2.51 (0.81)**

CBSM cognitive behavioral stress management, *HP* health promotion, *Coping* brief COPE questionnaire, *BMI* body mass index, *YrsDiagnosis* years since diagnosis, *ADT* androgen deprivation therapy, *RT* radiotherapy, *Chemo* chemotherapy, *RRP* radical retropubic prostatectomy, *Coef* coefficient, *SE* standard error

*$p < 0.05$; **$p < 0.01$

condition. Further evidence of the intervention efficacy is provided by the significant interaction between condition and time. The nature of this interaction indicates that CBSM may have had short- and long-term effects. Participants in the CBSM condition reported significantly greater improvements in PC-related fear at 6-month and 12-month follow-up, compared to those in the HP control condition who deteriorated across time. Overall, our results appear to be consistent with recent findings that CBT-based intervention reduces psychological symptoms [36, 37].

Although the CBSM intervention effects on symptom burden-related QoL were not confirmed by inferential tests, clinically important differences (MIDs) between the two conditions have been observed for the urinary domain. MIDs were evaluated based on previously published threshold values of 8 for urinary function [38], of 6 for urinary incontinence, and of 5 for urinary irritation [39]. In the present study, while the CBSM condition showed an improvement in urinary domain, the HP condition reported increased levels of symptom burden. From baseline to 12 months, the between-condition MIDs in urinary function, urinary incontinence, and urinary irritation were all greater than the threshold values. This finding is especially promising given that clinically meaningful benefits in urinary domain were sustained in the long-term. The previous studies have well established that psychological factors are associated with urinary health [40]. It is likely that CBSM-based psychological benefits (in our case, reduced cancer-related anxiety and distress) mediate the impact of CBSM intervention on perceived urinary symptom burden, which in turn may influence psychological well-being. However, such direction of causality has yet to be proven among APC survivors. Future researcher may consider using structure equation models and a larger sample for more in-depth investigations.

Contrary to our hypotheses, the data did not provide evidence that CBSM significantly improved PC-specific symptom burden (i.e., sexual function and hormonal function), cancer-related anxiety (i.e., anxiety about cancer, and anxiety specific to PSA), and cancer-specific distress (i.e., avoidance and hyperarousal). One plausible explanation is that participants in both conditions were provided with educational materials aimed at enhancing understanding

of APC, including information on managing potential side effects, accessing health-related information, and the importance of follow-up care. This educational component may have served as a mitigating factor, reducing the differences in improvements between the conditions. It would be useful for future studies to combine CBSM and HP modules to deliver more comprehensive care when compared to standard care alone. Another explanation could be that the subsample size in the current analysis was relatively small. In fact, we detected significant changes in hormonal function across time only within the CBSM condition. This result may reflect a subtle pattern of CBSM intervention effect, indicating that more research with larger samples is needed. Additionally, it is important to note that the subscale measuring anxiety specific to PSA has poor internal consistency ($\alpha = 0.58$). Hence, the lack of a significant intervention effect on PSA-specific anxiety remains inconclusive.

Overall Improvements Throughout Conditions

Interestingly, two main effects of time were observed. Participants, regardless of condition, reported increased levels of social support from and relationship satisfaction with friends/family in both short- (6 months) and long-term (12 months). Moreover, all participants were found to use problem-focused coping strategies less frequently over a 12-month period. These main effects of time do suggest some insights into patients' perceptions of their own affective and coping experiences, especially long-term. First, the design of group-based delivery of CBSM intervention may play a role. Participants in both conditions met weekly in small groups where they had opportunities interacting with other peers going through similar life experiences. This supportive social environment may have enhanced perceived social support and relationship satisfaction for all participants [17]. Second, it may be that this progression pattern is unique for APC survivors with low baseline SWB. Previous research has indicated that cancer patients have different levels of expectations as they move through different stages of responsibility for managing their condition [41]. Compared to patients with localized prostate cancer, APC survivors presumably may have adapted physically (normalizing bodily changes) and mentally (normalizing affective reactions), resulting in less coping efforts. For instance, Moreno and Stanton [42] found that individuals with advanced cancer experienced personal growth, reduced cancer-related distress, and improved positive well-being. We argue that this adaptation process can be especially so for our APC patients who had survived their cancer for approximately 5 years on average and who reported increased levels of social support and relationship satisfaction. Indeed, our finding on problem-focused coping is consistent with several oncology studies [27, 43] that problem-focused coping (i.e., active coping and positive reframing) seems to be predominantly associated with psychosocial adaptation. Future studies are needed to further understand what underpins the complex interactions between SWB, psychosocial adaptation, and coping styles, in order to develop effective psychosocial interventions that incorporate the three concepts.

Social cultural norms on masculinity may exert influence on health-related coping styles for men with cancer. In the current analysis, it is not surprising that our patient cohort (aged 60 above) who had undergone ADT are substantially influenced by traditional dominant masculinity values. We note that prior research suggested that male patients tended to adopt certain coping strategies to ease distress associated with ADT therapy, such as loss of masculinity and sex drive, and feminization of the body. Men with prostate cancer have been found to frequently engage in physical activity and exercise [44, 45], and to pressure spouses/partners to engage in health behaviors [46]. Accordingly, our APC patients might have adopted similar coping strategies to preserve their masculine identity. Therefore, we should be cautious in interpreting our findings on coping given the use of the generic scale of brief COPE. It may be that APC patients in the present study do not feel being personally relevant to the coping questions, which are not specifically related to PC cancer and masculinity threat. Future studies are needed to address this conceptual issue.

Limitations

This study has some limitations. First, we must be cautious in interpreting the results, due to the fact that the relatively smaller sample sizes lead to reduced power compared to the initial study cohort. Nonetheless, this post hoc subgroup analysis is valuable as it helps identify the specific subgroups that benefit the most from the CBSM intervention, potentially informing more precise and targeted intervention enhancements. Second, almost all participants were senior APC patients. Research has suggested some age-related dependency on emotional well-being and coping [47, 48]. Compared to younger counterparts, older patients may be better at managing their emotions in a range of cancer types. Perhaps our patients perceived less negativity, or they became more experienced in coping as they age, resulting in less coping efforts in general. Consequently, our results may not be generalizable to other age groups of PC cancer patients. Third, the observed increase in social support could be attributed to a combination of CSBM and the participants' preexisting relationships and networks. However, we acknowledge the limitation of being unable to distinguish between the two in the current analysis. In addition, the current analysis focused on patients' general perceptions on SWB and did not consider, for instance, specific types of social support (e.g., instrumental/emotional). Future

research should examine how different ways of measuring SWB can influence the intervention effects on psychosocial outcomes. Lastly, our findings are based on self-reports. It is likely that male patients participating in this study might not feel comfortable disclosing their vulnerability (sexual impotence, distress related to avoidance and hyperarousal). It would be helpful to collect data from multiple sources, such as spouse, caregivers and physicians, to gain a deep understanding of patients' actual experiences with APC.

Conclusion

In conclusion, our findings suggest that CBSM can lead to improvements in PC-specific symptom burden and affect-based HRQOL for APC patients with low SWB. Such findings have important clinical and research implications as we seek to further understand how SWB interacts with other variables to influence the effects of psychosocial interventions on APC cancer survivors. For instance, SWB may indirectly affect cancer growth and metastatic potential via inflammation processes and tumor microenvironment [49, 50]. Methodologically, it would be ideal to collect and integrate social and biological data on a cohort of APC cancer survivors, to gain more holistic insights of disease progression and cancer-related psychological well-being.

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Data Availability Data available on request due to privacy and ethical restrictions.

Declarations

Ethics Approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee (Institutional Review Board) of the Northwestern University Feinberg School of Medicine.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare no competing interests.

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