

A randomized comparison of group mindfulness and group cognitive behavioral therapy vs control for couples after prostate cancer with sexual dysfunction

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Abstract

Background: Sexual dysfunction is the most common and most distressing consequence of prostate cancer (PCa) treatment and has been shown to directly affect the sexual function and quality of life of survivors' partners. There are currently no established therapies to treat the emotional and psychological burden that sexual issues impose on the couple after PCa.

Aim: Our study examined the impact of 2 therapies—cognitive behavioral therapy (CBT) and mindfulness therapy—on sexual, relational, and psychological outcomes of PCa survivor and partner couples.

Methods: PCa survivors ($n=68$) who self-reported current sexual problems after PCa treatments and their partners were randomized to 4 consecutive weeks of couples' mindfulness therapy, couples' CBT, or no treatment (control).

Outcomes: Couples' sexual distress, survivors' sexual satisfaction, and couples' relationship satisfaction, quality of life, psychological symptoms (anxiety and depression), and trait mindfulness were measured at baseline, 6 weeks after treatment, and 6 months after treatment.

Results: Sexual distress and sexual satisfaction were significantly improved 6 weeks after the CBT and mindfulness interventions as compared with the control group, but only sexual distress remained significantly improved at 6 months. Relationship satisfaction decreased and more so for partners than survivors. There were increases in domains of quality of life for survivors vs their partners 6 months after treatments and an overall increase in general quality of life for couples 6 weeks after mindfulness. There were no significant changes in psychological symptoms and trait mindfulness. Qualitative analysis showed that the mindfulness intervention led to greater personal impact on couple intimacy after the study had ended.

Clinical Implications: CBT and mindfulness can be effective treatments for helping couples adapt to and cope with changes to their sexual function after PCa treatments and could help improve the most common concern for PCa survivors—that is, couples' sexual intimacy—after cancer, if added to routine clinical care.

Strengths and Limitations: We used established standardized treatment manuals and highly sensitive statistical methodology and accounted for covariable factors and moderators of primary outcomes. Due to difficulty in recruitment, we had a smaller control group than treatment, reducing our power to detect between-group differences. Our sample was mostly White, heterosexual, and affluent, thereby limiting the generalizability.

Conclusion: This is the first randomized clinical trial to test and demonstrate benefits among PCa survivors and partners' sexual outcomes after CBT and mindfulness as compared with a nontreatment control group.

Keywords: prostate cancer; mindfulness; cognitive behavioral therapy; couples; sexual health; sexual satisfaction; sexual dysfunction.

Introduction

Prostate cancer in North America

Prostate cancer (PCa) is the second-most common cancer diagnosis for men in North America, where 1 in 9 in Canada¹ and 1 in 8 in the United States² will be diagnosed with the disease in their lifetimes. Fortunately, due to advances in treatments, these countries have 5-year survival rates of 93% and 97%, respectively.^{1,2} However, PCa treatments leave survivors with a high degree of symptom burden.^{3,4} When put into perspective, the frequency of disease combined with the extremely high survival rates means that there are large

numbers of patients with PCa and their partners who require supportive care during their survivorship journey.

PCa and related sexual dysfunctions

Sexual dysfunction is the most frequently reported side effect by PCa survivors and occurs as a result of all PCa treatments.^{3,4} For example, Barocas et al examined 3-year outcomes on sexual health after PCa treatments in a well-powered randomized clinical trial with a sample of 2550 racially diverse PCa survivors.⁵ For men who had erections sufficient for intercourse before cancer treatments, 3 years

later this number decreased to 43% for patients undergoing radical prostatectomy, 53% for external beam radiation therapy, and 75% for active surveillance.⁵ Current treatments addressing sexual problems in PCa survivors focus largely on the medical restoration of erectile function, such as vacuum erection devices and at-home intracavernosal injections, which successfully manage erectile dysfunction in up to 85% and 92% of individuals, respectively.⁶ Yet long-term adherence is poor, with up to 86% of patients discontinuing therapy within a year,^{4,6} likely as a result of losing the spontaneity in sex and the invasiveness, discomfort, and pain from using aids.^{7,8}

Psychological outcomes following PCa treatment

Survivors of PCa experience rates of distress, anxiety, and depression much higher than the general population.^{3,9–11} Sexual difficulties after PCa are also correlated with psychological symptoms. As well, the degree of erectile dysfunction predicts the quality of life in PCa survivors.^{9,10} The emotional needs of all PCa survivors are often unaddressed and left unresolved,¹¹ leaving a large number of men experiencing feelings of despair and isolation. To date, there are no established therapies to help PCa survivors cope with the psychological distress related to their sexual dysfunction.

Role of the partner

Partners of PCa survivors carry a significant burden in terms of the emotional and physical care of their partners and experience negative psychological and sexual outcomes.^{7,12–14} Female partners of PCa survivors report high levels of distress, anxiety, and depression, as well as worse overall sexual functioning and satisfaction, as compared with a cancer-free sample.^{12,13} The degree of sexual difficulty in the PCa survivor directly affects the severity of sexual difficulty in the partner,^{13,14} and improving a survivor's sexual function improves the sexual function of the partner.⁷ Despite these well-documented survivor and partner sexual and relational correlations, partners (regardless of gender) and PCa survivors express frustration with the lack of involvement of partners during and after treatment.⁸ There is thus a clinical need for psychological interventions that address the emotional needs of survivors and partners and that focus less on the mechanics of erection but rather the sexual experiences of the couple.^{3,8,11}

Psychological trials evaluating sexual health interventions

Over the past decade, there has been an increasing number of psychological treatment trials evaluating nonpharmacologic treatments for post-PCa sexual problems.^{15–18} The current literature consists mostly of pilot studies or small trials,^{15–17} where almost all lack sufficient power to draw significant conclusions and where posttreatment changes in sexual and psychological outcomes are often nonsignificant or do not last long term.^{16–18} Study samples also differ widely in whether partners were included.^{16–18} Nearly all studies focused on sexual education or general counseling¹⁷ instead of evaluating empirically supported psychological treatments for this population.^{15,17,18}

As well, several individual factors that may alter trial outcomes in this population are often unaccounted for.^{15,17} Time since one's PCa treatments were completed, whether

these treatments are ongoing (as with radiation or androgen deprivation therapy), and age may all affect sexual outcomes.^{5,9} Additionally, greater treatment adherence (practice), positive treatment expectations, and some personality traits have shown to improve treatment outcomes in psychological interventions^{19–21} and are mostly unexamined in previous interventions for this population.¹⁵ Teaching participants to navigate sex and intimacy rather than trying to “cure” sexual dysfunction following PCa treatment also led to better outcomes,^{17,18} as did including partners in treatments.¹⁷

Cognitive behavioral therapy and mindfulness therapy for sexual dysfunction

Cognitive behavioral therapy (CBT) aims to recognize and challenge negative thought patterns as a means to improve mood and challenge avoidance behavior.²² Over the past 50 years, CBT has been established as an effective intervention for mood, anxiety, and depression,²² as well as sex therapy,^{22,31} and in couples with sexual dysfunction.^{23–25} Internet-based CBT improved breast cancer survivors' sexual function and body image,²⁴ and participation of partners led partners to experience improvement in long-term sexual satisfaction, intimacy satisfaction, and relationship satisfaction.²⁵ Furthermore, an uncontrolled pilot trial evaluating cognitive-based therapy to enhance intimacy in PCa and survivor couples found that sexual function improved immediately after CBT and sexual satisfaction improved 6 months after treatment.²⁶

Mindfulness is a practice that aims to cultivate a “non-judgmental present-moment awareness.”²⁷ Unlike CBT, mindfulness involves recognizing and accepting psychological and physical feelings and does not attempt to change thoughts, therefore improving attentional focus on feelings and bodily sensations and letting distractions exist in the background.²⁷ A significant body of research has established mindfulness-based therapy as an effective treatment for sexual dysfunction in women experiencing sexual problems, including gynecologic cancer.^{28–31} In a study of patients with PCa, mindfulness improved quality of life, mood, and, interestingly, some immunologic parameters.³² A pilot study of a mindfulness program that was effective for gynecologic cancer survivors led to notable effect size increases in sexual satisfaction and mindfulness in a small group of PCa survivors and their partners.³³ Given the limited but promising evidence in favor of CBT and mindfulness for improving domains of sexuality in PCa survivors and their partners, we sought to evaluate these treatments against a nontreatment control group in a larger sample of survivors and partners.

Hypothesis 1: The primary outcomes of PCa survivor and partners' sexual distress, survivors' sexual satisfaction, and couples' relationship satisfaction will improve after CBT and mindfulness treatment, and these improvements will be sustained at 6 months posttreatment for survivors and partners as compared with controls.

Hypothesis 2: The secondary outcomes of quality of life, anxiety, and depression will improve in survivors and partners after both treatment arms and will be sustained at 6-month follow-up as compared with the control group. Mindfulness treatment will significantly increase participants' levels of mindfulness.

Hypothesis 3: The exploratory outcomes of sexual behavior and sexual function will be examined in both members of the couple. We expect sexual behavior to increase, specifically

in nonpenetrative sexual behaviors as they are encouraged in both treatment arms. Sexual function will also increase in both treatment arms.

Hypothesis 4: We expect treatment expectations, number of minutes of homework completed, and personality traits to moderate the primary endpoints: sexual distress, sexual satisfaction, and relationship satisfaction.

Methods

Participants

We recruited PCa survivors who self-reported current sexual problems after PCa treatments and their partners. A total of 22 couples were recruited through scheduled sexual health service appointments at a local Prostate Cancer Supportive Care Program. Patients were identified by clinicians during their appointments as being possibly eligible for the study and were given the contact information of the study coordinator or, if the patient expressed an interest, spoke to a researcher at the end of the regular visit. The study was also advertised through the program's learning modules, quarterly newsletter, and posters put up in the offices. An additional 42 couples were recruited from online patient databases of PCa survivors who indicated that they were available for clinical study contact. These databases consisted of the supportive care program, a separate prostate clinic within the same hospital, and a database of general cancer survivors within the province. Eligible patients were mailed invitation letters. For a broader outreach, recruitment posters were sent to urologists and general health practitioner offices and posted on local hospital community bulletins. Advertisements were additionally published in local community newspapers and online through Glacier Media, which targets relevant social media platforms. Twelve couples were recruited through physician outreach and advertising, 8 from the pilot study for this trial, and 1 via a colleague's referral. Participants who contacted the research assistant were given further information and subsequently screened.

Inclusion criteria required participants to have been in a relationship for at least a year prior to the study, where at least 1 member of the couple had received a diagnosis of PCa a year or more before participation. The study was open to those who had received treatment and to those undergoing active surveillance only. Participants were required to be fluent in English, written and spoken, and they needed to be able to commute to our academic health center, located in a large Canadian metropolitan city. Exclusion criteria included health conditions that would prevent participants from attending in-person therapy sessions.

Procedure

Once consent was obtained, couples were assigned study identification numbers and randomized to 1 of 3 arms: 4 consecutive weeks of CBT, mindfulness-based therapy, or control, which involved no treatment other than what they had been receiving already. A randomization list was created by the study coordinator via a random number generator at www.researchrandomizer.com.

All couples completed an initial questionnaire online through REDCap software (<https://redcap.ubc.ca>). For couples in the control group, questionnaires were completed at baseline (t1), approximately 6 weeks after completing the

first questionnaire (t2), and approximately 6 months (t3) after t2. For couples randomized to CBT or mindfulness, treatment consisted of 4 consecutive weeks of group couple therapy at 2 hours per session, led by a trained clinician who had experience with sexual health, mindfulness and/or CBT, and psychosocial oncology. Groups consisted of 2 to 6 couples. Treatment group participants completed follow-up measures approximately 6 weeks (t2) and 6 months (t3) after t1. To complement the quantitative outcomes, participants were invited to take part in a semistructured interview to probe their experiences of the group. All study procedures were approved by the UBC Behavioural Research Ethics Board (H17-02857). The trial was preregistered on clinicaltrials.gov (NCT03365518).

Intervention contents

We used separate 100-page facilitator manuals and accompanying 100-page participant guides for the CBT³⁴ (Table 1) and mindfulness^{33,34} (Table 2) arms, with the former evaluated in a prior feasibility study.³³ In brief, the mindfulness-based treatment adapted the contents of a similar program for women,^{30,31} as well as aspects of the Mindfulness in Sex Therapy and Intimate Relationships program.³⁵ The CBT treatment contained instruction on the cognitive behavioral model,³⁶ thought records, avoidance behavior, sensate focus, and how to challenge behaviors and thoughts to improve affect and sexual response. Both arms included psychosocial information pertaining to cancer survivorship and sexual health.

Measures

Primary outcomes: sexual and relational

Sexual distress was the primary outcome and was measured with the Female Sexual Distress Scale-Revised, a 13-item measure that examines the level of distress related to one's sexual concerns.³⁷ This scale is valid in male samples given its gender-neutral wording,³⁸ with good internal consistency and test-retest reliability across gender and sexual function.^{37,38} Both PCa survivor and partner completed this measure, with higher scores indicating a higher level of sexual distress and with a maximum score of 52 indicating the most distress. Cronbach alpha at t1 was $\alpha = 0.92$.

Survivors' sexual satisfaction was our second primary outcome and was measured with the overall sexual satisfaction domain of the International Index of Erectile Function (IIEF)³⁹; for participants who identified as men and had male partners, the IIEF for Men Who Have Sex With Men (IIEF-MSM) was used.⁴⁰ Considered the gold standard for measuring male sexual function,³⁹ the IIEF demonstrates good test-retest reliability and sensitivity and specificity for assessing sexual outcomes for men, including those with PCa.³⁹ Both questionnaires assess 5 domains of sexual function, with maximum scores ranging from 8 to 15, where higher scores indicate better function. Participants were asked to respond to the IIEF and IIEF-MSM considering their sexual experiences when sexual aids were not used. In line with previous studies,^{26,33} only the overall sexual satisfaction domain was considered a primary outcome, which consists of 2 Likert-scale response questions that assess satisfaction of one's overall sex life and overall sexual relationship with a partner. Cronbach alpha for overall sexual satisfaction at t1 was $\alpha = 0.79$ for the IIEF and $\alpha = 0.93$ for the IIEF-MSM.

Table 1. Therapeutic contents of the CBT intervention.

| Session | Education and exercises | Home practice (time) |
|---------|---|---|
| 1 | 5-part diamond model Introduction to CBT rationale and research Introduction to the sexual response cycle/model | Diamond model handout Sexual response cycle exercise handout |
| 2 | Introduction to thinking traps Noticing beliefs Introduction to non-goal-directed sex Introduction to sensate focus | Thinking traps and noticing beliefs handout Sensate focus (1/7 d) |
| 3 | Introduction to thought record Addressing thinking traps Introduction to sexual avoidance Introduction to sexual communication | Thought record handout Sensate focus (1/7 d) |
| 4 | Introduction to behavioral experiments Understanding what enjoyable sex is for oneself Maintaining skills beyond the group | Attempt a behavioral experiment Sex and Intimacy: What's Important to Me? (handout) Sensate focus (1/7 d) |

Abbreviation: CBT, cognitive behavioral therapy.

Table 2. Therapeutic contents of the mindfulness intervention.

| Session | In-session meditation | Education and exercises | Home practice (time) |
|---------|--|--|---|
| 1 | "Eating a raisin" meditation Body scan | Introduction to mindfulness research and rationale in the context of sexuality/intimacy Introduction to sexual response cycle/model | Formal mindfulness practice—body scan (30 min/d; 6/7 d) Informal mindfulness practice (10 min/d; 7/7 d) Sexual response exercise—complete handout |
| 2 | Back-to-back sensing | Non-goal-directed sex Introduction to sensate focus | Formal mindfulness practice—body scan (30 min/d; 6/7 d) Informal mindfulness practice (10 min/d; 7/7 d) Sensate focus (1/7 d) |
| 3 | Breath, body, sounds, and thoughts | Introduction to sexual avoidance Introduction to sexual communication Understanding thoughts during mindfulness practice | Formal mindfulness practice—body scan (30 min/d; 6/7 d) Informal mindfulness practice (10 min/d; 7/7 d) Sensate focus (1/7 d) |
| 4 | Mindful listening 3-min breathing space | "Sex and Intimacy: What's Important to Me?" (handout) Maintaining mindfulness beyond the group | Formal mindfulness practice—body scan (30 min/d; 6/7 d) Informal mindfulness practice (10 min/d; 7/7 d) 3-min breathing (as needed) Complete "Sex and Intimacy" handout Sensate focus (1/7 d) |

Relationship satisfaction was the third primary outcome and was measured for both members of the couple with the adapted Dyadic Adjustment Scale (DAS-7): a 7-item measure derived from Spanier's⁴¹ Dyadic Adjustment Scale (DAS).⁴² This short form maintains the core structure of the DAS by assessing dyadic consensus, dyadic cohesion, and a 1-item measure of global dyadic satisfaction.⁴¹ Scores range from 0 to 36, with higher scores indicating more relationship satisfaction. The DAS-7 has shown stable internal-reliability across multiple samples and was comparable to the DAS.⁴² It also accurately distinguished between distressed and nondistressed couples and has been frequently used to measure the satisfaction of long-term partners and examine clinical treatment outcomes.⁴² Cronbach alpha for our sample at t1 was $\alpha = 0.79$.

Secondary outcomes: quality of life, psychological symptoms (anxiety and depression), and mindfulness

Quality of life was measured for all participants with the World Health Organization Quality of Life–BREF (WHOQOL-BREF) scale, a validated and widely used 26-item measure to quantify 4 aspects of quality of life⁴³: psychological, physical, social and relational, and environmental.

Higher domain scores represent better quality of life, and a participant can achieve a maximum score of 20 for each domain. The scale also includes 2 general quality of life and health questions: "How would you rate your quality of life?" and "How satisfied are you with your health?" (range, 1–5). The WHOQOL-BREF demonstrated high test-retest reliability and validity in an older population.⁴⁴ Cronbach alpha at t1 was $\alpha = 0.81$ for psychological quality of life, 0.80 for physical, 0.50 for social, and 0.85 for environmental.

The Hospital Anxiety and Depression Scale (HADS) was used as a measure of psychological symptoms, and we were particularly interested in the separate assessment of both HADS domains: anxiety and depression.⁴⁵ The HADS shows good internal consistency and reliability and effective sensitivity in detecting anxiety and depression in clinical populations and the general population.⁴⁶ Scores are scaled where higher scores indicate worse symptoms (ie, higher anxiety and depression), and a maximum score of 7 is possible for either domain. Cronbach alphas at t1 for PCa survivor and partners' anxiety and depression scores were $\alpha = 0.83$ and 0.80, respectively.

Trait mindfulness was measured at all time points for survivors and partners with the Five Facet Mindfulness

Questionnaire–Short Form. This is a 24-item measure of 5 domains of mindfulness, where each domain can have a maximum score of 35 or 40 and higher scores indicate more mindfulness tendencies.⁴⁷ We calculated a total score by calculating the sum of these domains, with a maximum of 120. The 5-factor structure of the short form scale has been supported and validated in older samples.⁴⁸ Cronbach alpha at t1 was $\alpha = 0.66$.

Exploratory outcomes: sexual behavior and sexual function

We used the Sexual Activity Scale, developed for this study, to measure sexual activity and behavior as exploratory outcomes. Both members of the couple were asked if they had engaged in listed sexual behaviors over their entire life, since PCa treatments, and in the past 2 weeks. Total scores were calculated as the sum of *yes* answers to penetrative and nonpenetrative behaviors at these times. For the purpose of this study, we considered only the sum of nonpenetrative and penetrative sexual behaviors in the last 2 weeks.

Sexual function was measured for survivors and partners separately. Survivor sexual function was measured by the other 4 IIEF³⁹ and IIEF-MSM⁴⁰ domains: erectile function, orgasmic function, sexual desire, and intercourse satisfaction. Cronbach alphas for each domain of the IIEF at t1 are $\alpha = 0.91, 0.70, 0.94$, and 0.94 , respectively. Cronbach alphas on the IIEF-MSM at t1 for survivors' responses were $\alpha = 0.79$ for orgasmic function, 0.94 for sexual desire, and 0.94 for intercourse satisfaction. Cronbach alpha could not be computed for erectile function, as too few participants participated in penetrative sex.

Female partners' sexual function was measured with the Female Sexual Function Index (FSFI), a widely used 19-item measure of self-reported experiences of sexual dysfunction in women.⁴⁹ The FSFI has excellent discriminant validity, and its subscales are reasonably stable across demographics.⁵⁰ We used the FSFI total score, with an overall score ≥ 36 indicating better overall sexual function. We examined the FSFI total scores in our sample. Given that responses on the FSFI require sexual activity in the preceding 4 weeks and that sexual activity rates are known to be lower in PCa couples,¹³ scores for those who were not sexually active were considered missing. Cronbach alpha at t1 for the FSFI total score was $\alpha = 0.84$.

Moderators of primary outcomes

We had 3 putative moderators for the 3 primary outcomes.¹⁹

The first moderator was treatment expectations, for which we asked the following 2 questions: "To what extent do you think the treatment is logical for alleviating sexual dysfunction?" and "To what extent do you expect improvement in your sexual function after treatment?" Participants answered these questions on a scale from 0 (lowest level of treatment logical/expectations for improvement) to 10 (highest level).

The second moderator was time spent per day in minutes on homework skills captured from participants' daily logs. Participants in the CBT treatment arm recorded how many minutes they spent completing take-home handouts and practicing sensate focus each day. Participants in the mindfulness group recorded daily minutes of meditation or sensate focus (formal mindfulness) and daily minutes of practicing mindfulness during everyday tasks (informal mindfulness).

The third moderator was personality, which we measured with an abridged 10-item version of the Big Five Inventory. The abridged scale uses 2 items to assess each of 5 aspects

of personality (extraversion, agreeableness, conscientiousness, neuroticism, and openness), correlates with the 44-item scale, and has shown good test-retest reliability and structural validity.⁵¹ Cronbach alphas in our sample were low since this abridged version of the scale consists of only 2 items for each personality domain.⁵² Cronbach alphas for the 5 factors at t1 were $\alpha = 0.55$ for extraversion, $\alpha = 0.52$ for conscientiousness, $\alpha = 0.32$ for agreeableness, $\alpha = 0.64$ for neuroticism, and $\alpha = 0.54$ for openness to experience.

Qualitative interviews: clinical significance

Clinical significance, defined as whether an effect has a real-world or practical meaning and impact for participants, was assessed through semistructured exit interviews of couples postintervention.⁵³ All participants, including the control group, were invited to participate in exit interviews at some point between t2 and t3; this was a convenience sample of participants who were available and willing to be interviewed. Interviews were conducted for couples together over 30 to 60 minutes by a trained research team member who was not otherwise involved in the intervention. Exit interviews consisted of 19 questions divided into subgroups of expectations, general feedback, group format, and personal impact, which were analyzed as part of a larger qualitative analysis. For this study, we chose to examine participants' responses to personal impact as a measure of how meaningful the CBT or mindfulness group was for the couple.⁵³ Open-ended questions were as follows: "How did this group impact you personally?" "How did this group impact you as a couple?" "How did the group impact, if at all, your sexual functioning and your intimacy?" We conducted a basic thematic analysis to interpret participants' meaning given to their lived experience. Common themes that emerged in the interviews were identified and discussed.

Data analysis plan

Power analysis

The prestudy power analysis was calculated for a repeated measures mixed design analysis of variance (1 within-subject factor [3 time points] and 1 between-subject factor [3 treatment groups]) and a small to medium anticipated effect size based on past studies,³³ a power of 0.80, and an alpha of 0.05, which called for 99 couples, or 33 in each group.

Analysis of primary, secondary, and exploratory treatment outcomes

Effects of treatment were analyzed with multilevel modeling with SPSS software version 28 (IBM). To account for the interdependence of members in a dyad, we built a 3-level model where the repeated measures—pretreatment (t1), post-treatment 6-week follow-up (t2), and posttreatment 6-month follow-up (t3; a factor called *time*)—of each outcome were nested in participants, who were then nested in their dyads. Participant and dyad random effects were included in the model. The level 1 fixed effect of time (treated as a categorical variable; t2 and t3 vs t1), the level 3 fixed effect of treatment (CBT and mindfulness vs control), and their interaction were in each model. Sexual function was analyzed separately for PCa survivors and partners (IIEF and FSFI, respectively) with a 2-level model. Initially, the models for primary and secondary outcomes included 3-way interactions of time, treatment, and role (whether participant was a survivor or partner) to examine for differences between survivor and partner in treatment

outcomes. When there were no significant 3-way interactions (no difference between survivor and partner), we proceeded to evaluate the interaction of treatment and time: specifically, changes from t1 to posttreatment follow-ups were compared between the treatment groups and the control group. Three-way interactions were not examined for exploratory outcomes of reported sexual behavior (since we expected no differences) and sexual function (since survivors and partners were analyzed separately). Additionally, each model initially included 2 covariates—age and years since treatment (coded as 0 years if treatment was ongoing)—which have shown to affect sexual, relational, and psychological outcomes after PCa.^{5,9,15} Since some participants (30%) completed their 6-month assessment after COVID-19 lockdown restrictions were implemented, a dummy-coded “COVID” variable was created (third assessment before or after COVID-19 restrictions) as an additional covariate in initial models.

Analysis of treatment moderators

We used the same multilevel model structure to examine 3-way interactions of moderators, treatment, and time for our primary outcomes. For our moderator analysis of personality factors—where there were 5 personality variables examined for each of 3 outcomes, resulting in 15 models—the Benjamini-Hochberg correction for multiple comparisons was applied to reduce the likelihood of type 1 errors with multiple tests.⁵⁴ This approach allowed us to control for the false discovery rate while maintaining more power than other multiple-comparison corrections.^{41,54} We allowed for a 10% chance of false-positive findings, and each *P* value was compared against a corresponding corrected *P* value based on the Benjamini-Hochberg formula.⁵⁵ *P* values greater than their corrected values were considered nonsignificant, and the null hypothesis was not rejected.

This study used an intent-to-treat approach, which is a conservative method that protects the comparability of the randomization of treatment arms.⁵⁶ The multilevel model estimation was achieved through restricted maximum likelihood, which is a highly precise way of utilizing all information available regardless of missing data.⁵⁷ Restricted maximum likelihood dealt with missing data at both follow-up time points and is considered particularly useful for clinical trials.⁵⁷

Results

Participants

Of the 231 individuals who expressed an interest, a total of 85 couples were eligible and consented, and 17 couples withdrew after providing consent, leaving 68 couples who were randomized. t1 measures were completed by 67 couples and 1 additional PCa survivor (partner did not complete t1). A total of 55 couples completed all 4 weeks of the intervention, with 28 in CBT, 27 in mindfulness, and 9 in the control group (see CONSORT diagram in Figure 1).

As shown in Table 3, the sample was mostly heterosexual, with 3 gay couples (in which both members identified as men). One survivor identified as nonbinary. The average participant was White and well educated, with some form of postsecondary education, and had an annual household income >\$100 000. The average couple's relationship length was 29 years, with a minimum of 1 year and a maximum of 59 years together. The average time since PCa treatments

were completed was slightly >2.5 years prior to study participation. Given known sexual dysfunction with active surveillance,⁵ active surveillance patients were included in the sample (*n* = 16), with 3 survivors undergoing active surveillance only (no other treatments).

Recruitment of couples for a study that requires a consecutive 4-week commitment from this vulnerable population proved to be difficult. This, combined with our participants' eagerness to engage in treatment, led us to allow people randomized to the control condition to enroll randomly into 1 of the 2 treatment arms. This led to an increase in the numbers of participants in the treatment groups while decreasing the size of the control group.

Session attendance and homework completion

A total of 100% of couples in CBT and 87% in mindfulness completed all 4 sessions of the intervention. All participants completed some homework (Table 4). Over the 4 sessions, CBT participants spent an average of 421 minutes on all homework, and mindfulness participants spent 427 minutes on formal mindfulness practice.

Effects of treatment

For the models where the effects of role (whether respondents were a PCa survivor or partner) and covariates were nonsignificant, results are reported not including those additional variables. When findings were significant, results are described accordingly. Inclusion of covariates for age and COVID-19 did not affect any of the significant findings.

Table 5 shows mean values and standard deviations for all outcomes by treatment arm and time of measurement. Tables 6 to 8 show the results of the multilevel analysis.

Primary outcomes: sexual distress, sexual satisfaction, and relationship satisfaction

There was a main effect of time for changes in sexual distress; across treatment conditions, participants reported significantly less sexual distress at t2 and t3 as compared with t1. This effect was qualified by a significant interaction with treatment. This interaction is illustrated in Figure 2, and all analysis statistics are presented in Table 6. Sexual distress was significantly more reduced at t2 and t3 than t1 for the CBT group and for the mindfulness group as compared with control.

Survivors' sexual satisfaction, as measured by the IIEF, significantly increased from t1 to t2 and t3 across both treatment groups. This main effect of time was qualified by a significant interaction (Figure 3, Table 6). At t2, the CBT group had greater improvement in overall satisfaction from t1 as compared with the control group. This effect was not sustained at t3. There was also a time × group interaction for mindfulness such that survivors' sexual satisfaction improved significantly more after mindfulness as compared with the control group from t1 to t2.

The third primary outcome, relationship satisfaction, decreased over time for all participants regardless of treatment group, but this was not significant. Although there were no significant interactions between time and treatment, there was a significant 3-way interaction of role (survivor or partner), time, and group for the CBT and mindfulness groups at t3.

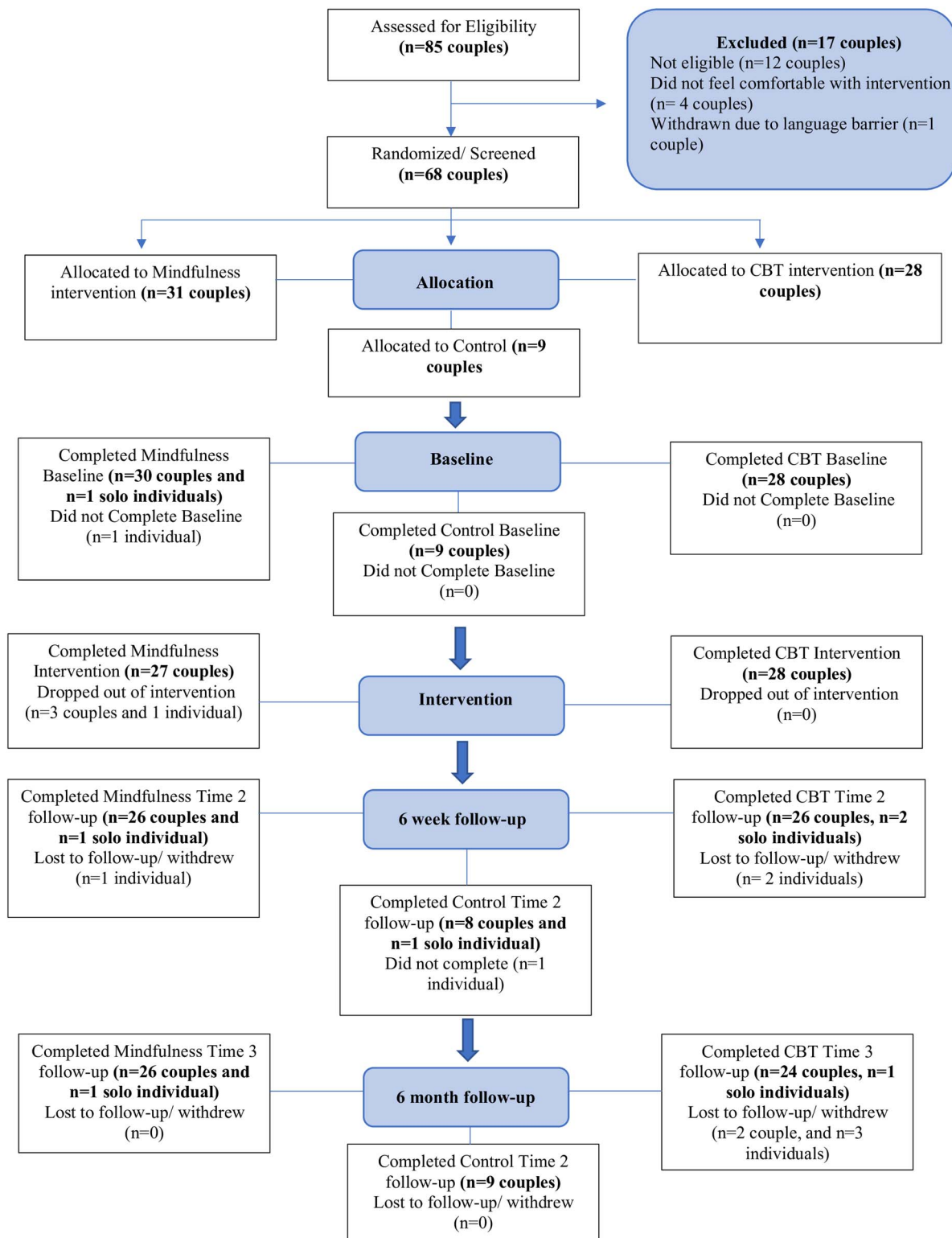


Figure 1. CONSORT diagram⁵⁸ for participants in the CBT arm, mindfulness arm, and control arm. CBT, cognitive behavioral therapy.

While relationship satisfaction decreased for all, this was more pronounced in the partners than the survivors from t1 to t3 in CBT ($b = 3.83$, $P = .042$, $d = 0.84$) and mindfulness ($b = 3.77$, $P = .043$, $d = 0.83$) vs control. However, this effect became only marginally significant when controlling for years since PCa treatment (CBT: $b = 3.78$, $P = .085$, $d = 0.83$; mindfulness: $b = 3.73$, $P = .087$, $d = 0.82$). Since large effect sizes of this interaction remained when controlling for time since PCa

treatment, the original interactions were graphed without the covariate (Figure 4).

Secondary outcomes: quality of life, psychological symptoms, and mindfulness

Table 5 shows mean values and standard deviations for the secondary outcomes by treatment arm and time of

Table 3. Characteristics of couples in the study.^a

| Measure | PCa survivors (n = 68) | Partners (n = 67) |
|---|-------------------------|----------------------|
| Gender identity | | |
| Man | 67 (99) | 3 (5) |
| Woman | 0 (0) | 64 (96) |
| Nonbinary | 1 (1) | 0 (0) |
| Age, y ^b | 68.13 (7.45) [48-82] | 62.99 (9.26) [32-82] |
| Sexual orientation | | |
| Heterosexual | 63 (93) | 62 (93) |
| Gay | 3 (4) | 3 (5) |
| Bisexual | 2 (3) | 0 (0) |
| Pansexual | 0 (0) | 1 (2) |
| Decline to answer | 0 (0) | 1 (2) |
| Relationship status | | |
| Married | 55 (81) | |
| Common law | 9 (13) | |
| Not married or common law | 4 (6) | |
| Relationship length, y ^b | 29.15 (16.52) [1-59] | |
| Years since last PCa treatment ^b | 2.82 (2.27) [0.14-8.72] | |
| PCa treatment type | | |
| Radical prostatectomy | 51 (75) | |
| Full nerve sparing | 25 (49) | |
| Partial nerve sparing | 16 (31) | |
| Non-nerve sparing | 3 (6) | |
| Nerve-sparing status unknown | 8 (16) | |
| External beam radiation therapy | 15 (22) | |
| Brachytherapy | 5 (7) | |
| Androgen deprivation therapy | 16 (24) | |
| Chemotherapy | 1 (1) | |
| Active surveillance | 16 (24) | |
| Treatment ongoing (excluding active surveillance) | 9 (13) | |
| Active surveillance only | 3 (4) | |
| Ethnicity | | |
| White (European) | 63 (93) | 56 (84) |
| Hispanic or Latin American | 1 (2) | 3 (5) |
| East Asian | 1 (2) | 3 (5) |
| Black | 2 (3) | 1 (1) |
| South Asian | 1 (1) | 1 (1) |
| Arab/West Asian | 0 (0) | 1 (1) |
| Southeast Asian | 0 (0) | 1 (1) |
| Prefer not to answer | 0 (0) | 1 (1) |
| Religious affiliation | | |
| No religious beliefs | 18 (41) | 26 (39) |
| Christian: Protestant | 23 (34) | 17 (26) |
| Christian: Catholic | 8 (12) | 15 (22) |
| Christian: Orthodox | 0 (0) | 1 (2) |
| Jewish | 4 (6) | 3 (5) |
| Buddhist | 0 (0) | 1 (2) |
| More than 1 religion | 0 (0) | 1 (2) |
| Prefer not to answer | 5 (7) | 3 (5) |
| Years of formal education ^b | 17.03 (3.09) [12-26] | 17.19 (3.65) [11-27] |
| Education | | |
| Some high school | 1 (2) | 1 (2) |
| High school or GED | 3 (4) | 7 (10) |
| Attended some college | 12 (18) | 7 (10) |
| Graduated 2-y college | 7 (10) | 7 (10) |
| Graduated 4-y college | 20 (29) | 18 (27) |
| Postgraduate degree | 25 (37) | 27 (40) |
| Employment status | | |
| Retired | 44 (65) | 42 (63) |
| Employed full-time | 9 (13) | 13 (19) |
| Self-employed | 5 (7) | 7 (10) |
| Employed part-time | 2 (3) | 4 (6) |
| Semiretired | 4 (6) | 1 (2) |
| Unemployed | 2 (3) | 0 (0) |
| On disability | 2 (3) | 0 (0) |
| Annual household income, \$ (in thousands) | | |
| <20 | 1 (2) | |
| 40-59 | 8 (12) | |
| 60-79 | 7 (10) | |
| 80-99 | 14 (19) | |
| 100-119 | 8 (12) | |
| 120-139 | 5 (7) | |
| 140-159 | 6 (9) | |
| >160 | 15 (22) | |
| Prefer not to say | 5 (7) | |

Abbreviation: PCa, prostate cancer. ^aData are presented as No. (%) unless noted otherwise. ^bMean (SD) [range].

Table 4. Minutes of homework practice completed by participants.

| Homework activity | Minutes, mean (SD) | Minimum | Maximum |
|---|--------------------|---------|---------|
| Mindfulness homework ^a | | | |
| Formal practice | 427 (212) | 52 | 823 |
| Informal practice | 271 (133) | 28 | 623 |
| Total | 698 (270) | 94 | 1098 |
| CBT homework | | | |
| Diamond model | 50 (40) | 0 | 180 |
| Sexual response cycle | 48 (41) | 0 | 220 |
| Thinking traps | 48 (50) | 0 | 190 |
| Noticing sexual beliefs | 36 (44) | 0 | 240 |
| Sensate focus | 138 (107) | 0 | 430 |
| Thought record | 51 (46) | 0 | 165 |
| Behavioral experiments | 24 (35) | 0 | 120 |
| "Sex and Intimacy: What's Important to Me?" | 25 (37) | 0 | 210 |
| Total | 421 (245) | 35 | 990 |

Abbreviation: CBT, cognitive behavioral therapy. ^aIn the mindfulness arm, sensate focus homework was included in formal mindfulness.

measurement. Table 7 displays the results of the multilevel analysis for secondary outcomes.

There was a 3-way interaction of role, time, and group for participant scores on the physical quality of life subdomain; in the CBT group, PCa survivors' physical quality of life had greater improvements over time vs their partners from t1 to t3 relative to these changes in the control group ($b = 2.06$, $P = .036$, $d = 0.83$). There were no main effects of time for physical quality of life and no time \times group contrasts. There was an additional 3-way interaction for participants' responses on the psychological quality of life domains. PCa survivors had a greater increase in psychological quality of life vs their partners from t1 to t3 after mindfulness relative to survivors' changes over time in the control group ($b = 1.69$, $P = .046$, $d = 0.70$). There was also a main effect of time: psychological quality of life increased in the sample from t1 to both follow-up assessments. There were no significant time \times group interactions. Three-way interactions are graphed for physical quality of life (Figure 5) and psychological quality of life (Figure 6).

There was a main effect of time for social and relational quality of life, where scores increased after treatment for participants from t1 to t2, but there was no change from t1 to t3 and no significant time \times group interactions. There was no main effect of time for environmental quality of life and no significant time \times group interaction.

When we examined the 2 general WHOQOL-BREF questions, we found a significant time \times group interaction of mindfulness at t2 for the general quality of life question. Mindfulness participants reported better quality of life at t2 relative to t1 when compared with the controls. There were no main effects of time. For the general health question, there was a main effect of time indicating that general health increased from t1 to t2, but there were no time \times group interactions.

HADS anxiety scores significantly decreased from t1 to t2, but there were no significant interactions of time \times group. Depression, as measured by HADS, did not significantly change (no main time or interaction effects).

There was a main effect of time on mindfulness such that scores significantly increased in the sample from t1 to t2 but not at t3. However, there were no time \times group interactions.

Table 5. Primary, secondary, and exploratory outcomes measures by time and group.^a

| Measure | Baseline | 6-wk follow-up | 6-mo follow-up |
|--|---------------|----------------|----------------|
| Sexual distress: FSDS-R | | | |
| CBT | 21.82 (10.24) | 18.10 (9.45) | 18.69 (10.22) |
| Mindfulness | 19.61 (10.66) | 17.02 (11.46) | 17.50 (11.22) |
| Control | 17.61 (8.24) | 19.76 (11.99) | 20.06 (9.00) |
| Survivor–overall satisfaction: IIEF | | | |
| CBT | 2.40 (2.25) | 3.89 (2.52) | 3.26 (2.42) |
| Mindfulness | 2.55 (2.37) | 3.72 (2.69) | 3.14 (2.59) |
| Control | 3.89 (2.09) | 3.56 (2.24) | 3.89 (1.76) |
| Relationship satisfaction: DAS-7 | | | |
| CBT | 23.36 (4.60) | 23.73 (4.71) | 22.79 (4.25) |
| Mindfulness | 25.10 (4.46) | 24.95 (4.97) | 24.10 (4.48) |
| Control | 25.33 (4.37) | 24.59 (4.05) | 25.83 (3.75) |
| WHOQOL-BREF | | | |
| Physical quality of life | | | |
| CBT | 16.57 (2.70) | 16.54 (2.89) | 16.57 (2.90) |
| Mindfulness | 16.47 (2.41) | 16.57 (2.26) | 16.30 (2.70) |
| Control | 17.05 (2.37) | 17.14 (2.17) | 17.11 (1.68) |
| Psychological quality of life | | | |
| CBT | 15.48 (2.33) | 16.07 (2.48) | 16.00 (2.51) |
| Mindfulness | 15.44 (2.63) | 15.79 (2.43) | 15.67 (2.46) |
| Control | 16.26 (1.65) | 16.31 (1.46) | 16.22 (1.50) |
| Social and relational quality of life | | | |
| CBT | 13.96 (2.51) | 15.09 (3.18) | 14.58 (2.80) |
| Mindfulness | 14.25 (2.71) | 14.97 (2.71) | 14.59 (3.02) |
| Control | 15.26 (1.78) | 15.45 (2.06) | 14.96 (2.44) |
| Environmental quality of life | | | |
| CBT | 17.58 (2.02) | 17.76 (1.78) | 17.77 (1.90) |
| Mindfulness | 17.50 (2.23) | 17.87 (2.24) | 17.67 (2.12) |
| Control | 18.22 (1.82) | 18.09 (1.83) | 18.39 (2.02) |
| General quality of life | | | |
| CBT | 4.38 (0.73) | 4.43 (0.74) | 4.49 (0.66) |
| Mindfulness | 4.44 (0.79) | 4.58 (0.69) | 4.42 (0.81) |
| Control | 4.61 (0.78) | 4.41 (0.62) | 4.50 (0.71) |
| General health | | | |
| CBT | 3.66 (1.12) | 3.98 (1.16) | 3.74 (1.13) |
| Mindfulness | 3.75 (1.14) | 3.91 (1.02) | 3.82 (1.08) |
| Control | 3.83 (1.25) | 4.12 (0.86) | 3.94 (0.87) |
| HADS | | | |
| Anxiety | | | |
| CBT | 6.70 (3.72) | 5.51 (3.24) | 5.87 (3.59) |
| Mindfulness | 5.87 (3.83) | 5.17 (3.92) | 5.07 (3.59) |
| Control | 5.35 (3.23) | 4.88 (3.24) | 5.39 (2.75) |
| Depression | | | |
| CBT | 3.89 (3.41) | 3.68 (3.47) | 3.15 (3.05) |
| Mindfulness | 3.05 (2.75) | 2.98 (2.74) | 3.59 (3.12) |
| Control | 2.65 (1.81) | 3.00 (1.66) | 2.96 (1.79) |
| Overall mindfulness: FFMQ-SF | | | |
| CBT | 87.47 (11.68) | 89.55 (13.71) | 89.41 (13.58) |
| Mindfulness | 89.04 (12.19) | 93.57 (13.29) | 91.58 (14.78) |
| Control | 87.99 (10.62) | 89.15 (12.03) | 89.58 (11.92) |
| Activity sum | | | |
| Nonpenetrative | | | |
| CBT | 1.89 (2.16) | 2.24 (2.06) | 1.59 (1.95) |
| Mindfulness | 1.90 (2.29) | 1.85 (1.93) | 1.51 (1.95) |
| Control | 3.94 (2.84) | 3.88 (2.91) | 3.33 (2.61) |
| Penetrative | | | |
| CBT | 0.21 (0.41) | 0.22 (0.42) | 0.17 (0.37) |
| Mindfulness | 0.39 (0.61) | 0.30 (0.54) | 0.26 (0.56) |
| Control | 0.83 (1.15) | 0.71 (0.99) | 0.56 (0.70) |
| IIEF | | | |
| Survivor–erectile function | | | |
| CBT | 4.12 (4.28) | 5.17 (5.10) | 4.55 (4.68) |
| Mindfulness | 6.89 (8.05) | 6.52 (8.66) | 6.18 (8.74) |
| Control | 4.67 (2.45) | 7.56 (9.96) | 5.38 (7.03) |
| Survivor–orgasmic function | | | |
| CBT | 2.85 (2.65) | 3.52 (3.49) | 2.80 (2.76) |
| Mindfulness | 3.93 (3.58) | 2.88 (2.61) | 3.71 (2.97) |
| Control | 5.33 (3.12) | 5.22 (3.49) | 3.78 (3.38) |
| Survivor–sexual desire | | | |
| CBT | 4.04 (2.31) | 3.93 (2.45) | 4.55 (2.04) |
| Mindfulness | 3.72 (2.48) | 3.35 (2.13) | 3.23 (2.14) |
| Control | 3.89 (2.37) | 4.22 (2.28) | 4.11 (2.62) |
| Survivor–intercourse satisfaction | | | |
| CBT | 2.52 (3.54) | 3.56 (4.19) | 2.52 (3.87) |
| Mindfulness | 3.55 (4.68) | 2.46 (4.12) | 2.91 (4.33) |
| Control | 4.67 (3.57) | 4.00 (5.22) | 2.89 (3.79) |
| Partner–female sexual function: FSFI | | | |
| CBT | 22.01 (6.53) | 22.18 (7.19) | 19.18 (8.57) |
| Mindfulness | 25.69 (8.28) | 24.88 (6.22) | 24.49 (7.24) |
| Control | 23.77 (6.29) | 24.17 (7.27) | 25.63 (8.00) |

Abbreviations: CBT, cognitive behavioral therapy; DAS-7, adapted Dyadic Adjustment Scale; FFMQ-SF, Five Facet Mindfulness Questionnaire–Short Form; FSDS-R, Female Sexual Distress Scale–Revised; FSFI, Female Sexual Function Index; HADS, Hospital Anxiety and Distress Scale; IIEF, International Index of Erectile Function; WHOQOL-BREF, World Health Organization Quality of Life–BREF. ^aData are presented as mean (SD).

Table 6. Time and group comparisons and interaction effects from random coefficient analysis models for primary outcome measures at baseline, 6 weeks, and 6 months.

| Variable | <i>b</i> | SE | <i>P</i> value | <i>d</i> | 95% CI for <i>b</i> |
|---|----------|-------|----------------|----------|---------------------|
| Sexual distress: FSDS-R | | | | | |
| Constant | 20.201 | 0.921 | <.001 | | 18.37, 22.03 |
| Time | | | | | |
| t2-t1 | -2.589 | 0.686 | <.001 | -0.25 | -3.94, -1.24 |
| t3-t1 | -1.647 | 0.700 | .019 | -0.16 | -3.03, -0.27 |
| Group | | | | | |
| CBT | 0.917 | 2.654 | .731 | 0.09 | -4.39, 6.22 |
| Mindfulness | -1.218 | 2.630 | .645 | -0.12 | -6.47, 4.04 |
| Time × group | | | | | |
| t2-t1 × CBT | -5.212 | 2.096 | .014 | -0.51 | -9.34, -1.08 |
| t2-t1 × mindfulness | -5.224 | 2.094 | .013 | -0.51 | -9.35, -1.10 |
| t3-t1 × CBT | -4.458 | 2.092 | .034 | -0.44 | -8.58, -0.34 |
| t3-t1 × mindfulness | -5.114 | 2.065 | .014 | -0.50 | -9.18, -1.05 |
| Overall satisfaction: IIEF | | | | | |
| Constant | 2.661 | 0.302 | <.001 | | 2.06, 3.26 |
| Time | | | | | |
| t2-t1 | 1.220 | 0.284 | <.001 | 0.53 | 0.66, 1.78 |
| t3-t1 | 0.683 | 0.303 | .026 | 0.30 | 0.08, 1.28 |
| Group | | | | | |
| CBT | -0.664 | 0.801 | .411 | -0.29 | -2.27, 0.94 |
| Mindfulness | -0.539 | 0.792 | .499 | -0.23 | -2.12, 1.05 |
| Time × group | | | | | |
| t2-t1 × CBT | 2.005 | 0.833 | .018 | 0.87 | 0.35, 3.66 |
| t2-t1 × mindfulness | 1.693 | 0.831 | .044 | 0.73 | 0.05, 3.34 |
| t3-t1 × CBT | 0.998 | 0.859 | .248 | 0.43 | -0.71, 2.70 |
| t3-t1 × mindfulness | 0.626 | 0.843 | .459 | 0.27 | -1.05, 2.30 |
| Relationship satisfaction: DAS-7 | | | | | |
| Constant | 24.432 | 0.484 | <.001 | | 23.47, 25.39 |
| Time | | | | | |
| t2-t1 | -0.038 | 0.305 | .900 | 0.01 | -0.64, 0.56 |
| t3-t1 | -0.535 | 0.311 | .087 | -0.12 | -1.15, 0.08 |
| Group | | | | | |
| CBT | -2.065 | 1.416 | .150 | -0.45 | -4.90, 0.76 |
| Mindfulness | -0.361 | 1.402 | .797 | -0.08 | -3.16, 2.44 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.914 | 0.941 | .332 | 0.20 | -0.94, 2.77 |
| t2-t1 × mindfulness | 0.642 | 0.942 | .496 | 0.14 | -1.21, 2.50 |
| t3-t1 × CBT | -1.234 | 0.937 | .189 | -0.27 | -3.08, 0.61 |
| t3-t1 × mindfulness | -1.217 | 0.929 | .191 | -0.27 | -3.05, 0.61 |

Abbreviations: CBT, cognitive behavioral therapy; DAS-7, adapted Dyadic Adjustment Scale; FSDS-R, Female Sexual Distress Scale-Revised; IIEF, International Index of Erectile Function; t1, before treatment; t2, 6 weeks posttreatment (or after t1 if control); t3, 6 months posttreatment (or after t1 if control).

Exploratory outcomes: sexual behavior and sexual function

Table 5 shows mean values and standard deviations for the exploratory outcomes by treatment arm and time. Table 8 displays the results of the multilevel analysis for exploratory outcomes. The sum of penetrative and nonpenetrative activities decreased over time in the sample. This was a marginally significant effect for nonpenetrative activities from t1 to t3 and a significant effect for penetrative activities from t1 to t2. There was no significant interaction between group and time for nonpenetrative and penetrative activities, although there was a marginal increase in penetrative sexual activities from t1 to t3 in the CBT group relative to the control group ($b = 0.211$, $P = .062$, $d = 0.32$). There were no significant changes in any other IIEF domain for survivors (erectile function, orgasmic function, sexual desire, and intercourse satisfaction) and no changes in FSFI total scores for partners.

Effect of moderators (treatment expectations, homework completion, and personality) on primary outcomes

Neither treatment expectations nor homework completion moderated changes in any of the primary outcomes.

Personality moderated 2 primary treatment outcomes—specifically, survivors' sexual satisfaction and couple's relationship satisfaction. However, the moderation effects for personality characteristics failed to remain significant after applying the Benjamini-Hochberg correction to control for the false discovery rate.

Exploration of clinical significance

A total of 19 exit interviews were conducted: 13 from the mindfulness group and 6 from the CBT group. No control participants chose to participate. In the CBT group, 5 of

Table 7. Time and group comparisons and interaction effects from random coefficient analysis models for secondary outcome measures at baseline, 6 weeks, and 6 months.

| Variable | <i>b</i> | SE | <i>P</i> value | <i>d</i> | 95% CI for <i>b</i> |
|---|----------|-------|----------------|----------|---------------------|
| Physical quality of life: WHOQOL-BREF | | | | | |
| Constant | 16.596 | 0.260 | <.001 | | 16.08, 17.11 |
| Time | | | | | |
| t2-t1 | 0.025 | 0.158 | .873 | 0.01 | −0.29, 0.34 |
| t3-t1 | −0.065 | 0.162 | .691 | −0.03 | −0.39, 0.26 |
| Group | | | | | |
| CBT | −0.590 | 0.780 | .452 | −0.23 | −2.15, 0.97 |
| Mindfulness | −0.583 | 0.773 | .454 | −0.23 | −2.13, 0.96 |
| Time × group | | | | | |
| t2-t1 × CBT | −0.173 | 0.490 | .725 | −0.07 | −1.14, 0.79 |
| t2-t1 × mindfulness | 0.056 | 0.492 | .910 | 0.02 | −0.91, 1.02 |
| t3-t1 × CBT | −0.187 | 0.489 | .703 | −0.07 | −1.15, 0.78 |
| t3-t1 × mindfulness | −0.119 | 0.487 | .806 | −0.05 | −1.08, 0.84 |
| Psychological quality of life: WHOQOL-BREF | | | | | |
| Constant | 15.568 | 0.240 | <.001 | | 15.09, 16.04 |
| Time | | | | | |
| t2-t1 | 0.396 | 0.137 | .004 | 0.17 | 0.13, 0.67 |
| t3-t1 | 0.286 | 0.140 | .043 | 0.12 | 0.01, 0.56 |
| Group | | | | | |
| CBT | −0.512 | 0.728 | .485 | −0.21 | −1.97, 0.94 |
| Mindfulness | −0.519 | 0.721 | .474 | −0.22 | −1.96, 0.92 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.561 | 0.423 | .186 | 0.23 | −0.27, 1.39 |
| t2-t1 × mindfulness | 0.533 | 0.423 | .210 | 0.22 | −0.30, 1.37 |
| t3-t1 × CBT | 0.270 | 0.422 | .522 | 0.11 | −0.56, 1.10 |
| t3-t1 × mindfulness | 0.475 | 0.419 | .258 | 0.20 | −0.35, 1.30 |
| Social and relational quality of life: WHOQOL-BREF | | | | | |
| Constant | 14.268 | 0.273 | <.001 | | 13.73, 14.81 |
| Time | | | | | |
| t2-t1 | 0.831 | 0.207 | <.001 | 0.33 | 0.42, 1.24 |
| t3-t1 | 0.339 | 0.212 | .112 | 0.13 | −0.08, 0.76 |
| Group | | | | | |
| CBT | −0.748 | 0.791 | .347 | −0.29 | −2.33, 0.83 |
| Mindfulness | −0.544 | 0.783 | .490 | −0.21 | −2.11, 1.02 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.958 | 0.641 | .136 | 0.38 | −0.30, 2.22 |
| t2-t1 × mindfulness | 0.757 | 0.641 | .239 | 0.30 | −0.51, 2.02 |
| t3-t1 × CBT | 0.698 | 0.640 | .276 | 0.28 | −0.56, 1.96 |
| t3-t1 × mindfulness | 0.779 | 0.635 | .221 | 0.31 | −0.47, 2.03 |
| Environmental quality of life: WHOQOL-BREF | | | | | |
| Constant | 17.631 | 0.223 | <.001 | | 17.19, 18.07 |
| Time | | | | | |
| t2-t1 | 0.124 | 0.114 | .281 | 0.06 | −0.10, 0.35 |
| t3-t1 | 0.102 | 0.118 | .386 | 0.05 | −0.13, 0.33 |
| Group | | | | | |
| CBT | −0.635 | 0.681 | .355 | −0.30 | −2.00, 0.73 |
| Mindfulness | −0.513 | 0.674 | .449 | −0.25 | −1.86, 0.83 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.289 | 0.352 | .413 | 0.14 | −0.41, 0.98 |
| t2-t1 × mindfulness | 0.621 | 0.352 | .079 | 0.30 | −0.07, 1.32 |
| t3-t1 × CBT | −0.257 | 0.351 | .465 | −0.12 | −0.95, 0.44 |
| t3-t1 × mindfulness | 0.089 | 0.349 | .799 | 0.04 | −0.60, 0.78 |
| General quality of life: WHOQOL-BREF | | | | | |
| Constant | 4.438 | 0.073 | <.001 | | 4.29, 4.58 |
| Time | | | | | |
| t2-t1 | 0.049 | 0.060 | .414 | 0.06 | −0.07, 0.17 |
| t3-t1 | 0.008 | 0.061 | .894 | 0.01 | −0.11, 0.13 |
| Group | | | | | |
| CBT | −0.114 | 0.206 | .581 | −0.15 | −0.53, 0.30 |
| Mindfulness | 0.002 | 0.205 | .993 | 0.00 | −0.41, 0.41 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.237 | 0.184 | .200 | 0.31 | −0.13, 0.60 |
| t2-t1 × mindfulness | 0.391 | 0.184 | .035 | 0.52 | 0.03, 0.75 |
| t3-t1 × CBT | 0.140 | 0.184 | .446 | 0.18 | −0.22, 0.50 |
| t3-t1 × mindfulness | 0.139 | 0.182 | .447 | 0.18 | −0.22, 0.50 |

(Continued)

Table 7. Continued.

| Variable | <i>b</i> | SE | <i>P</i> value | <i>d</i> | 95% CI for <i>b</i> |
|------------------------------------|----------|-------|----------------|----------|---------------------|
| General health: WHOQOL-BREF | | | | | |
| Constant | 3.728 | 0.103 | <.001 | | 3.52, 3.93 |
| Time | | | | | |
| t2-t1 | 0.231 | 0.064 | <.001 | 0.20 | 0.10, 0.36 |
| t3-t1 | 0.087 | 0.066 | .189 | 0.08 | −0.04, 0.22 |
| Group | | | | | |
| CBT | −0.176 | 0.309 | .572 | −0.15 | −0.79, 0.44 |
| Mindfulness | −0.087 | 0.306 | .777 | −0.08 | −0.70, 0.53 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.070 | 0.200 | .726 | 0.06 | −0.32, 0.46 |
| t2-t1 × mindfulness | −0.034 | 0.200 | .867 | −0.03 | −0.43, 0.36 |
| t3-t1 × CBT | −0.093 | 0.199 | .641 | −0.08 | −0.49, 0.30 |
| t3-t1 × mindfulness | 0.030 | 0.198 | .879 | 0.03 | −0.36, 0.42 |
| Anxiety: HADS | | | | | |
| Constant | 6.145 | 0.346 | <.001 | | 5.46, 6.83 |
| Time | | | | | |
| t2-t1 | −0.717 | 0.257 | .006 | −0.19 | −1.22, −0.21 |
| t3-t1 | −0.475 | 0.263 | .072 | −0.13 | −0.99, 0.04 |
| Group | | | | | |
| CBT | 0.951 | 1.009 | .349 | 0.26 | −1.06, 2.96 |
| Mindfulness | 0.234 | 0.999 | .815 | 0.06 | −1.76, 2.23 |
| Time × group | | | | | |
| t2-t1 × CBT | −0.740 | 0.798 | .355 | −0.20 | −2.31, 0.83 |
| t2-t1 × mindfulness | −0.269 | 0.799 | .736 | −0.07 | −1.84, 1.30 |
| t3-t1 × CBT | −0.459 | 0.797 | .565 | −0.12 | −2.03, 1.11 |
| t3-t1 × mindfulness | −0.717 | 0.788 | .364 | −0.19 | −2.27, 0.84 |
| Depression: HADS | | | | | |
| Constant | 3.338 | 0.313 | <.001 | | 2.71, 3.96 |
| Time | | | | | |
| t2-t1 | 0.002 | 0.188 | .990 | 0.00 | −0.37, 0.37 |
| t3-t1 | 0.178 | 0.192 | .355 | 0.06 | −0.20, 0.56 |
| Group | | | | | |
| CBT | 0.907 | 0.936 | .337 | 0.31 | −0.96, 2.78 |
| Mindfulness | 0.221 | 0.927 | .812 | 0.07 | −1.63, 2.07 |
| Time × group | | | | | |
| t2-t1 × CBT | −0.564 | 0.581 | .333 | −0.19 | −1.71, 0.58 |
| t2-t1 × mindfulness | −0.610 | 0.582 | .295 | −0.21 | −1.76, 0.54 |
| t3-t1 × CBT | −0.494 | 0.580 | .395 | −0.17 | −1.64, 0.65 |
| t3-t1 × mindfulness | 0.147 | 0.574 | .798 | 0.05 | −0.98, 1.28 |
| Mindfulness: FFMQ-SF | | | | | |
| Constant | 88.253 | 1.203 | <.001 | | 85.86, 90.64 |
| Time | | | | | |
| t2-t1 | 2.536 | 0.881 | .004 | 0.22 | 0.80, 4.27 |
| t3-t1 | 1.509 | 0.900 | .095 | 0.13 | −0.26, 3.28 |
| Group | | | | | |
| CBT | −0.423 | 3.510 | .904 | −0.04 | −7.44, 6.59 |
| Mindfulness | 2.075 | 3.477 | .553 | 0.18 | −4.87, 9.02 |
| Time × group | | | | | |
| t2-t1 × CBT | 1.337 | 2.739 | .626 | 0.11 | −4.06, 6.73 |
| t2-t1 × mindfulness | 2.948 | 2.740 | .283 | 0.25 | −2.45, 8.35 |
| t3-t1 × CBT | −1.024 | 2.732 | .708 | −0.09 | −6.41, 4.36 |
| t3-t1 × mindfulness | 0.747 | 2.703 | .782 | 0.06 | −4.58, 6.07 |

Abbreviations: CBT, cognitive behavioral therapy; FFMQ-SF, Five Facet Mindfulness Questionnaire–Short Form; HADS, Hospital Anxiety and Distress Scale; t1, before treatment; t2, 6 weeks posttreatment (or after t1 if control); t3, 6 months posttreatment (or after t1 if control); WHOQOL-BREF, World Health Organization Quality of Life–BREF.

the 6 exit interviews included survivor and partner, with the sixth interview conducted with a solo PCa survivor. Both members of the couple were present for 12 of the mindfulness interviews, and 1 PCa survivor attended alone.

Results from the thematic analysis revealed that participants in the mindfulness arm had a greater belief in treatment working vs the CBT arm. Of the 13 mindfulness

interviews, 8 (61.5%) mentioned having positive personal and intimate impacts that carried through even after the study was finished.

“I think there was a positive impact, in that I believe both of us are able to look at intimacy—sexual intimacy—maybe differently than we did before. . . . When we have that kind of interaction to the sexual habits or patterns that we

Table 8. Time and group comparisons and interaction effects from random coefficient analysis models for exploratory outcome measures at baseline, 6 weeks, and 6 months.

| Variable | <i>b</i> | SE | <i>P</i> value | <i>d</i> | 95% CI for <i>b</i> |
|---|----------|-------|----------------|----------|---------------------|
| Nonpenetrative activity sum | | | | | |
| Constant | 2.185 | 0.260 | <.001 | | 1.67, 2.70 |
| Time | | | | | |
| t2-t1 | 0.203 | 0.153 | .186 | 0.08 | −0.10, 0.50 |
| t3-t1 | −0.298 | 0.155 | .055 | −0.12 | −0.60, 0.01 |
| Group | | | | | |
| CBT | −1.751 | 0.751 | .023 | −0.73 | −3.25, −0.25 |
| Mindfulness | −1.717 | 0.743 | .024 | −0.71 | −3.20, −0.23 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.609 | 0.474 | .200 | 0.25 | −0.32, 1.54 |
| t2-t1 × mindfulness | 0.417 | 0.474 | .380 | 0.17 | −0.52, 1.35 |
| t3-t1 × CBT | 0.246 | 0.471 | .602 | 0.10 | −0.68, 1.17 |
| t3-t1 × mindfulness | 0.462 | 0.468 | .324 | 0.19 | −0.46, 1.38 |
| Penetrative activity sum | | | | | |
| Constant | 0.376 | 0.068 | <.001 | | 0.24, 0.51 |
| Time | | | | | |
| t2-t1 | −0.062 | 0.037 | 0.09 | −0.09 | −0.14, 0.01 |
| t3-t1 | −0.125 | 0.037 | <.001 | −0.19 | −0.20, −0.05 |
| Group | | | | | |
| CBT | −0.491 | 0.198 | 0.016 | −0.74 | −0.89, −0.10 |
| Mindfulness | −0.363 | 0.196 | 0.069 | −0.54 | −0.75, 0.03 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.167 | 0.113 | .143 | 0.25 | −0.06, 0.39 |
| t2-t1 × mindfulness | 0.073 | 0.113 | .521 | 0.11 | −0.15, 0.30 |
| t3-t1 × CBT | 0.211 | 0.113 | .062 | 0.32 | −0.01, 0.43 |
| t3-t1 × mindfulness | 0.147 | 0.112 | .190 | 0.22 | −0.07, 0.37 |
| Survivor-erectile function: IIEF | | | | | |
| Constant | 5.613 | 0.893 | <.001 | | 3.84, 7.39 |
| Time | | | | | |
| t2-t1 | 0.799 | 0.755 | .292 | 0.13 | −0.70, 2.30 |
| t3-t1 | 0.354 | 0.787 | .654 | 0.06 | −1.21, 1.92 |
| Group | | | | | |
| CBT | −1.328 | 2.457 | .591 | −0.21 | −6.25, 3.59 |
| Mindfulness | 1.465 | 2.430 | .549 | 0.24 | −3.40, 6.33 |
| Time × group | | | | | |
| t2-t1 × CBT | −2.242 | 2.254 | .322 | −0.36 | −6.72, 2.23 |
| t2-t1 × mindfulness | −2.695 | 2.250 | .234 | −0.44 | −7.16, 1.77 |
| t3-t1 × CBT | −0.186 | 2.299 | .936 | −0.03 | −4.75, 4.38 |
| t3-t1 × mindfulness | −0.590 | 2.273 | .796 | −0.10 | −5.10, 3.92 |
| Survivor-orgasmic function: IIEF | | | | | |
| Constant | 3.765 | 0.395 | <.001 | | 2.98, 4.55 |
| Time | | | | | |
| t2-t1 | −0.188 | 0.435 | .667 | −0.06 | −1.05, 0.67 |
| t3-t1 | −0.283 | 0.457 | .537 | −0.09 | −1.19, 0.62 |
| Group | | | | | |
| CBT | −1.677 | 0.962 | .087 | −0.52 | −3.61, 0.25 |
| Mindfulness | −1.041 | 0.953 | .280 | −0.33 | −2.95, 0.87 |
| Time × group | | | | | |
| t2-t1 × CBT | 0.559 | 1.292 | .666 | 0.17 | −2.01, 3.12 |
| t2-t1 × mindfulness | −0.743 | 1.287 | .565 | −0.23 | −3.30, 1.81 |
| t3-t1 × CBT | 1.326 | 1.318 | .317 | 0.41 | −1.29, 3.94 |
| t3-t1 × mindfulness | 1.699 | 1.305 | .196 | 0.53 | −0.89, 4.29 |
| Survivor-sexual desire: IIEF | | | | | |
| Constant | 3.842 | 0.288 | <.001 | | 3.27, 4.14 |
| Time | | | | | |
| t2-t1 | 0.094 | 0.189 | .621 | 0.04 | −0.28, 0.47 |
| t3-t1 | 0.149 | 0.202 | .463 | 0.06 | −0.25, 0.55 |
| Group | | | | | |
| CBT | 0.030 | 0.851 | .972 | 0.01 | −1.67, 1.73 |
| Mindfulness | −0.382 | 0.842 | .651 | −0.16 | −2.07, 1.30 |
| Time × group | | | | | |
| t2-t1 × CBT | −0.297 | 0.571 | .603 | −0.13 | −1.43, 0.83 |
| t2-t1 × mindfulness | −0.263 | 0.575 | .648 | −0.11 | −1.40, 0.88 |
| t3-t1 × CBT | 0.224 | 0.589 | .704 | 0.10 | −0.94, 1.39 |
| t3-t1 × mindfulness | −0.368 | 0.583 | .529 | −0.16 | −1.52, 0.79 |

(Continued)

Table 8. Continued.

| Variable | <i>b</i> | SE | <i>P</i> value | <i>d</i> | 95% CI for <i>b</i> |
|--|----------|-------|----------------|----------|---------------------|
| Survivor–intercourse satisfaction: IIEF | | | | | |
| Constant | 3.304 | 0.519 | <.001 | | 2.28, 4.33 |
| Time | | | | | |
| t2–t1 | −0.001 | 0.472 | .999 | 0.06 | −0.94, 0.94 |
| t3–t1 | −0.071 | 0.496 | .649 | −0.02 | −1.21, 0.76 |
| Group | | | | | |
| CBT | −1.015 | 1.430 | .481 | −0.25 | −3.88, 1.85 |
| Mindfulness | −0.418 | 1.416 | .769 | −0.10 | −3.25, 2.42 |
| Time × group | | | | | |
| t2–t1 × CBT | 1.454 | 1.417 | .307 | 0.35 | −1.36, 4.26 |
| t2–t1 × mindfulness | 0.122 | 1.414 | .931 | 0.03 | −2.68, 2.93 |
| t3–t1 × CBT | 1.856 | 1.442 | .201 | 0.45 | −1.00, 4.72 |
| t3–t1 × mindfulness | 1.847 | 1.433 | .200 | 0.45 | −1.00, 4.69 |
| Partner–female sexual function: FSFI | | | | | |
| Constant | 22.777 | 1.092 | <.001 | | 20.60, 24.95 |
| Time | | | | | |
| t2–t1 | 0.387 | 0.867 | .657 | 0.05 | −1.34, 2.11 |
| t3–t1 | −0.994 | 0.884 | .264 | −0.13 | −2.76, 0.77 |
| Group | | | | | |
| CBT | −4.246 | 3.148 | .184 | −0.57 | −10.58, 2.09 |
| Mindfulness | 0.118 | 3.160 | .970 | 0.02 | −6.24, 6.48 |
| Time × group | | | | | |
| t2–t1 × CBT | 0.591 | 2.626 | .823 | 0.08 | −4.65, 5.83 |
| t2–t1 × mindfulness | −0.529 | 2.612 | .840 | −0.07 | −5.74, 4.68 |
| t3–t1 × CBT | −3.311 | 2.634 | .213 | −0.45 | −8.57, 1.94 |
| t3–t1 × mindfulness | −3.324 | 2.639 | .212 | −0.45 | −8.59, 1.94 |

Abbreviations: CBT, cognitive behavioral therapy; FSFI, Female Sexual Function Index; IIEF, International Index of Erectile Function; t1, before treatment; t2, 6 weeks posttreatment (or after t1 if control); t3, 6 months posttreatment (or after t1 if control).

have established over the years . . . I think the group was very beneficial in helping to reframe what was, and what potentially can be”. (partner, mindfulness)

However, 2 couples and the single survivor mentioned that there was no positive effect after the trials were done. Patients gave different reasons, but lack of commitment was a common theme: “There was no impact, I am always rushing to meetings . . . and didn’t have any commitment because I wanted to have sex and that wasn’t happening” (survivor, mindfulness).

Only a third (33%) of interviewees in the CBT group ($n = 5$ couples and 1 individual) mentioned that the treatment was meaningful after the trial ended. They described how the CBT group gave them the tools to navigate negative feelings that arose during intimacy, especially in relation to sexual dysfunction from PCa treatments: “Worrying caused me trouble and I realized that if I am not worrying, [I] can perform better, sexually” (survivor, CBT).

The other two-thirds of participants stated that the intervention did not have any personal impact on them after the trial had finished:

We were scheduling [sex] before, so that has not changed. What changed is during those 4 weeks we actually did our homework. I would have to say that the impact on us was excellent during the course, but we definitely have fallen off. (survivor, CBT)

Discussion

The aim of this study was to examine the effectiveness of CBT and mindfulness for improving couples’ sexual health and intimacy after PCa. We hypothesized that CBT and mindfulness would improve participants’ primary outcomes

of sexual distress, survivors’ overall sexual satisfaction, and couples’ relationship satisfaction, as well as the secondary outcomes of participants’ anxiety and depression, quality of life, and mindfulness; we also hypothesized that treatment would improve the exploratory outcomes of sexual behaviors and sexual function and that these improvements would be sustained long term. CBT and mindfulness led to significant improvements in sexual distress at t2 and t3 after treatment when compared with controls, indicating long-term and long-lasting benefits of the interventions. Both therapies significantly improved survivors’ sexual satisfaction at t2, although this effect was short-lived and not sustained at t3. Both these effects had moderate to large effect sizes ($d = 0.43$ – 0.87). Partners had a decrease in relationship satisfaction as compared with their corresponding survivors at t3 after both treatments. Other significant changes were that physical quality of life and psychological quality of life improved for survivors and general quality of life improved for couples after treatment. General health and mindfulness improved in all participants with time, regardless of treatment, and anxiety decreased in all participants with time. General health improved only in the mindfulness group at t2.

Impact of treatment on sexual distress and sexual satisfaction

Our interventions reduced sexual distress in our sample: CBT and mindfulness were effective at doing so. This is particularly impactful as sexual dysfunction is repeatedly among the most distressing concerns for both survivor and partner after PCa treatment.^{9–14} A previous study investigating mindfulness in women with sexual dysfunction based on a similar intervention revealed significant decreases in sexual distress long term,³⁰ which was attributed to improved

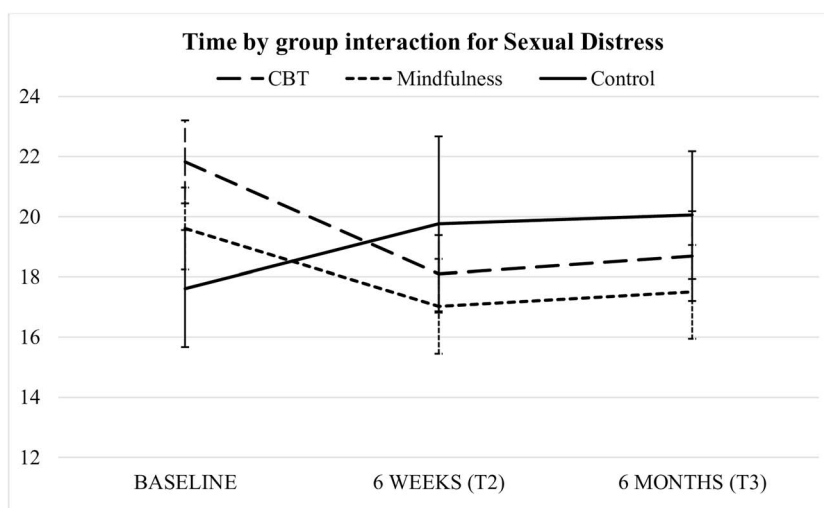


Figure 2. Effects of treatment (CBT or mindfulness) and control on sex-related distress over time. CBT, cognitive behavioral therapy.

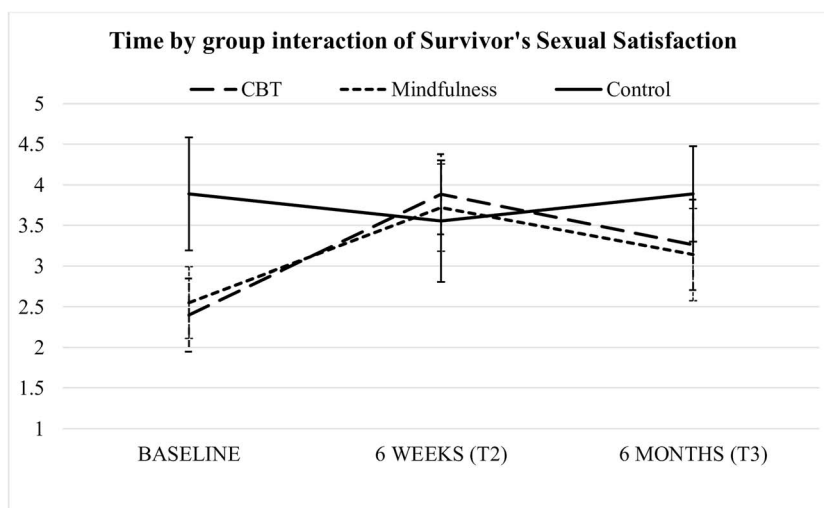


Figure 3. Effects of treatment (CBT or mindfulness) and control on sexual satisfaction over time. CBT, cognitive behavioral therapy.

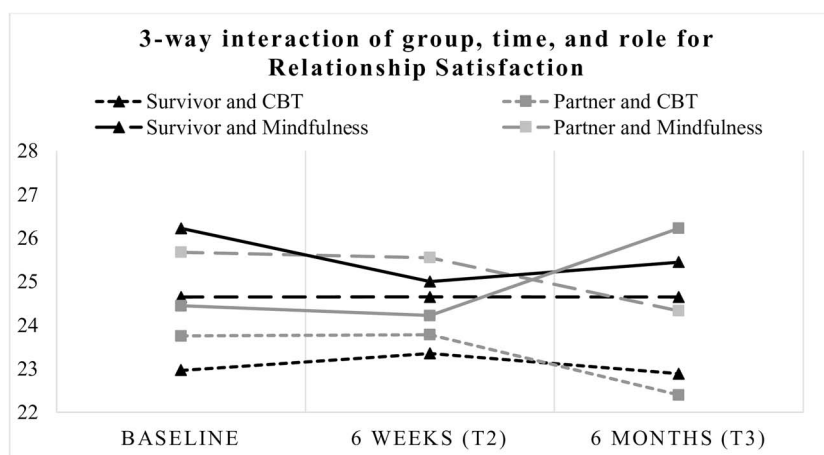


Figure 4. Effects of treatment (CBT or mindfulness), control, and role (survivor or partner) on relationship satisfaction over time. CBT, cognitive behavioral therapy.

mindfulness meditation skills that encourage self-acceptance and nonjudgment in addition to reducing negative thoughts, something that mindfulness and CBT both target. Similarly,

a randomized clinical trial comparing CBT and mindfulness interventions for women with sexual dysfunction, with similar methods to those employed in the current study, noted that

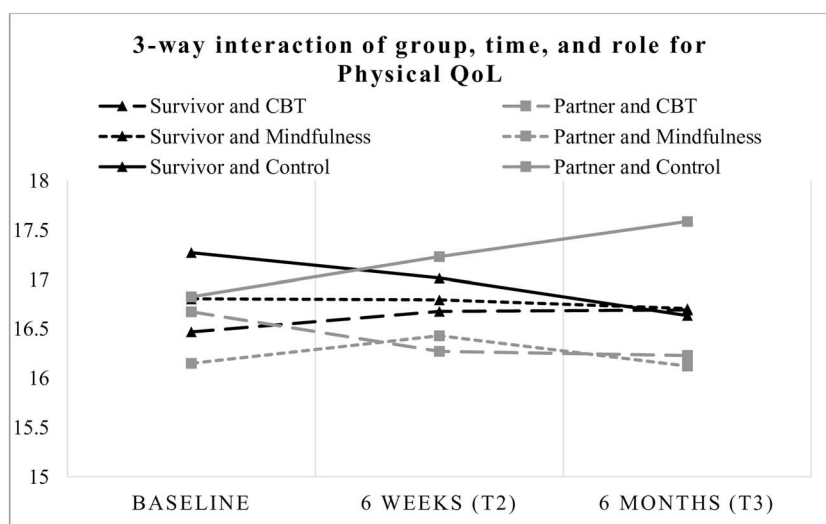


Figure 5. Effects of treatment (CBT or mindfulness), control, and role (survivor or partner) on physical QoL over time. CBT, cognitive behavioral therapy; QoL, quality of life.

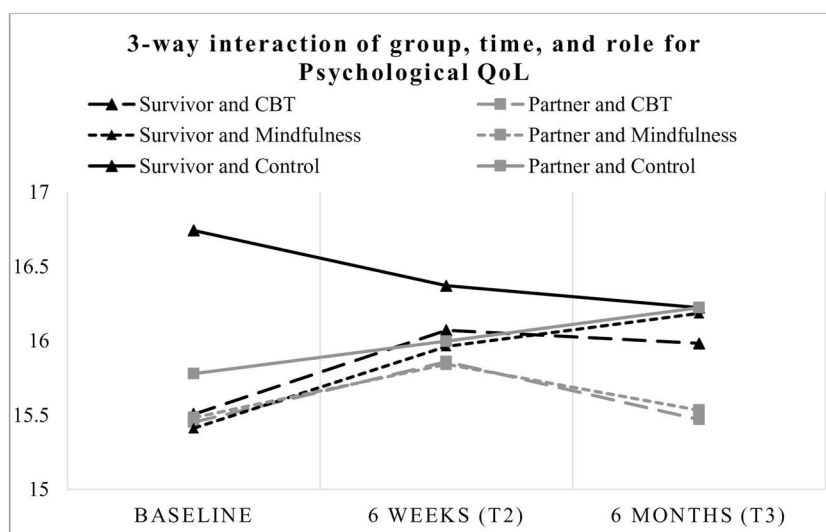


Figure 6. Effects of treatment (CBT or mindfulness), control, and role (survivor or partner) on psychological quality of life over time. CBT, cognitive behavioral therapy.

interventions led to improvements in sexual distress, with no differences between therapy types.³¹ While we did not explore self-acceptance in this study, it is possible that worry can be reduced and patient outcomes improved when couples are supported in accepting their current levels of sexual function postcancer, as opposed to the typical medical model approach of, often fruitless, attempts to improve physical sexual function.

Separate from the CBT and mindfulness skills, the sexual education component of the intervention may have contributed to reductions in sexual distress, given that sexual education and relationship counseling for PCa survivors and their partners support couples in developing more flexible sexual beliefs. No other psychological intervention in PCa survivors has examined sexual distress, although a few have examined sexual bother, which is highly correlated to sexual distress; these studies found little to no improvements in sexual bother.^{15–17} As these few studies largely focused on peer support and sexual education, it is likely that the therapeutic components of the present randomized clinical

trial consolidate sexual education while adding nonjudgment and self-acceptance skills and these together lead to long-term benefits. The current study supports incorporation of CBT and mindfulness into post-PCa treatment sexual education as standard care to help maintain long-lasting benefits to the patients.

Sexual distress is an important concept to consider in studies of sexual health after cancer treatment, as it allows for a comprehensive biopsychosocial conceptualization of one's sexual experience and it is distinct from sexual function.^{58,59} As well, PCa survivors may have high or low sexual distress unrelated to their erectile function recovery,⁵⁸ which can vary widely in this population based on treatment type, time since treatment, and psychological distress, among other factors.^{58,59} Sexual distress has therefore been strongly recommended as a more clinically relevant target for interventions after PCa treatment.⁵⁸ The long-lasting improvements to sexual distress observed within our study population, despite no changes in couple's sexual function, highlight the effectiveness of our intervention at targeting the psychosocial elements of

participants' sexual health needs. Future studies of sexual health interventions should consider the use of the Female Sexual Distress Scale-Revised as a primary outcome, as a focus on sexual function improvements alone may miss important psychosocial improvements that are not otherwise measured.

PCa survivors' overall sexual satisfaction increased at t2 for the CBT and mindfulness groups as compared with the control group, with large effect sizes ($d = 0.87$ and 0.73 , respectively), but this was not maintained long term (at t3). Two other interventions to date have examined CBT and sexual education in PCa survivors.^{26,60} Canada et al randomized PCa survivors to a 4-session sexual education intervention with or without the partner's participation.²⁶ CBT techniques were part of the session, but sexual education was at the forefront. There were improvements in all IIEF domains for survivors in both groups; however, at 6 months, only overall sexual satisfaction remained significant.²⁶ Siddons et al evaluated an 8-week CBT and sexual education intervention for PCa survivors.⁶⁰ Satisfaction with orgasm significantly improved immediately after the intervention, yet long-term outcomes of sexual function were not assessed.⁶⁰ The reasons why improvements to sexual satisfaction are not sustained beyond the end of group interventions are not clear and form an area worthy of future investigation.

The lack of long-term changes to sexual satisfaction after our intervention could be explained through several reasons: even though our measure of overall sexual satisfaction is non-specific to physical sexual function, the domain's questions are still embedded within the IIEF, where other questions inquire about penetrative intercourse or stimulation.^{39,40} In our intervention, we encouraged participants to focus on sexual pleasure and intimacy instead of on penetration or the achievement/maintenance of erection. It could be that survivors related to this distinction directly after the intervention, but at 6 months, their beliefs migrated back to pretreatment assumptions (ie, that "good sex" is synonymous with reliable erections). As well, changes in erectile function recovery, sexual aid use, and changes in PCa status may all affect sexual satisfaction.⁶⁻¹⁰ To show long-lasting changes on the overall sexual satisfaction domain, an intervention may need incorporate sexual aids to meet the sexual function needs that are captured by the whole IIEF, like that of Canada et al.²⁶

However, sexual satisfaction is affected by a variety of factors beyond sexual function, and relational and psychological factors may outweigh the impact of function on satisfaction.⁶¹ Since our intervention focused on improving the psychological and relational elements of sexual function, the IIEF may not be an accurate measure of these targets. Santos-Iglesias et al recommend using the Interpersonal Exchange Model of Sexual Satisfaction⁶² to assess meaningful improvements for PCa survivors.⁶¹ This model defines sexual satisfaction as a sum of cost and reward in a sexual relationship and could more accurately capture the changes of sexual satisfaction from a biopsychosocial framework after therapy in PCa survivors.⁶² As well, partner answers and gender-diverse respondents could be included since the model is not gender specific. In reflection, we recommend that this measure be validated and used for future PCa couple interventions.

A third consideration is that the process of recovering sexual intimacy for couples after cancer, especially in regard to sexual function, waxes and wanes over time.⁶¹ It may simply be that our intervention, while beneficial overall, was

not long enough or did not have a big enough impact on sexual satisfaction to provoke long-lasting changes that overcome PCa survivors' natural fluctuations in sexual function over time. Indeed, sexual outcomes in women³¹ have been shown to experience sustained improvements after 8 weeks of CBT or mindfulness. Furthermore, continuous therapeutic practice could provide survivors with resilience against future variables that may affect sexual satisfaction from a biopsychosocial framework after treatment and over the lifetime.

Although this study does not provide definitive conclusions about how to maintain sexual satisfaction gains following psychosocial interventions, results do support our primary hypothesis: that CBT and mindfulness were effective at improving couples' sexual health and intimacy post-PCa. Since we found no improvements in the control group, these positive outcomes appear to be a direct result of the interventions experienced and not general changes in this population over time.

One highly notable outcome of this study was that, while there were improvements in sexual distress and overall sexual satisfaction, there were no significant changes in sexual function for participants. In other words, couples can experience benefits in sexual distress or sexual satisfaction even when sexual function does not change (eg, erectile function, arousal, orgasm). This is particularly important for this population, where sexual dysfunction in PCa survivors is a direct result of medical treatments and it is unlikely that function, particularly erectile function, is to be restored.⁴ Indeed, other trials have reported improvements in PCa survivors' sexual satisfaction and sexual function following psychological treatment, although they attributed those improvements to their use of medical aids.^{26,63} By contrast, our intervention did not discuss sexual aid use, and participants were instructed to respond to sexual function measures and overall sexual satisfaction only in situations when sexual aids were not used.

Long-term improvements in sexual distress, regardless of changes in sexual function, indicate that CBT and mindfulness are effective at addressing the distressing domains of sexuality that often prompt people to seek treatment, and these therapies may be particularly useful in clinical situations when erectile aids are not sufficient for survivors. As well, unlike with sexual aids, there is no invasiveness or physical discomfort and pain with these psychological therapies, and they may be helpful to survivors who struggle with aid use for those reasons.^{6,8}

Impact of treatment on relationship satisfaction

Given that the interventions in this study targeted sexual intimacy as a couple and included components of couple activities, such as sensate focus and sexual communication, we expected to see improvements in relationship satisfaction. However, relationship satisfaction decreased over time, and notably, partners in both treatment arms had large decreases in relationship satisfaction (CBT, $d = 0.83$; mindfulness, $d = 0.82$) at t3 vs their survivor counterparts. There were no changes for partners in the control group.

To better understand the observed decrease in relationship satisfaction in this group, we explored time since PCa treatment. When added as a covariate, relationship satisfaction worsened with time since treatment. Although our 3-way interactions were nonsignificant when the covariate was included in the model, effect sizes remained large (CBT,

$d = 0.81$; mindfulness, $d = 0.83$), and we deemed this interaction important to describe. The decline in relationship satisfaction since treatment does map onto findings from several studies that reported a decline over time in couples after PCa.⁶³ In particular, spouses tend to report worse relationship satisfaction as time passes since diagnosis, while survivors remain unchanged.^{64,65} Ross et al explained this phenomenon by the initial diagnosis being an event that brings couples together, creating a bonding experience, which then dissipates over time for partners.⁶³ Similarly, our therapy may bring couples close together, which dissipated for partners by the 6-month assessment.

Other studies have attributed a decline in partner relationship satisfaction to spouses' desire for better communication, particularly around cancer concerns.^{65,66} In contrast to our findings, 2 couple's-based interventions post-PCa that aimed to improve cancer-related emotional communication and build mutual support and understanding found that partners' relationship satisfaction improved postintervention while PCa survivors remained unchanged and couple's sexual outcomes were unchanged.^{66,67} Our study had a greater focus on sexual intimacy; the sensate focus and sexual communication exercises were likely not enough to address the couples' relational needs.

Despite the observed decrease in relationship satisfaction over time, we still recommend our interventions for couples. Both members of the couple reported large reductions in their sexual distress over time, and upon examination of marginal means, this interaction was greater for partners. As sexual distress has poor associations with relationship satisfaction,⁵⁹ our intervention simply targeted sexual outcomes rather than relational ones. As well, qualitative interviews showed the importance of the intervention for both members of the couple, who enjoyed the experience of participating together.

Regarding the impact of the intervention on partners, it is important to consider that partners' needs are largely unknown. For instance, exploratory studies have found that sexual function is less important to partners than patients, who instead prioritize health and well-being.¹² Loeb et al released a call to action for researchers to explore more partner needs, especially the discrepancies in what patients and partners need from their relationships after PCa.⁶⁸ Clinicians should keep this in mind when treating couples and choose to incorporate similar components of relationship counseling with sexual intimacy and education to target the relationship as a whole.

Impact of treatment on quality of life and psychological symptoms

Since sexual function and satisfaction are related to quality of life and mental health in this population,^{9,10,14} we expected to see improvements in quality of life and psychological symptoms as secondary benefits of CBT and mindfulness. There was a general increase in psychological, social and relational quality of life and general health for all groups. With respect to treatment and time interactions, mindfulness participants saw short-term increases (6 weeks) on their assessment of general quality of life ($d = 0.52$). Practicing mindfulness could increase participants' sense of calm and security, which could explain this increase in general quality of life. Our 3-way interactions for improvements in physical quality of life 6 months after

CBT and in psychological quality of life 6 months after mindfulness for survivors indicate that our therapies were effective for PCa survivors in particular. There was a general decrease in anxiety for all groups at both time points, but there were no group-specific changes in anxiety or depression over time. Similar interventions also noted no significant changes on the HADS for PCa survivors,^{16,60} and a pilot trial examining mindfulness actually identified general increases in anxiety in PCa couples long term, despite observing clear benefits to other aspects of their sexual and relational well-being.³³

Other interventions examining the use of CBT to improve sexual outcomes revealed no changes in quality of life and psychological symptoms.^{26,60} In contrast, we found that improving sexual intimacy through CBT and mindfulness improved quality of life, particularly for PCa survivors. With prior evidence of CBT and mindfulness for quality of life in PCa survivors^{32,69} and, in one study, anxiety and depression of their family caregivers,⁷⁰ this provides evidence for CBT and mindfulness to benefit the well-being and sexual intimacy of couples after PCa.

There was no group-related change in mindfulness, but there were overall increases in mindfulness at t2 and t3 for both groups. This contrasts with a previous study where PCa survivors had large increases on the Five Facet Mindfulness Questionnaire–Short Form at 6 months.³³ Improvements in psychological outcomes can occur after mindfulness despite no changes in trait mindfulness,⁷¹ and it is possible that both interventions led to improvements in mindfulness due to the extensive discussions and homework focused on sexual health that encouraged couples to attend more to their sexuality.

Impact of treatment on sexual behavior and sexual function

Our intervention encouraged couples to participate in a variety of sexual activities and to consider putting penetration “on hold” with the intent to improve sexual satisfaction. So expectedly, there was a main effect of time for penetrative activities such that couples engaged in fewer sexual penetration activities in both treatment groups. No changes to sexual function, via IIEF scores, were observed; this, too, is unsurprising, given the known and permanent effects of PCa treatments on erectile function.⁴ This provides further evidence for CBT and mindfulness as treatments for sexual health in PCa partners and survivors, since improvements in some sexual domains, such as satisfaction, may be possible despite no changes in sexual function. There were no changes in female partners' sexual function, as measured by the FSFI. Canada et al found improvements on the FSFI when including components of an intervention that discussed women's sexual function (menopause and lubrication), although this improvement could have been attributed to the increase in PCa survivors' sexual aid use observed in that study, which was not an element of the current intervention.²⁶

Impact of moderators on primary treatment outcomes

Homework practice is strongly linked to positive treatment outcomes.²¹ However, we found no moderating effect of homework practice on treatment outcomes, indicating that for our study, more practice did not change sexual and relational outcomes. Of note is that survivors and their partners were equally diligent in completing a great deal of practice in both

arms, with at least 7 hours of practice completed while attending group sessions. The issue of homework requirements is a balance between not overburdening patients, which could negatively influence their commitment to a group treatment, and recognizing that change requires regular homework practice. As well, there was no moderating effect of treatment expectations on our primary outcomes, indicating that regardless of whether participants believed that the treatment was logical or would improve their symptoms, they still experienced improvements in sexual distress and sexual satisfaction. This carries clinically relevant implications: posttreatment improvements were due to the interventions and not a belief that one would get better, or a placebo effect.¹⁹ Thus, even skeptical patients can benefit from these interventions.

Some domains of personality moderated treatment outcomes for survivors' sexual satisfaction and couples' relationship satisfaction, but this was not significant once correcting for the false discovery rate via a fairly well-powered method.⁵⁴ Personality moderated treatment and health outcomes for PCa survivors in a previous study,²⁰ but these effects were mostly small to moderate, suggesting that our treatments can benefit survivors regardless of personality trait. With this, it is likely that our treatment improved sexual outcomes regardless of variability in participants' homework practice, treatment expectations, and personality characteristics, improving its generalizability to the greater population of PCa survivors.

Clinical significance

The mindfulness group showed higher clinically significant results, with participants reporting sustained and beneficial changes to their intimacy and sexual function after the trial ended. In contrast, those after CBT reported fewer long-term and sustained benefits from the intervention. Components of the mindfulness intervention, perhaps self-acceptance, may have been more appealing to participants as compared with the worksheet approach to CBT. As well, it may be easier to practice mindfulness long term, whereas CBT practice may require more support. When applying these therapies to PCa survivors and partners, clinicians may want to choose an intervention format that better meets patients' expressed desires. A larger in-depth qualitative analysis will give greater insight into couples' experiences with intimacy after PCa and the impact of treatment on these experiences, as well as a deeper investigation into what sexual outcomes are meaningful for this population.

Strengths and limitations

The participants in this study were mostly White, cisgender, heterosexual, well educated, and of a medium to high socioeconomic status. Given that these domains of identity can directly affect quality of life after PCa,^{8,72,73} future studies should proactively recruit more diverse participants. Although this is one of the few psychological interventions that included gay couples after PCa, the sample size was too small to power group comparisons, despite the finding that gay men are more likely to be sexually open and explore nonpenetrative sexual activities after PCa.⁸ Given a more open approach to sexual function that is in line with the content of our interventions, gay and bisexual men may actually respond better to CBT and mindfulness than their heterosexual counterparts.

We did not encourage the use of sexual aids in our intervention or measure their use; we instead asked PCa survivors to respond to measures of sexual function and satisfaction

for sexual scenarios in which aids were not being used. Despite this, participants may have used aids, which could have improved sexual outcomes. As well, sexual aids may be a necessary aspect of recovery for some survivors, and by not actively encouraging their use or supporting participants in ways to incorporate sexual aids into a post-PCa sexual script, our interventions may have overlooked the biological aspect to their recovery. Future studies would do well to include teachings of sexual aids to truly adhere to a biopsychosocial framework.

Due to the aforementioned challenges in recruitment, we allowed couples randomized to the control group to then be randomized to 1 of the treatment arms after the initial wait period. Given the novelty of this intervention and these therapies, we prioritized maximizing our power when examining pre- and postdifferences of treatment, while sacrificing precision to find difference between treatment groups and control. We then accordingly used these participants' data only in the treatment group and not as part of the control group, leading to a smaller control group size. We are aware that this decision compromises random assignment; therefore, we carefully tested for any potential differences between the treatment and control groups on demographics and baseline measures of the outcomes and found that they were equivalent.

For the mindfulness group, we considered daily diary recordings of sensate focus practice as a part of formal mindfulness practice. As a consequence, we were unable to evaluate for differences in practice between the mindfulness and CBT groups or vice versa, which may affect treatment outcomes. Since sensate focus involves present-moment awareness, CBT participants could unknowingly be engaging in mindfulness practice as well, thereby affecting their treatment outcomes. Future interventions should consider examining sensate focus separate from other treatment modalities.

There were several strengths to the study. First, we utilized a highly powerful and sensitive data analytic approach that allowed us to account appropriately for the distribution of variance of couples and individuals.⁵⁷ This allowed us to account for missing data without drastically affecting our results as with other methods, such as analysis of variance.⁵⁷ Unlike prior interventions in this population,¹⁷ we examined several covariates and moderators of treatment to explore factors affecting treatment outcomes. PCa survivors are often extremely heterogeneous in their cancer treatments, with many opting for multiple treatments or different treatments due to recurrence.^{4,6} By examining time since treatment as a covariate, we ensured that our intervention improvements were not simply due to PCa treatment recovery over time.

Conclusions

Mindfulness and CBT were effective at improving select sexual outcomes in PCa survivors and their partners. Interventions led to long-term improvements in sexual distress for couples after PCa despite no changes to sexual function, and PCa survivors' overall sexual satisfaction improved in the short term. As well, therapies improved secondary outcomes of quality of life, especially for PCa survivors. These therapies could improve sexual outcomes after PCa treatments, thus addressing the largest reported unmet need among this population, if included as adjunct or additional therapy to traditional posttreatment cancer care.

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