# Preliminary Development of a Mindfulness-Based Group Therapy to Expand Couples' Sexual Intimacy after Prostate Cancer: A Mixed Methods Approach



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#### **ABSTRACT**

**Introduction:** Sexual health and intimacy are consistently reported among the top unmet supportive care needs of prostate cancer (PC) survivors. With an aging population and advances in PC detection and treatment, the need for better PC sexual health interventions is acute.

**Aim:** Examine the feasibility of a mindfulness-based therapy group aimed at improving sexual intimacy for couples following PC treatments.

**Methods:** A 4-session mindfulness-based group intervention was developed for PC survivors (mean age 65.6 yrs) and their partners (mean age 61.4 yrs). A mixed-methods approach was adopted to account for small sample sizes (N = 14 couples). Findings will guide future treatment refinement via participants' lived experiences.

Main Outcome Measures: Quantitative outcomes assessed pretreatment, immediately after treatment, and 6 months later included relationship adjustment, sexual satisfaction, sexual function, depression, anxiety, and mindfulness. Qualitative outcomes used Grounded Theory Approach following posttreatment exit interviews.

**Results:** Effect sizes 6 months posttreatment indicated moderate improvements in overall sexual satisfaction and large increases in mindfulness in PC survivors, small decreases in sexual intimacy reported by partners, and small increases in anxiety in PC survivors and partners. Qualitative outcomes revealed 6 themes: (i) PC treatments must view PC as a couple's disease; (ii) PC treatments must consider the impact of illness on individuals and the couple; (iii) Mindfulness was a valued treatment modality; (iv) Individual factors contribute to outcomes, and therefore, must be considered; (v) Multiple perceived mechanisms for change exist; (vi) Group format is a therapeutic element of the process.

Conclusion: An acceptance-based approach to sexual intimacy needs among PC survivors and their partners is feasible. While this small-scale preliminary study suggests that mindfulness may address some currently unmet needs among this population, randomized clinical trials are needed. JA Bossio, CS Higano, LA Brotto. Preliminary Development of a Mindfulness-Based Group Therapy to Expand Couples' Sexual Intimacy after Prostate Cancer: A Mixed Methods Approach. Sex Med 2021;XX:XXX—XXX.

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Key Words: Prostate Cancer; Mindfulness; Sexual Intimacy; Sexual Function

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### BACKGROUND

Presently, one in every 7 Canadian men<sup>1</sup> will be diagnosed with prostate cancer (PC). As a result of advances in PC detection and treatments, PC is now considered a chronic illness as opposed to a "death sentence", with 5-, 10-, and 15-year relative survival rates at 100%, 98%, and 95%, respectively.<sup>2</sup> However, despite advances in the effectiveness of PC treatment in eradicating cancer, up to 90% of men treated will experience significant sexual side effects.<sup>1,3</sup> These side effects negatively impact patient and partner quality of life (QoL),<sup>4-6</sup> and for some men will impact their decision to undergo treatment at all.<sup>7-9</sup> With an aging population, the number of men treated for and surviving PC are expected

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to rise, <sup>10</sup> and as this number grows, so too does the number of men requiring supportive care following PC treatment.

Sexual health and intimacy are consistently reported among the top unmet supportive care needs of PC survivors. <sup>11–13</sup> Side effects of PC treatments impact the sexual lives of men and their partners, including erectile dysfunction, climacturia (loss of urine with ejaculation), anorgasmia (inability to reach orgasm), urinary or fecal incontinence, penile shortening, and/or loss of sexual desire. <sup>1,3–6,8,12</sup> Following PC treatments, sexual functioning and satisfaction sharply decline. <sup>1,2,14</sup> The loss of sexual intimacy can be devastating for partners, relationship satisfaction, health outcomes, mental health outcomes, and overall QoL. <sup>4–6</sup>

To date, sexual health research has largely focused on improving erectile functioning in PC survivors; more specifically, restoration of an erection sufficient for penetrative intercourse. Current guidelines recommend oral medication (ie, PDE5 inhibitors) as front-line treatment. 15 However, PDE5is have variable effectiveness for PC survivors, 1,16 effectiveness decreases over time in approximately 50% of men, <sup>17</sup> failure rates have been noted as high as 80%, and the significant financial burden is a barrier for many. 18 Across medical interventions for erectile function (PDE5is, penile injections, vacuum erection device<sup>19</sup>), uptake rates are low (around 50%), 19,20 and discontinuation rates are exceedingly high (50-61%) irrespective of treatment effectiveness. 21-26 Inconsistent efficacy and low adherence suggest that medical interventions aimed at erectile function alone are insufficient in meeting the needs of PC survivors, perhaps because they do not address psychosocial sequelae. Indeed, sexuality is a complex interplay of biological, psychological, and social factors, and current front-line interventions fail to address the broader scope of factors that contribute to a fulfilling intimate life.

Over the past 10 years, psychosocial interventions aimed at improving sexual outcomes following PC treatments have been developed and tested. However, the efficacy of these interventions has fallen short of expectations: sexual functioning, and relationship satisfaction are minimally improved. 27,28 While a shift toward psychosocial interventions is promising, outcomes across these studies are variable; thus, we cannot draw firm conclusions about efficacy or even mechanisms of specific interventions.<sup>29</sup> It is likely that poor outcomes are due, at least in part, to the lack of evidence-based practices incorporated into existent psychosocial interventions for PC survivors.<sup>30</sup> Indeed, there is considerable heterogeneity in the content and format of treatment groups that comprise the existing literature, as they vary in duration (eg, number of sessions), content (eg, topics covered, skills covered), mode of delivery (eg, online, phone-based, in person), and treatment modality (eg, education, cognitive behavioral therapy). Many groups include partners,<sup>31,32</sup> but some groups do not. 29,33 Further, a central interventional component of many-if not all-of the groups studied is the focus on changing one's sexual functioning; that is, many of the interventions emphasize possible treatment options aimed at

helping regain erectile functioning to facilitate penile-vaginal intercourse. By focusing on changing or improving a PC survivor's erections, distress may be maintained or even worsened when his erections do not recover to pretreatment levels (which is the case in approximately 90% of men<sup>3</sup>). Moreover, the hetero-centric implication that penile-vaginal intercourse is the gold standard of sexual health is highly problematic in this approach. The present study aimed to address sexual distress among couples using an empirically supported acceptance-based treatment modality, with the aim of improving quality of life in prostate cancer survivors and their partners without focusing on a return to pretreatment sexual function, but rather, practicing acceptance of a "new sexual normal."

Mindfulness refers to non-judgmental present-moment awareness.<sup>34</sup> Mindfulness-based sex therapy employs this acceptance-based approach to help couples move away from a performance-based focus on sexual function and instead make room for the enjoyment of the intimacy available to them at the moment. The efficacy of mindfulness as a treatment modality has been demonstrated in individuals with a variety of health-related problems. 35,36 In samples of men with PC, mindfulness training improves psychological outcomes such as mood and overall QoL,<sup>37,38</sup> as well as physiological variables, such as immunological parameters.<sup>37</sup> Recent advances in sexual health research support the benefits of mindfulness for women with a variety of sexual dysfunctions, including low sexual desire, genital pain, and sexual dysfunction secondary to gynecologic cancer. 34,39-41 Further, a pilot study has demonstrated the feasibility of adapting mindfulness via group format to men with situational erectile dysfunction. 42 Mindfulness has also been used with couples who do not have cancer in order to improve sexual intimacy. 43 It is hypothesized that mindfulness improves attentional focus, thus reducing distractions related to poor erectile functioning, body image, or distress from a cancer diagnosis/treatments, and in turn, improving sexual and relationship outcomes.

The purpose of this study was to examine the feasibility of a mindfulness-based therapy group aimed at improving sexual intimacy for couples following PC treatments and to assess preliminary efficacy data in the form of effect sizes. Given the demonstrated benefits of a mixed-methods approach for elucidating understudied aspects of human sexuality and developing new treatments, 44-48 this study utilized quantitative and qualitative analyses to explore self-reported patient outcomes, as well as lived experiences of taking part in the mindfulness group. Findings are intended to determine the feasibility of mindfulness as an intervention to address intimacy concerns in PC survivors and their partners; that is, whether this is a treatment avenue worth exploring. Further, results are intended to inform further treatment development and identify barriers to treatment prior to beginning the next stage of testing mindfulness for this patient population in a randomized clinical trial. We hypothesized that mindfulness would be a feasible intervention for couples dealing with the side effects of PC

**Table 1.** Therapeutic contents of mindfulness group sessions

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Session	In-session Meditation	Sexuality education and exercises	Home practice (Length/day)
_	Body scan Back-to-back sensing	<ul> <li>Non-goal directed sex</li> <li>Introduction to informal mindfulness practice</li> <li>What "helps" and "hurts" your sex life</li> </ul>	Mindful practice (your choice; 30 minutes) Informal mindfulness practice (10 minutes)
7	Breathing together	<ul> <li>Review of home practice</li> <li>Role of mindfulness in avoidance of sexual activity after prostate cancer</li> <li>The sexual response cycle</li> <li>Introduction to Sensate Focus</li> </ul>	Mindful practice (your choice; 30 minutes) Complete Sensate Focus at least 2 days Informal mindfulness practice (10 minutes)
М	Breath, body, sounds, and thoughts Self-exploration with touch	<ul> <li>Review of home practice</li> <li>Acceptance of changing roles in sexuality after prostate cancer</li> <li>5-part model</li> </ul>	Exercise of their choice (body scan, mindful breathing, or mindful movement) (40 minutes) Informal mindfulness practice (10 minutes)
4	Mindful listening Three-minute breathing space	<ul> <li>Review of home practice</li> <li>Using mindfulness and coping skills to redefine sex</li> <li>Maintaining practice beyond the group and troubleshooting techniques for long-term practice</li> <li>Check out and solicitation of feedback about the group</li> </ul>	Continuing regular practice of their choice (40 minutes) Continuing informal mindfulness practice (40 minutes)

treatments, and that meaningful improvements to participants' sexual enjoyment would be observed both quantitatively (via improvements on standardized measures) and qualitatively (via participants self-reports).

#### **METHODS**

# **Participants**

Couples with sexual dysfunction secondary to PC treatments were recruited from patients enrolled in the Prostate Cancer Survivorship Program (PCSC) at Vancouver General Hospital, Vancouver, BC, Canada. Inclusion criteria consisted of PC survivors who underwent any type of PC treatment (eg, radical prostatectomy, androgen deprivation therapy, radiation, etc.) who were currently in a relationship (minimum 1-year duration) where both members of the couple were willing and able to comply with all study procedures (including committing to daily homework over the 4-week period of the treatment program). Partners of any gender were eligible. Participants were excluded on the basis of having a current significant health condition (eg, severe cardiovascular health problems, unmanaged diabetes mellitus), physical disabilities prohibiting attendance at groups, or severe mental health issues (eg, severe/unmanaged psychiatric conditions).

#### Intervention

A 4-session mindfulness-based therapy group manual for couples was developed. The intervention integrated empirically supported elements of psychoeducation, sex therapy principles, cognitive therapy principles, and mindfulness skills practice. The intervention was developed based on pre-existing mindfulness-based cognitive therapy treatment groups for sexual dysfunction, elements from a couples-based mindfulness therapy manual, and expert input. The groups lasted 2 hours in length and were scheduled once per week in successive weeks. In addition, participants were invited to complete approximately 10—60 minutes of at-home practice/skills each day. See Table 1 for a breakdown of the weekly sessions.

#### Measures

Adapted Dyadic Adjustment Scale (ADAS)

The ADAS<sup>51</sup> is a validated, 7-item measure that assesses relationship adjustment. The ADAS assesses marital satisfaction along 3 dimensions: consensus, satisfaction, cohesion. Higher scores indicate better relationship adjustment. Cronbach's alpha for the 3 time points assessed was  $\alpha = 0.85$ , 0.86, and 0.90, indicating good internal consistency.

#### Global Measure of Sexual Satisfaction (GMSEX)

The GMSEX<sup>52</sup> is a validated, 5-item measure of distress related to sexual functioning with one's partner, whereby individuals rate their sexual experiences on a 7-point Likert scale for the following

descriptive pairs: Good vs Bad, Pleasant vs Unpleasant, Positive vs Negative, Satisfying vs Unsatisfying, and Valuable vs Worthless. Higher scores indicate better sexual satisfaction. Cronbach's alpha for the 3 time points was  $\alpha=0.94,\ 0.97,\$ and  $0.96,\$ indicating excellent internal consistency.

# International Index of Erectile Functioning (IIEF)

The IIEF<sup>53</sup> is a 15-item validated measure of men's self-reported sexual functioning. While male participates completed the entire IIEF measure, only the Overall Satisfaction subscale score was assessed for the purpose of this study, as we did not anticipate changes to erectile functioning as a result of treatment. Higher scores indicate better sexual satisfaction. Cronbach's alpha for the 3 time points was  $\alpha=0.83$ , 0.85, and 0.97, indicating good to excellent internal consistency.

# Female Sexual Function Index (FSFI)

The FSFI<sup>54</sup> is a 19-item measure of self-reported sexual dysfunction in women. The FSFI assesses key dimensions of sexual function, including desire, arousal, lubrication, orgasm, satisfaction, and pain. Higher scores indicate better sexual functioning. Cronbach's alpha for the 3 time points was  $\alpha = 0.97, 0.66$ , and 0.89, indicating a range of acceptable to excellent internal consistency.

# Hospital Anxiety and Depression Scale (HADS)

The HADS<sup>55</sup> is a validated, 14-item measure comprised of a depression and an anxiety subscale, intended to measure psychological distress in a general population. The scale has been shown to be invariant across gender.<sup>56</sup> Lower scores indicate less distress. Cronbach's alpha for the 3 time points was  $\alpha = 0.80$ , 0.76, and 0.83, indicating good internal consistency.

#### Five Facet Mindfulness Questionnaire; Short form (FFMQ-SF)

The FFMQ-SF<sup>57</sup> is a 24-item measure that assesses 5 facets of mindfulness: observing sensation, describing sensations, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience. It produces a single total score. Items are responded to on a 5-point Likert-type scale, such that higher scores indicate higher endorsement of the facets of mindfulness. Cronbach's alpha for the 3 time points was  $\alpha=0.92,\,0.91,\,$  and  $0.92,\,$  indicating excellent internal consistency.

#### Qualitative interviews

Interviews were semi-structured following completion of the group sessions. Core questions were asked with the intent to assess the feasibility and gather information to guide future refinement of treatment. PC survivors and their partners were invited to partake in the interview either singly or as a couple.

Related clarifying questions were asked as needed, at the discretion of the trained interviewer. Questions consisted of the following: general feedback on the treatment, personal impact of the treatment, whether the interviewee would recommend the group to others, feedback on group format, comprehension check (ie, "what is your understanding of mindfulness?").

#### Procedure

All study procedures were approved by the University of British Columbia Ethics Committee (Approval No. H16-02857). Patients from the PCSC Program were recruited through 3 pathways: 1. They were informed about the study during their routine urologist appointment by their physician; 2. They were identified from an existing PCSC Program patient database as potentially eligible and contacted by phone or letter by the Study Coordinator; 3. Interested participants responded to poster advertisements placed around the medical facility. All potentially eligible participants underwent a screening interview (either in person or over the phone) with the Study Coordinator where they were provided more information about the study, screened for eligibility, and—if interested—provided consent to participate.

Couples were assigned to the next available treatment group, and prior to the beginning of the group, they were provided with a link to complete the initial pretreatment assessment online (Time 1). One week following the end of the 4-session group, all participants were sent a link to complete the posttreatment measures (Time 2), and the third and final link was sent 6 months after completion of the treatment group (Time 3).

Qualitative data about the participants' lived experiences in the treatment group were collected via an exit interview, in which all participants (PC survivors and their partners) were contacted and invited to take part. The interview was 30–60 minutes and was conducted by a Study Coordinator who was known to the participants but who did not take part in treatment facilitation.

# Data Analysis

As the focus of this study was on determining effect sizes to power a future randomized trial of mindfulness versus a control group, we report outcomes focused on Cohen's *d* measure of effect sizes with a change between T1 and T3. For the sake of completion, we also carried out linear mixed-effects model analyses <sup>42,58,59</sup> to explore the main effect of Time on self-reported participant outcomes [ie, pretreatment (Time 1), immediately after treatment (Time 2), or 6-months after treatment (Time 3)] via univariate tests, as this statistical analysis technique has been shown to be effective with small sample sizes. Analyses were computed separately for PC survivors and their partners.

Qualitative data were analyzed using a Grounded Theory Approach using open coding (concepts extracted from patient data) and axis coding (properties and dimensions of concepts were established). A team of 3 researchers not involved in facilitating the treatment groups independently reviewed the

**Table 2.** Demographic Information for Prostate Cancer (PC) Survivors and their Partners

Characteristics	PC survivors	Partners
Education (n, %)		
High school	2 (14.3)	2 (15.4)
Trade school	2 (14.3)	0 (0)
Some college/undergraduate degree	4 (28.6)	3 (23.1)
Completed college/ undergraduate degree	3 (21.4)	2 (15.4)
Some graduate school/ professional training	1 (7.1)	1 (7.7)
Complete graduate school/ professional training	2 (14.3)	5 (38.5)
Occupational status (n, %)		
Employed full-time	5 (33.3)	2 (15.4)
Employed part-time	1 (6.7)	2 (15.4)
Retired	6 (40.0)	7 (53.8)
Self-employed	2 (13.3)	1 (7.7)
Student	0 (0)	1 (7.7)
On disability	1 (6.7)	0 (0)
Ethnicity (n, %)		
Caucasian	12 (85.7)	11 (84.6)
Latin American	0 (0)	1 (7.7)
First nations	1 (7.1)	0 (0)
South Asian	1 (7.1)	0 (0)
Other	0 (0)	1 (7.7)
Declined to answer	1 (6.7)	0 (0)

interview transcripts and, via a multi-meeting iterative process, arrived at the final, all agreed upon, list of themes.

# **RESULTS**

#### Sample Characteristics

Fourteen couples completed the group treatment; a total of 5 groups were run. Of the PC survivors (N=14), all were

**Table 3.** Baseline Self-Reported Measures for Prostate Cancer (PC) Survivors and their Partners

Measures (M, SD)	PC survivors	Partners
ADAS	23.47 (5.33)	22.50 (5.11)
GMSEX	23.71 (5.68)	24.40 (7.81)
IIEF — Overall Satisfaction Subscale	2.07 (1.91)	_
FSFI	-	16.93 (9.78)
HADS — Depression Scale	4.93 (4.30)	6.08 (4.52)
HADS — Anxiety Scale	6.07 (4.51)	7.31 (2.43)
FFMQ-SF	80.21 (15.87)	79.08 (14.28)

NOTE: ADAS = Adapted Dyadic Adjustment Scale; GMSEX = Global Measure of Sexual Satisfaction; IIEF = International Index of Erectile Functioning; FSFI = Female Sexual Function Index; HADS = Hospital Anxiety and Depression Scale; FFMQ-SF = Five Facet Mindfulness Questionnaire, Short form.

self-identified men between the of ages (Mage = 65.6 yrs; SD = 6.6). Of the partners, all identified as women (N = 14) between the ages of 44-74 (Mage = 61.4 yrs; SD = 8.2). With respect to feedback interview participation, 7 PC survivors (Mage = 68.3; SD = 3.4, Range = 64-74) and 4 partners (Mage = 62 yrs; SD = 8.1, Range = 44-68) took part in a total of 8 exit interviews (some chose to participate as a couple while some took part alone). All PC survivors had received a diagnosis of prostate cancer in the past and undergone treatment for such, although recruitment did not select for the type of prostate cancer treatment. The average time since completion of PC treatment was 2.27 years (SD = 1.98 yr, Range = 1-9 years). See Table 2 for a breakdown of demographic information.

# Baseline Relationship and Sexual Function Scores

Baseline (Time 1) scores on self-reported measures were examined against clinical cutoff scores (see Table 3 for a breakdown of scores at Time 1). With respect to relationship adjustment (via the ADAS and GMSEX), couples reported levels of satisfaction consistent with community samples, as opposed to clinical or "distressed" samples. PC survivors and partner's scores were statistically similar on both the ADAS [F(14, 26) = 1.59, P = .21] and the GMSEX [F(15, 21) = 0.85, P = .63].

Men's self-reported overall satisfaction with sexual function (via the IIEF overall satisfaction subscale) indicated severe dysfunction. The average sexual function score reported by partners (via the FSFI total score) met the clinical cut off for sexual dysfunction.

With respect to depression and anxiety, average HADS scores for both PC survivors and their partners were within the "normal" range. Depression [F(12, 27) = 1.57, P = 0.20] and anxiety [F(11, 27) = 1.58, P = 0.20] scores did not significantly differ across PS survivors or partners.

### Relationship Satisfaction

Mixed-models analysis for ADAS total scores for PC survivors and their partners revealed effect sizes that indicated no meaningful change at the 6 months follow-up (see Table 4) and differences were not statistically significant between  $t_1-t_2$  and  $t_1-t_3$  (see Tables 5 and 6).

#### Sexual Intimacy

Analysis of GMSEX Total Scores indicated a small decrease in sexual intimacy at the 6 months follow-up reported by partners (Cohen's d=0.41; see Table 4), although no significant change in sexual intimacy for PC survivors or their partners was observed between  $t_1-t_2$  and  $t_1-t_3$  (see Tables 5 and 6).

# Sexual Function

The IIEF Overall Satisfaction scores indicated a moderate improvement between Time 1 and Time 3 (Cohen's d = 0.50; see Table 4), although the mixed-models analysis was not

**Table 4.** Effect Sizes (Cohen's d) for PC survivors and their Partners between Time 1 (pregroup assessment) and Time 3 (6 month follow up) on Dyadic Adjustment, Sexual Satisfaction, Overall Women's Sexual Function, Depression, Anxiety, and Mindfulness

Group	ADAS	GMSEX	IIEF overall satisfaction	FSFI	HADS depression subscale	HADS anxiety subscale	FFMQ-SF
PC survivors	0.04	0.04	0.50 <sup>M</sup>	NA	0.04	0.25 <sup>S</sup>	0.91 <sup>L</sup>
Partners	0.07	0.41 <sup>S</sup>	NA	0.15	0.09	0.42 <sup>S</sup>	0.09

Note: ADAS = Adapted Dyadic Adjustment Scale; GMSEX = Global Measure of Sexual Satisfaction; IIEF = International Index of Erectile Functioning; FSFI = Female Sexual Function Index; HADS = Hospital Anxiety and Depression Scale; FFMQ-SF = Five Facet Mindfulness Questionnaire, Short form.

S = small effect size.

significant between  $t_1-t_2$  or  $t_1-t_3$ . For partners, FSFI Total Scores indicated a significant change between  $t_1-t_2$ , such that overall sexual function appeared to decrease in the time immediately before the treatment and immediately after; however, the observed effect size between  $t_1-t_3$  indicated no meaningful difference (Table 4), and this change was no longer significant between  $t_1-t_3$  (see Tables 5 and 6).

# Mental Wellbeing

With respect to HADS Depression Index, mixed-model analyses indicated no meaningful change between Time 1 and Time 3 (Table 4), nor were significant changes observed for PC survivors or their partners between  $t_1-t_2$  and  $t_1-t_3$  (Tables 5 and 6).

HADS Anxiety index indicated a small increase in anxiety symptoms between Time 1 and Time 3 (Cohen's d = 0.25; see Table 4) for both PC survivors and their partners, although these changes were not statistically significant (Tables 5 and 6).

# Mindfulness

With respect to total scores on the 5 facets of mindfulness short-form questionnaire, PC survivors reported a large improvement in overall mindfulness (Cohen's d=0.91; Table 4); the mixed-model approached significance between  $t_1-t_3$  (Table 4). Partners reported no meaningful change in mindfulness (Tables 3 and 5).

**Table 5.** Repeated Mixed-Models Analysis for Outcome Measures before Treatment, After Treatment, and at 6 months Follow-Up for PC Survivors

Variable	В	SE	t	Р	95% CI
Model for Adapted Dyad	ic Adjustment Scale				
Constant	23.64	1.48	15.96	0.00	[20.51, 26.77]
Time $(t_1 - t_2)$	-0.32	0.91	-0.35	0.73	[-2.26, 1.62]
Time $(t_1 - t_3)$	0.42	1.34	0.31	0.76	[-2.39, 3.22]
Model for GMSEX					
Constant	21.86	2.80	7.81	0.00	[16.06, 27.66]
Time $(t_1 - t_2)$	<b>–1.3</b> 1	3.10	-0.42	0.68	[-8.02, 5.40]
Time $(t_1 - t_3)$	0.34	3.88	0.09	0.93	[-7.75, 8.44]
Model for International I	ndex of Erectile Functio	n — Overall Satisfact	tion Sale		
Constant	1.93	0.49	3.91	.001	[.091, 2.95]
Time $(t_1 - t_2)$	0.15	0.59	0.25	0.81	[-1.11, 1.41]
Time $(t_1 - t_3)$	1.12	0.76	1.48	0.15	[-0.44, 2.70]
Model for Hospital Anxie	ety and Depression Sca	le — Depression Sca	le		
Constant	5.00	1.30	3.86	0.001	[2.25, 7.75]
Time $(t_1 - t_2)$	0.37	0.68	0.55	0.59	[-1.06, 1.80]
Time $(t_1 - t_3)$	-0.02	0.96	-0.02	0.98	[-2.03, 1.99]
Model for Hospital Anxie	ety and Depression Sca	le — Anxiety Scale			
Constant	6.43	1.14	5.64	0.00	[4.07, 8.79]
Time $(t_1 - t_2)$	0.96	1.17	0.82	0.43	[-1.52, 3.43]
Time $(t_1 - t_3)$	1.14	1.51	0.76	0.46	[-1.98, 4.26]
Five Facet Mindfulness C	Questionnaire				
Constant	80.21	3.39	20.52	0.00	[71.98, 88.45]
Time $(t_1 - t_2)$	1.56	2.97	0.53	0.61	[-4.75, 7.88]
Time $(t_1 - t_3)$	8.50	4.24	19.44	0.06	[-0.36, 17.37]

 $<sup>^{\</sup>mathrm{M}}=\mathrm{medium}$  effect size.

L = large effect size.

**Table 6.** Repeated Mixed-Models Analysis for Outcome Measures Before Treatment, After Treatment, and at 6 months' Follow-Up for Partners

Variable	В	SE	t	P	95% CI
Model for Adapted Dyad	lic Adjustment Scale				
Constant	21.58	1.49	14.52	0.00	[18.42, 24.74]
Time $(t_1 - t_2)$	0.76	0.75	1.02	0.33	[-0.84, 2.36]
Time $(t_1 - t_3)$	1.97	1.22	1.61	0.13	[-0.62, 4.56]
Model for GMSEX					
Constant	23.97	2.29	10.47	0.00	[19.11, 28.84]
Time $(t_1 - t_2)$	2.24	1.86	1.20	0.25	[-1.83, 6.31]
Time $(t_1 - t_3)$	-0.88	2.97	-0.29	0.77	[-7.24, 5.47]
Model for Female Sexua	l Function Index				
Constant	16.92	2.70	6.27	0.00	[11.33, 22.51]
Time $(t_1 - t_2)$	-5.49	2.46	-2.23	0.04	[-10.66, -0.33]
Time $(t_1 - t_3)$	-3.71	3.90	-0.95	0.35	[-11.72, 4.30]
Model for Hospital Anxie	ety and Depression Sca	ale — Depression Sca	ale		
Constant	5.93	1.09	5.42	0.00	[3.59, 8.26]
Time $(t_1 - t_2)$	-0.74	0.36	-2.08	0.06	[-1.50, 0.02]
Time $(t_1 - t_3)$	1.08	0.57	1.91	0.08	[-0.12, 2.29]
Model for Hospital Anxie	ety and Depression Sca	ale — Anxiety Scale			
Constant	6.86	0.85	8.05	0.00	[5.05, 8.66]
Time $(t_1 - t_2)$	1.17	0.65	1.80	0.09	[-0.23, 2.58]
Time $(t_1 - t_3)$	1.61	0.99	1.63	0.12	[-0.46, 3.68]
Five Facet Mindfulness (	Questionnaire				
Constant	79.08	3.59	22.05	0.00	[71.40, 86.75]
Time $(t_1 - t_2)$	2.68	1.85	1.45	0.17	[–1.27, 6.63]
Time $(t_1 - t_3)$	-0.26	2.89	-0.09	0.93	[-6.37, 5.86]

# Qualitative Analyses

Six distinct themes emerged from qualitative analyses, including: (i) PC treatments must view PC as a couple's disease; (ii) PC treatments must consider the impact of illness on individuals and the couple; (iii) Participants perceived mindfulness as a valuable treatment modality; (iv) Individual factors contribute to outcomes, and thus, they must be considered; (v) There is a multitude of perceived mechanisms for change for participants; and (vi) Group format is an important (and helpful) element of the therapeutic process.

#### DISCUSSION

# Discussion of Self-Report Quantitative Outcomes

Effect sizes revealed some notable effects for participants between pregroup measures and 6 months follow-up assessments. While no significant change was observed in any quantitative dimension assessed, the pattern of results is revealing. Anxiety appeared to increase slightly for PC survivors and the partners who participated in the mindfulness-based intervention. It is possible that the intervention was, in fact, harmful to participants in that it increased anxiety levels. However, the increase in anxiety levels fell within the normal (PC survivors) to borderline (partners) range. Further, the interpretation that the intervention was harmful is inconsistent both with the plethora of research indicating that mindfulness is an

effective anxiety management tool for cancer survivors<sup>62</sup> and noncancer survivors, 63 as well as the lived experience reported by participants in the qualitative exit interviews, who consistently reported that the mindfulness intervention was helpful, overall. While the data collected in this study are preliminary, possible insights into the unexpected finding of slightly increased anxiety 6 months after treatment may come from consideration of the mechanisms through which mindfulness is hypothesized to work. That is, mindfulness principles teach people to "feel their feelings" as opposed to avoiding them; higher anxiety ratings may indicate improved awareness of one's inner experience, as cancer is an understandably anxiety-provoking life event. This improved awareness of anxiety then affords people the opportunity to employ tools, such as mindful acceptance of these experiences, to better cope. Thus, higher anxiety levels—while distressing in the short term—do not appear to be clinically significant and may represent a movement toward healing, improved coping, and ultimately lower distress, all of which would be beneficial toward improving sexual intimacy and enjoyment. It is also possible that the elevated rates of anxiety represent a reaction toward the group's de-emphasis of the importance of erections, given the traditional focus on restoring erections among survivors seeking sexual health care.

Based on effect sizes, overall sexual satisfaction (via the IIEF) showed a moderate increase for PC survivors but no meaningful change for partners' sexual wellbeing 6 months after treatment.

Improved sexual satisfaction among PC survivors is a notable finding, as sexual function (ie, erectile function) did not change by any measurable amount as a result of mindfulness training. Given the often permanent detrimental impact of PC treatment on men's sexual functioning,<sup>64</sup> focusing not on return to pretreatment function, but instead on the enjoyment of "what is" was theorized to improve sexual satisfaction following PC, consistent with the underlying tenets of mindfulness approaches. 30,65 Further evidence to this point comes from the observed large effect size increase in men's self-reported mindfulness (via FFMQ-SF). As men move away from erection-oriented sexual performance and instead focus on the present moment, it creates space for a more mindful, flexible orientation toward other ways of being sexual and enjoying sexual pleasure. Why the same increase in sexual satisfaction was not observed in women is unclear, especially given the levels of sexual satisfaction across PC survivors and their partners via the GMSEX were nearly identical at baseline. Perhaps the gender difference in sexual satisfaction is related to the lack of an observable change in women's self-reported mindfulness. Indeed, research shows that improved mindfulness-awareness in women is related to improved sexual enjoyment, including sexual desire. 41

# Discussion of Qualitative Outcomes

This section explores themes that emerged from the Exit Interviews. Names of participants have been changed to protect participant confidentiality. Also, it is important to note that findings for each theme include both ends of the thematic spectrum, from positive to negative, representing the diverse span of reported experiences among participants in this study.

# Theme 1: PC treatments must consider PC as a couple's disease

For some couples, the cancer experience can bring them closer together, but for others—presumably, those who do not have healthy means of coping/communicating prior to diagnosis—the PC experience can act as a significant relational stressor. 66,67 Mindful acceptance of the cancer experience has been shown to facilitate couple wellbeing<sup>68</sup> and to impart psychological benefits on both members of the couple.<sup>69</sup> The benefits of joint couple attendance in mindfulness-based interventions for cancer coping have been supported by previous research.<sup>69</sup> A couples-based interventional format for PC can support both members of a couple toward improving resilience and cancer coping together. The importance of partners attending treatment was illustrated by one participant in the current study, who said, "The way it's affected us and every woman there was expressing incredible loyalty, and showing that they-you know-they're there, they're there for the men, they're there for the relationship" (Harris, PC survivor, age 66). Many who took part in the exit interview shared this sentiment. Conversely, one couple acknowledged that the relational aspect of the cancer experience was a point of difficulty for them, particularly with respect to sexual intimacy:

"We can't even seem to have conversations about [sexual intimacy]. Like if I raise it, it goes nowhere... I sort of leave it up to him to raise it as an issue or a subject. And that's not happening, so it's basically just this—you know—blank space... it's just at the point where there's just not a conversation" (Maisey, partner, age 44).

While not every man who experiences prostate cancer will be in a relationship, it is well documented that the impact on sexual intimacy is a critical element often missing in PC survivorship care. 11–13 Sexual intimacy is linked with relationship satisfaction and wellbeing, 10 and social support is linked with higher rates of cancer survivorship. 11 For example, married men diagnosed with PC have been shown to have significantly longer median survival than those who were divorced, single, separated or widowed. 12 Thus, participants in this study generally agreed that psychosocial treatments aimed toward PC survivors would benefit from taking a relational approach to treatment.

Theme 2: PC treatments must consider the impact of illness. Due to extremely high survival rates of PC, it can be easy for even the most well-meaning health care providers to trivialize the profound impact of a cancer diagnosis, even when it is a "good" prognosis. Further, the impact of the PC diagnosis on individuals and couples can vary widely over the stages of the cancer journey, from "watchful waiting" to active treatment, to years after treatment. Couples in the current study reported a myriad of ways that they were differentially impacted by the disease and treatment process, and as a whole, they valued the fact that mindfulness tools could apply to any stage of their cancer journey.

Participants studied here represented all stages of the PC cancer journey. Due to the differing needs and priorities across cancer stages, the question of outcome variables for feasibility studies such as this one becomes an important question—and a potential challenge—for clinical researchers. One participant spoke to priorities in the early stages of PC diagnosis by saying:

That's life... it's the same as when you go into your prostate operation. The most important thing is that you survive it. The second most important thing is that you don't have any incontinence. And the third most important thing is that you have sex. (Elias, PC survivor, age 71).

Another spoke to the way in which mindfulness can address different priorities across the PC journey:

"After prostate surgery you're just grateful for life and for hope. And, and so—you know—you feel guilty if you feel 'oh my, our sex life isn't the same. But boy, my husband doesn't have cancer so I should just be happy'... the [mindfulness] course also helps us kind of be—you know—happy that we're both alive. But also we could rediscover our intimacy again and enjoy each other in a more relaxed way, just not having to have that pressure on you. To have fun." (Erica, Partner, age 66).

Additionally, one participant spoke to the potential benefit of early intervention:

"After we've been [intimate in this new way] for 5 years [after my PC surgery] it becomes—sex becomes cynical. It's not spontaneous. There isn't a similar foreplay you used to have. That's gone. And I was to the point after my operation, [which] was almost 6 years ago... [where I thought] I should try something different." (Elias, PC survivor, age 71).

Elias speaks to the timing of intervention, which can be difficult because intervention too early (ie, prior to treatment) may not be appropriate, as patients are focused on treating the cancer, as opposed to dealing with the potential side effects of that treatment. While waiting too long for the intervention may allow unhelpful patterns of sexual intimacy to emerge—as was the case for Elias and his partner. Indeed, the movement toward precision healthcare<sup>74</sup> within a psychosocial context aims to account for the wide range of patient goals and individually defined "successes."

With respect to the current study, differences in the impact of illness across those who participated—be it in the form of stage of illness or individual goals for the group—may account for a lack of statistically significant outcomes in the current group. Based on participant feedback, we would encourage health care providers to consider the timing of intervention, as well as address how different stages in a couple's recovery and different goals for the group may impact participants group experience, as opposed to limiting enrolment to couples at the same stage of their cancer journey. This could maximize benefit of the group by exposing participants to different models of coping across other couples present; perhaps giving hope to those newly diagnosed, and providing an opportunity to speak to and reflect on their "wins," for couples further along in the journey.

# Theme 3: Value of mindfulness as a treatment modality

Participants who took part in the exit interview spoke extensively about their thoughts on mindfulness as a treatment. For the purpose of this qualitative analysis, participant understanding of the concept of "mindfulness" was the focus, as this lens provides insight into patient's perception of the mechanisms that comprise mindfulness as a skill, and perhaps how they used this skill in their own lives. Interestingly, there was considerable

variability in participant's understanding of mindfulness; for some, it was in line with the commonly held understanding of mindfulness as an acceptance-based treatment. For example: "In our sexual practices [mindfulness] really has helped us just to be able to let go that goal of the climax and just enjoy each other as a couple." (Erica, partner, age 66) and:

"[Mindfulness is] attending to your thought processes in such a way that...you accept [the thoughts]... you have them, you just acknowledge it, that you don't refute it, you don't continue down the track of negative thoughts. You just say 'yeah that's a negative thought' and move on." (Charles, PC survivor, age 67).

Some participants, however, provided an explanation of mindfulness that suggests that—at least at an intellectual level—they misunderstood or failed to integrate the "acceptance" element of the concept. Examples of this include: "I just don't like thinking about nothing. I want to think about something." (Dario, PC survivor, age 74), or "So mindfulness is more this, the touchy, feely, part rather than having an actual erection...It's almost like self-hypnosis... It's the way to direct your mind the way, in a positive way... well just have positive thoughts rather than negative thoughts. And to arrange, organize your thoughts." (Elias, PC survivor, age 71).

While mindfulness is known to be an "experiential practice" more than an intellectual one, the range of participant-generated definitions suggests that at least some participants from the current pool may not have integrated the practice of non-judgmental acceptance into their intimate lives. The current study did not evaluate whether participant's description of mindfulness correlated with quantitative measures of mindfulness captured by our questionnaire, but future research could explore such a relationship and perhaps check in with participants' understanding of the concept of mindfulness partway through the intervention to ensure that participants have an understanding of the concepts being taught in session and that they are integrating these concepts into their own intimate practices.

# Theme 4: Individual factors contribute to outcomes

This theme is a broad one, and thus, will only be discussed preliminarily here. Indeed, a myriad of individual factors are known to impact psychological treatment outcomes, and the complexity and need for more research on this nebulous topic is widely acknowledged within the field of clinical psychology. Participants in the exit interviews identified a number of individual factors they perceived to be contributors to self-reported outcomes, including motivation, commitment (to the group, their partner), practice of skills between sessions, relationship

wellbeing, coping styles (of the individual and of the couple), generational factors, cultural background, expectations (for the group, for selves, for partners), perceived "fit" in the group, and readiness for change, to name a few. As an example, one participant spoke to his low readiness to change as a hindrance;

"When you're ready you're gonna share, and in my opinion, if you're not, you're never going to [share with the group]... I just think [my partner and I are] not interested in hashing it out... At least we're not ready yet, there was a readiness component... it's just something we don't talk about." (Sayed, PC survivor, age 67).

Readiness for change appears to be an important individual factor that undermined his—and ultimately his partner's—ability to fully engage in or benefit from the group. Identifying these individual factors is important, as they can act as target variables for clinical researchers to study in future psychosocial interventions aimed at sexual intimacy among PC survivors. These factors may also be relevant in deciding what treatment might be best suited for whom.

The most poignant individual factor from the qualitative analyses was the conflict between participant's desire for change within the context of post-PC sexual intimacy concerns, and their "buy-in" to mindfulness as a means for that change; that is, participants agreed to take part in the study because they were distressed about their current level of sexual intimacy and wanted it to improve (ie, they wanted a change); however, the treatment modality emphasized acceptance of their present-moment experience in order to improve their sexual intimacy. The contradiction of improvement via acceptance is one that many must wrestle with when first introduced to the concept of mindfulness. Some participants found that mindfulness provided structure to move them forward:

"But we, personally... I guess we kind of formalized things that were... possibilities before. Possibilities became opportunities, I'll say that. Things that I thought, 'maybe we could be doing or trying' became homework and we had to do it. And it was fun. And it was interesting...We were very dutiful about doing all the exercises and it was a really kind of a calm month for us. We totally devoted ourselves to the study. And, you know, we did our homework, it was a good thing to do." (Erica, partner, age 66).

Future research would benefit from exploring individual factors that predict participants' "fit" with an acceptance-based approach like mindfulness, compared to more change-based treatments, such as cognitive-behavioral therapy, for example, as a way to maximize participant's likelihood for success, whatever "success" may look like to them.

Theme 5: Perceived mechanisms that facilitate change

Similar to individual variables that may influence treatment outcome, participants had innumerable insights into the active mechanisms behind mindfulness, as taught in the group. Participant-generated hypotheses around mechanisms for change included: shared experience with group members, expectations for the group (whether participants had clearly defined expectations or attended with openness and curiosity), and the length of the group (ie, number of sessions). Further, participants raised questions about whether elements of sex therapy/education contributed to outcomes. Consistently, though, participants provided feedback that practicing mindfulness outside of the group was a critical component of improvement or, in some cases, the lack of practice was a source of worsening function. For example, one couple acknowledged that a failure to practice the mindfulness exercises was a significant contributor in increased distress and a decrease in outcomes after group:

"We weren't really good at getting the homework done or making the time for each other, and for sensate focus and those kinds of things, and then that becomes a bit of a wedge issue with us as a couple... I may be misquoting here but I seem recall [partner] saying 'Look, we signed up for this workshop, you can't be bothered to do the homework, you know, well why are we bothering? and then suddenly it's, it's, uh—actually becoming more a problem... rather than a solution." (Mac, PC survivor, age 64).

Similarly, those who did engage in practice of mindfulness exercises outside of the group considered mindfulness a fundamental mechanism for change:

"People need to go along with the practices you're doing. One couple who didn't stay, they were very uncomfortable with doing one of the activities we had on the first time. And it kind of makes you feel like oh they're- they're going to be um I don't know-" (Erica, partner, age 66).

Erica's partner completed her sentament more bluntly: "[Not practicing is] going to end up f\*\*\*ing everything that's suggested. That it isn't going to work very well." (Bruce, PC survivor, age 74).

Through participants' lived experience and resultant insights, future clinicians who decide to pursue mindfulness-based interventions to address sexual intimacy concerns for PC survivors would do well to include educational material about identified mechanisms for change. For example, information about the importance of practice and clear delineation of expectations for the group may be useful to present in the first session.

A final mechanism for change was identified by all participants interviewed: 4 sessions is not enough. Perhaps consistency with mindfulness-based standard protocols of 8 sessions would be beneficial for participants of future groups. Indeed, incorporation of participant's lived experience in the future development of groups holds promise both for both participant enjoyment, as well as effectiveness. It is worth noting that other clinical research programs have modeled the move from a 4-session intervention at the treatment development stage to an 8-session intervention with great success.

#### Theme 6: Treatment in a Group Format

Research comparing the value of group versus individual therapy is lacking, particularly with respect to sex therapy. However, the utility of group treatments can be beneficial for many reasons, <sup>75</sup> including time and resource efficiency compared to individual therapy, and for this reason, group interventions tend to be favored in hospital settings. Indeed, participants who took part in the exit interviews all touched on the group format as an important element of the treatment experience, and all except for one person interviewed who found it to be positive. The one negative comment about a group format spoke to comfort in a group and a willingness to be vulnerable: "Yeah I'm in a group but it's really none of your business until I'm ready to share it. And you're asking me to share it now, but I'm not ready." (Sayed, PC survivor, age 67). Other comments were generally very positive about the group format, for example:

"Part of it is you trusting the other couples are discreet. And you're building a very strong relationship there sharing things, you don't share sometimes with even friends. So there could be bit of a fear with a larger group, but it was very comfortable," (Ava, partner, age 68).

And the comment: "It was kind of comforting, I think...You're not alone. We had some good laughs as well in the group... So the atmosphere in the group was a supportive one." (Charles, PC survivor, age 67). Based on the lived experiences reported by participants in this study, we find results generally in favor of delivering treatments for improving sexual intimacy after PC in a group format, but it would be important for health care providers to properly assess all participants for willingness to take part in a group treatment and screen out those with contraindicates for group.

# **CONCLUSIONS**

Findings from qualitative interviews indicate the utility of mindfulness as a feasible, and perhaps, even promising intervention for improving sexual intimacy in the lives of PC survivors and their partners. Indeed, all participants interview explicitly reported enjoyment of the intervention and self-reported improvement, with the exception of one couple who reported a generally negative experience.

Consideration of observed effect sizes viewed through the lens of participant's lived experience supports the hypothesis that a mindfulness-based intervention is a feasible, novel treatment avenue for supporting PC survivors and their partners. Experts agree that the existing change-based model of PC survivorship care, which focuses on regaining pretreatment levels of sexual function, is a model that, more often than not, leaves clinicians and patients alike disappointed.<sup>30</sup> PC survivorship care is likely to benefit from following emergent research in the sex therapy field, which shows mindfulness to be an effective treatment protocol for improving sexual intimacy and enjoyment via acceptance of whatever items exist on a couple's sexual menu in the present moment. Indeed, acceptance in the face of often permanent changes to sexual function following PC treatment is hypothesized to allow for the mourning of a sexual life that once was, while also creating space to nurture and enjoy a rich, fulfilling, "new sexual normal." Clinically, this can include regular mindfulness practice, psychoeducation about the role of acceptance as a tool to reduce distress around sexual items that are no longer "on the menu" (such as penile penetration, in the case of some PC survivors), and how the well-demonstrated stressreduction benefits of mindfulness can lead to improved sexual functioning and enjoyment. The mixed-methods approach employed in this study offers preliminary evidence of mindfulness' feasibility, both from a theoretical perspective as well as via the outcomes gleaned from participants. Thus, in order to fully address the needs of the patients whom we aim to help, we propose that pursuing further development and testing of this new psychosocial treatment protocol is worthwhile.

The number of couples who completed the study was small, and attrition rates further lowered the final numbers. Thus, a significant limitation to the present study is the small sample size. Importantly, qualitative outcomes indicate that there was a bimodal distribution of experiences (that is, some participants experienced improvements, while some participants experienced no improvements or a worsening of some symptoms for each self-reported outcome measure). So while the quantitative data analysis did employ a statistical technique shown to perform well with small samples, 58,59 and the mixed-models analyses employed here account for small sample sizes, it is very likely that findings were not observed because the statistical analyses were simply not able to account for the range in self-reported outcomes (both positive and negative) in participants. However, the emphasis on effect sizes in quantitative analyses, as opposed to a strict focus on P values, does offer insight into the impact of the treatment of the participants.

Whether the findings reported—either quantitatively or qualitatively—can be directly attributed to mindfulness training without the inclusion of a control group cannot be inferred from the current study. Participant responses to the exit interview overwhelmingly imply that participants perceived mindfulness as the source for much of their self-reported improvements, but this assertion requires empirical support in the form of a control group accounting for non-specific factors. It is worthwhile to note that

research has shown declines in long-term follow-ups of PC survivors' sexual outcomes who do not receive adequate psychosocial interventions<sup>28</sup>; thus, the sustained or improved sexual intimacy outcomes identified in the current sample does suggest that the intervention may be responsible—at least in part—for the observed improvements.

#### Clinical Implications

The outcomes from this small-scale pilot study provide preliminary support in favor of treatment feasibility and add to mounting support in favor of adopting a mindfulness-based couples therapy to address intimacy concerns, this time in PC survivors and their partners. There is a strong theoretical rationale for moving toward acceptance of what is, as opposed to the existent approach of encouraging couples to work toward pre-PC treatment levels of sexual function, a stance that is often futile and discouraging.

Future research would benefit by incorporating information gathered from patients' lived experience into treatment development (eg, offering more sessions, including information about commitment to practice), as well as targeting outcome variables. Evaluation of a mindfulness-based intervention targeting sexual intimacy in PC survivors and their partners should be evaluated in a larger-scale randomized clinical trial format. Further, special attention should be paid to the active ingredients of such a mindful approach, including the timing of intervention in the PC journey, treatment dosage, and the mechanisms of change. In the immediate future, however, PC survivorship care may be improved by providing patients with acceptance-based messaging around intimacy, as opposed to an often-fruitless focus on return to pretreatment sexual function.

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