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RESEARCH ARTICLE



Feasibility and Acceptability of a Group-Based Mindfulness Intervention for Sexual Interest/Arousal Disorder Following Breast Cancer Treatment

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ABSTRACT

This study aimed to assess feasibility and preliminary efficacy of an 8-week Mindfulness-Based Cognitive Therapy (MBCT) group program to treat Sexual Interest/Arousal Disorder (SIAD) in women following breast cancer (BrCa) treatment. Thirty women participated, of whom 67% ($n=20$) attended at least 6 of 8 group sessions. Feedback indicated the program was relevant and valuable; minor modifications were suggested to further address survivorship concerns. Results of pre-post questionnaires demonstrated significant improvements in sexual distress and sexual interest/desire, with large effect sizes. Results support the feasibility and preliminary efficacy of an 8-week MBCT program among women following breast cancer treatment.

Prevalence of sexual concerns after breast cancer (BrCa) treatment is high, in the order of 45–86% (Kedde, Van De Wiel, Weijmar Schultz, & Wijsen, 2013; Raggio, Butryn, Arigo, Mikorski, & Palmer, 2014; Robinson, Bell, Christakis, Ivezic, & Davis, 2017). Common complaints include decreased sexual desire, arousal and lubrication, anorgasmia, and dyspareunia (Burwell, Case, Kaelin, & Avis, 2006; Kedde et al., 2013; Sadovsky et al., 2010). Sexual dysfunction significantly impacts quality of life (QOL) and intimate relationships (Katz, 2005; Sadovsky et al., 2010), and will generally persist if left untreated (Schover et al., 2014). While some interventions exist to support patients with the physiological aspects of cancer-related sexual dysfunction, such as vulvovaginal pain (Millman et al., 2020), low sexual desire is less commonly addressed. Given the multi-factorial nature of sexual desire, it is important to consider multiple contributing factors when designing interventions to address difficulties with desire.

Premature menopause, a common result of chemotherapy and endocrine therapy, is a significant precipitator of sexual difficulties (Leining et al., 2006; Ochsenkühn et al., 2011). In particular, severe vaginal dryness along with vaginal atrophy (causing vaginal tightening/reduced elasticity), often results in painful intercourse. Painful sexual experiences lead to fear of sex, behavioral avoidance, and a subsequent profound loss of sexual desire (Schover et al., 2014). Moreover, the experience of having cancer and cancer treatments can interfere with women's ability to see themselves as a 'sexual person' and their capacity to connect to the body in a sexual way, further compounding loss of desire (Boquiren et al., 2016). Cancer also frequently affects women's identity, self-image, confidence, social roles, and intimate relationships (Emilee, Ussher, & Perz, 2010; Wittmann, 2016), each of which can impact sexual desire alone or in combination.

The diagnostic category, Female Sexual Interest/Arousal Disorder (SIAD), was added to the Diagnostic and Statistical Manual of Mental Disorders (DSM), 5th edition, in 2013. This addition replaced the two separate DSM-IV-TR diagnoses of Hypoactive Sexual Desire Disorder (HSDD) and Female Sexual Arousal Disorder (FSAD), previously used to separately capture low sexual desire and difficulties with arousal. Diagnostic criteria indicate that individuals endorsing Sexual Interest/Arousal Disorder (SIAD) must manifest (at least 3 of) the following six symptoms: a lack of interest in sexual activity, few or no sexual thoughts, lack of receptivity to a partner's sexual advances and no initiation of sexual activity, lack of pleasure during sexual activity, lack of responsive desire to erotic stimuli, and difficulties with physical signs of sexual arousal (American Psychiatric Association, 2013). Such symptoms must also be accompanied by clinically significant personal distress to meet a diagnosis. Sexual distress is known as a myriad of negative feelings (e.g., embarrassment, worry) about sexuality (Stephenson & Meston, 2010) and is an important element of a diagnosis of SIAD.

Some interventions in the general population have been found to be effective among women who endorse low desire and/or arousal, however, evidence of the appropriateness and efficacy of these approaches within cancer populations is limited. For example, hormonal replacement therapy (HRT) can improve vaginal health and indirectly improve sexual function, but systemic HRT is contraindicated and localized HRT is still considered controversial in women with BrCa. Some evidence exists for Cognitive Behavioral Therapy in reducing symptoms of HSDD (e.g., low desire symptoms), but not FSAD (e.g., arousal symptoms) (ter Kuile, Both, & van Lankveld, 2010). Pharmacological interventions targeting FSAD (e.g., flibanserin) have not been taken up with great enthusiasm due to modest efficacy (Basson, Driscoll, & Correia, 2015). Furthermore, given the more recent change in diagnostic categorization, few treatments have been tested specifically for SIAD.

Considerable evidence supports the application of mindfulness meditation-based interventions in treating low sexual desire and arousal in women without cancer. Mindfulness approaches aim to foster engagement in one's present moment experiences in an accepting and non-judgmental manner. Findings from previous research support the effectiveness of a 4-session mindfulness-based program for the treatment of desire and arousal concerns of women in the general population, demonstrating improvements in sexual desire, arousal, lubrication, and satisfaction (Brotto & Basson, 2014). However, feedback from the majority of women in the trial indicated that they had only begun practicing mindfulness regularly at 4 weeks; therefore, a longer 8-session mindfulness-based program was developed for treating SIAD (Paterson, Handy, & Brotto, 2017). Indeed, lengthier mindfulness interventions (8 sessions) have shown efficacy in the broader mental health context, reducing depressive symptoms (Sipe & Eisendrath, 2012), depressive relapse (Teasdale et al., 2000), and anxiety (Evans et al., 2008). A recent randomized clinical trial assessed an 8-session Mindfulness-Based Cognitive Therapy (MBCT) intervention for women with sexual concerns against group sex education (Brotto et al., 2021). The authors hypothesized that participants' scores on measures of sexual desire and arousal, sexual distress, relationship satisfaction, rumination, and global treatment impressions would improve in both the MBCT and sex therapy groups from pre- to post-treatment, and that improvements would be greater for those in the MBCT treatment group (Brotto et al., 2021). In addition to devoting considerable in-session time to mindfulness practice and a guided inquiry, each session also contained elements of education—the latter of which was identical in the comparison arm. Both arms showed significant improvements in the primary outcome of sexual desire, though the MBCT arm led to significantly greater improvements in the co-primary endpoint of sex-related distress (Brotto et al., 2021). Importantly, improvements were retained 12 months later (Brotto et al., 2021).

The application of similar mindfulness-based interventions for sexual difficulties in cancer patients is in its infancy. To date, two small studies have tested a brief application (3 sessions) of mindfulness in gynecologic cancer patients (Brotto et al., 2008, 2012). These demonstrated positive effects on sexual desire, arousal, satisfaction, and sexual distress. Neither of these

interventions used active control groups, and the proportion of patients meeting the strict inclusion/exclusion criteria was low (11% (Brotto et al., 2008) and 18% (Brotto et al., 2012), respectively).

Given that BrCa is the most prevalent cancer affecting women (Canadian Cancer Society, 2018), and that reductions in sexual desire and arousal in women with BrCa are pervasive, it seems that there is a dire need to develop safe and effective treatments to address these concerns among patients. Building upon preliminary evidence supporting the use of a manualized, 8-week MBCT group protocol for women with SIAD who do not have cancer, the current study involves the adaptation of this treatment to the specific sexual concerns of BrCa patients, followed by preliminary testing, with the longer-term goal of a large-scale trial.

The primary objective of this pilot study was to evaluate feasibility and patient acceptability of MBCT. Secondary objectives concern preliminary efficacy.

The following questions anchored our investigation of feasibility:

1. Given that sexuality is a topic recognized for receiving poor attention by oncology providers, can sufficient referral pathways be established among health care providers?
2. What are appropriate inclusion criteria for participants (e.g., completion of active treatment, time passed since treatment, nature of sexual concerns, sexual activity status)?
3. Can enough participants be recruited to offer regular groups (Target: 8 participants per group, 1-2 groups per year)?

The following questions anchored our investigation of patient acceptability:

1. Are participants able to attend at least 6/8 group sessions (Cherkin et al., 2016) and complete weekly homework?
2. Do elements of the study design and intervention need further modification for the BrCa population (e.g., length and number of sessions, homework, nature of concerns)?
3. Is the intervention acceptable to and appreciated by participants?

Secondary objectives included a preliminary analysis of pre-post intervention outcomes, primarily on change in sexual distress and sexual interest/desire, with a focus on effect size estimates. Hypothesized changes included improvement in sexual distress and sexual interest/desire from pre- to post-intervention.

Materials and methods

Recruitment

Women treated for BrCa within the last 10 years were eligible to participate. Recruitment was conducted via three primary pathways: (1) self-referral in response to study flyers; (2) direct referral from a healthcare provider; (3) a list of patients who previously expressed interest and provided consent for future contact about sexual health programming. Recruitment flyers were placed in the cancer center and distributed in BrCa follow-up clinics, and cancer care providers were informed about the intervention and referral process. Interested candidates spoke with the study coordinator by phone and completed a detailed phone screen to assess eligibility. Consenting participants next completed a brief clinician-administered, structured assessment (i.e., the Sexual Interest and Desire Inventory) and a self-report questionnaire package.

Eligibility

Inclusion criteria included: cisgender women who had completed treatment for BrCa within the past 10 years (cohorts 3–4) or 5 years (cohorts 1–2), who were over the age of 18, and who

were fluent in English. Participants must also have engaged in at least one sexual encounter (alone or with a partner; intercourse was not a requirement) within the preceding 6 months. Participants were also required to meet diagnostic criteria for SIAD. Following recruitment of the first two cohorts, eligibility criteria were expanded to minimize barriers in establishing recruitment pathways. For remaining cohorts, women were considered eligible even if they completed cancer treatments within approximately 10 years prior, if they weren't experiencing significant sexual distress (as per screening interview), and if they hadn't been sexually active in the previous 6 months. Participants were asked to hold constant any other sexuality-related or vaginal health-related treatments from 2 weeks prior to starting the intervention until 2 weeks following intervention completion.

Exclusion criteria included: current active cancer treatment (e.g., chemotherapy or radiation, but not including endocrine or maintenance therapies), and more than 1 planned absence from the 8 weeks of group sessions.

Measures

Self-report measures

Demographic/health/sexual history form. This questionnaire assessed demographics, menopausal status, cancer diagnosis and treatments, and other health conditions. Sexual history included previous treatments for sexual difficulties, a measure of orgasmic frequency, age of first intercourse, history of non-consensual sex, and the duration of time experiencing sexual difficulties.

Female sexual distress scale – revised (FSDS-R). The 13-item FSDS-R (Derogatis, Clayton, Lewis-D'Agostino, Wunderlich, & Fu, 2008), assesses sexual distress using a 5-point Likert-scale (0 - Never to 4 - Always). Total scores range from 0 to 48, with higher scores indicating greater distress. The FSDS-R has been found to have excellent discriminant validity, correctly identifying 92.7% of women with HSDD using a cutoff score of 11 (Derogatis et al., 2008). Cronbach's alpha in the present sample ranged from $\alpha = .868$ (T0) to $\alpha = .967$ (T2).

Female sexual functioning index (FSFI). Overall sexual function was measured using the 19-item FSFI (Rosen et al., 2000). Meyer-Bahlburg and Dolezal (2007) recommendations (Meyer-Bahlburg & Dolezal, 2007) were used to modify the scale by reordering items to assess overall sexual satisfaction and sexual desire first, so that only sexually active women (i.e., solo or partnered) answer questions on the other domains of sexual arousal, lubrication, orgasm, sexual satisfaction, and pain with vaginal penetration. Total scores range from 2 to 36, with higher scores indicating better sexual function. The FSFI has been found to have good discriminant validity, correctly identifying 70.7% of women with sexual dysfunction using a cutoff score of 26.55 (Wiegel, Meston, & Rosen, 2005). Cronbach's alpha for the FSFI in the present sample ranged from $\alpha = .857$ (T0) to $\alpha = .921$ (T2).

Homework and adherence. Additional follow-up questions included a checklist of completed worksheets and exercises and questions relating to amount of mindfulness practice.

Post-intervention feedback. Participants were also given an opportunity to provide written feedback on the group and materials. Prompts included: 1. Please provide feedback about your experience in the group, 2. Please provide any considerations about the application of this treatment approach specially for women with breast cancer.

Clinician administered interview

Sexual interest/desire inventory (SIDI). The 14-item SIDI (Clayton et al., 2006) includes questions on both sexual initiation and receptivity. Total scores range from 0 to 51, with

higher scores indicating greater sexual interest/desire. The SIDI has excellent internal consistency (Cronbach's $\alpha = .90$), and discriminant validity, correctly identifying 94.7% of women with hypoactive sexual desire disorder (HSDD; now replaced by the SIAD diagnosis) using a cutoff score of 33 (Clayton et al., 2010). Cronbach's alpha in the present sample ranged from $\alpha = .713$ (T0) to $\alpha = .828$ (T2).

Procedure

Assessments occurred for all participants at three standardized time-points: 1 week prior to treatment commencement (T1, pretreatment baseline), within 2 weeks of treatment conclusion (T2, post-treatment), and approximately 8 weeks after the final session (T3, follow-up). A subset of the sample ($n = 16$, 53%) completed an additional assessment timepoint (T0, 8 weeks pre-treatment) while on a waitlist. The waitlist/first assessment was dropped at the mid-point of the study due to timing restraints of staff and clinical need of patients. Assessments at all time-points included the *Sexual Interest and Desire Inventory (SIDI)* (Clayton et al., 2006), a clinician-administered diagnostic interview to determine the presence and intensity of desire and arousal symptoms. Administration of the SIDI was conducted by trained clinicians, in person, at all time-points. Self-report questionnaires were administered online using REDCap survey software, hosted at the University of Calgary. The study was approved by the Health Research Ethics Board of Alberta—Cancer Committee (HREBA-CC#:17-0557) and all participants provided written consent prior to participating.

Group intervention

The group intervention was led by trained registered clinical psychologists. Groups consisted of 8, two-hour weekly sessions. Groups were audio-recorded to ensure treatment fidelity. The Mindfulness-Based Cognitive Therapy (MBCT) for sexuality intervention (Brotto et al., 2021; Paterson et al., 2017), based on the 8-week MBCT for depression program (Teasdale et al., 2000), is a manualized treatment approach that was adapted to specifically address sexual concerns of women with a history of BrCa. During group sessions, mindfulness practices were led by experienced facilitators with mindfulness training. Group sessions also involved education about sexual response, sexual beliefs, communication, and cancer-related changes in vulvo-vaginal health. Exercises related to bringing attention to body image, body exploration, genital pain and discomfort were also incorporated. Participants were provided with weekly handouts, home-based activities, and links for audio-recorded guided mindfulness practices, which they were asked to complete daily between weekly group sessions.

Data analysis

Descriptive statistics for demographic characteristics and baseline sexual function are presented in Table 1. T-tests and chi-square tests were conducted to explore potential differences between those who dropped out versus those who completed the study in terms of age, relationship duration, time since treatment completion, type of cancer treatments completed, sexual activity status, previous treatment for sexual difficulties, and total FSFI scores.

Thematic content analysis (Sandelowski, 2000) was used to analyze participants' written responses on open-ended, post-group feedback questions. A single coder conducted the analysis, the results of which were then reviewed by the PI. Discrepancies were minor and pertained to generation of additional subcodes and were discussed amongst the primary coder and the PI. Given the specificity of the prompts, a coding rubric was not necessary.

Primary treatment outcomes for the study were sexual distress (as per the SDS) and sexual interest/desire (as per the SIDI), with a focus on effect sizes associated with changes in scores

Table 1. Participant demographics and sexual history.

Variable	N (%) (n = 30)
Age (years)	54.10 ± 8.277
Mean ± SD (range)	(38 – 69)
Ethnicity	
White/Caucasian	27 (90.0)
Asian/Pacific Islander	2 (6.7)
Middle Eastern/Arab/Indian	1 (3.3)
Employment Status	
Currently working	14 (46.7)
Retired	8 (26.7)
Not working (illness)	7 (23.3)
Currently looking	1 (3.3)
Education	
University, graduate	11 (36.7)
Undergraduate	9 (30.0)
College/trade/technical	8 (26.7)
High school	2 (6.7)
Relationship status	
Married	25 (83.3)
Dating	3 (10.0)
Single	1 (3.3)
Divorced	1 (3.3)
Relationship duration (years)	23.518 ± 11.723
(n = 28) Mean ± SD (range)	(2 – 42)
Reproductive health details:	
Menopause status:	
Post-menopause	26 (86.7)
Peri-menopause	3 (10.0)
Pre-menopause	1 (3.3)
History of hysterectomy	5 (16.7)
History of oophorectomy	5 (16.7)
Proportion with children	19 (63.0)
Mental health conditions	
Anxiety	6 (20.0)
Depression	5 (16.7)
Years since initial BrCa diagnosis	3.086 ± 2.425
Mean ± SD (range)	(0.78 – 10.10)
Treatment type:	
Completed chemotherapy	21 (70.0)
Completed surgery	30 (100.0)
Completed radiation	17 (56.7)
Herceptin	2 (6.7)
(during study)	
Endocrine (AI/Tamoxifen)	19 (63.3)
(during study)	
Years since treatment completion¹	2.220 ± 2.292
Mean ± SD (range)	(0.15 – 9.64)
Sexual Activity Status:	
Sexually active (n = 26)	26 (86.7)
Sexually active alone (n = 26)	17 (65.4)
Sexually active with a partner (n = 25)	20 (80.0)
Duration of sexual difficulties (#years)	2.761 ± 2.248
Mean ± SD (range)	(0.5 – 10.0)
Previous treatment (sexual)	7 (23.3)
Baseline sexual function	
Desire	2.280 ± 0.508 (1.20 – 3.60)
Arousal	2.496 ± 0.759 (0.90 – 4.50)
Lubrication	2.450 ± 1.266 (1.20 – 5.10)
Orgasm	2.750 ± 1.636 (0.00 – 6.00)
Satisfaction	3.184 ± 1.383 (0.00 – 5.20)
Pain	1.920 ± 1.621 (0.00 – 6.00)
Total Score (n = 23)	15.430 ± 5.044 (7.70 – 28.90)

¹Treatment completion excludes endocrine/herceptin therapy.

from baseline to post-treatment. In addition, we carried out a series of one-way repeated measures multivariate analyses of variance (MANOVA) to compare mean sexual distress, and sexual interest/desire scores over time. As is commonly used in interpretation of univariate ANOVA analyses within psychological research, partial eta squared (η_p^2) was used to assess effect size (Cohen, 1988). Interpretation was based on established intervals for magnitude of effect sizes (small = .010 – .039, intermediate = .060 – .110, and large = .140 – .200, Cohen, 1988).

Over half the sample (53%) completed an additional baseline assessment 8 weeks before the pretreatment assessment and therefore acted as their own treatment control, using a waitlist control design. Baseline and pretreatment assessment change scores were compared using a paired samples t-test, to determine if any changes in primary outcomes were observed while participants waited for the intervention.

Results

Referral pathways

One hundred and thirty-four women were assessed for eligibility (Figure 1). The majority (77%, $n=103$) had previously accessed other sexual health resources at the local cancer center and had indicated willingness to be contacted about future projects. Sixteen women (12%) who were on a waitlist for other sexual health programming were also contacted about the current study. Of those referred directly to the study, 10 women (7.5%) self-referred via study posters and 5 (3.7%) were referred by a healthcare provider.

Recruitment was sufficient to establish adequate numbers of participants for each group. A total of 4 groups took place over 18 months, with a target of 8 participants per group. To account for attrition, an initial cutoff for registration was set at 10 participants per group. Registration and pretreatment assessment was completed by 9 participants for Group #1, 9 participants for Group #2, 7 participants for Group #3, and 8 participants for Group #4 (Figure 1).

Participant demographics and baseline sexual health

Participants were primarily white (90%, $n=27$), highly educated (93%, $n=28$), and ranged in age from 38 to 69 years ($M=54$, $SD=8.2$). All participants had a breast cancer diagnosis. The average length of time from first breast cancer diagnosis to study enrollment was approximately 3 years ($SD=2.42$ years) and ranged from 0.78–10.10 years. Women reported a history of sexual difficulties ranging in duration from 6 to 120 months ($M=33$ months, $SD=27$ months). Demographic and health information is summarized in Table 1. Of note, 100% had completed primary cancer treatment, and 63% ($n=19$) were on tamoxifen or an aromatase inhibitor at the time of enrolling in the study (Table 1). Of 30 participants who enrolled and attended at least one session, 93% ($n=28$) fell within 5 years from treatment completion, and 7% ($n=2$) within 5-10 years.

At baseline, all 30 women (100%) met criteria for SIAD, according to clinician assessment (SIDI) (Clayton et al., 2010). Similarly, 27 participants (90%) reported experiencing significant sexual distress, and 3 participants (10%) indicated only some degree of distress (as per screening interview).

Attendance and adherence

Thirty women attended at least one group session, of whom 67% ($n=20$) attended six or more sessions. According to self-reports of homework adherence from the 20 women who provided responses, 95% ($n=19$) completed >50% of 23 total weekly home activities (Figure 2). On average, participants completed 112 minutes of mindfulness practice per week, with weekly averages for the group ranging from 49.54 minutes (week 8) to 166.35 minutes (week 2; See Figure 3). Total minutes per week of mindfulness practice ranged from 0 to 401 minutes.

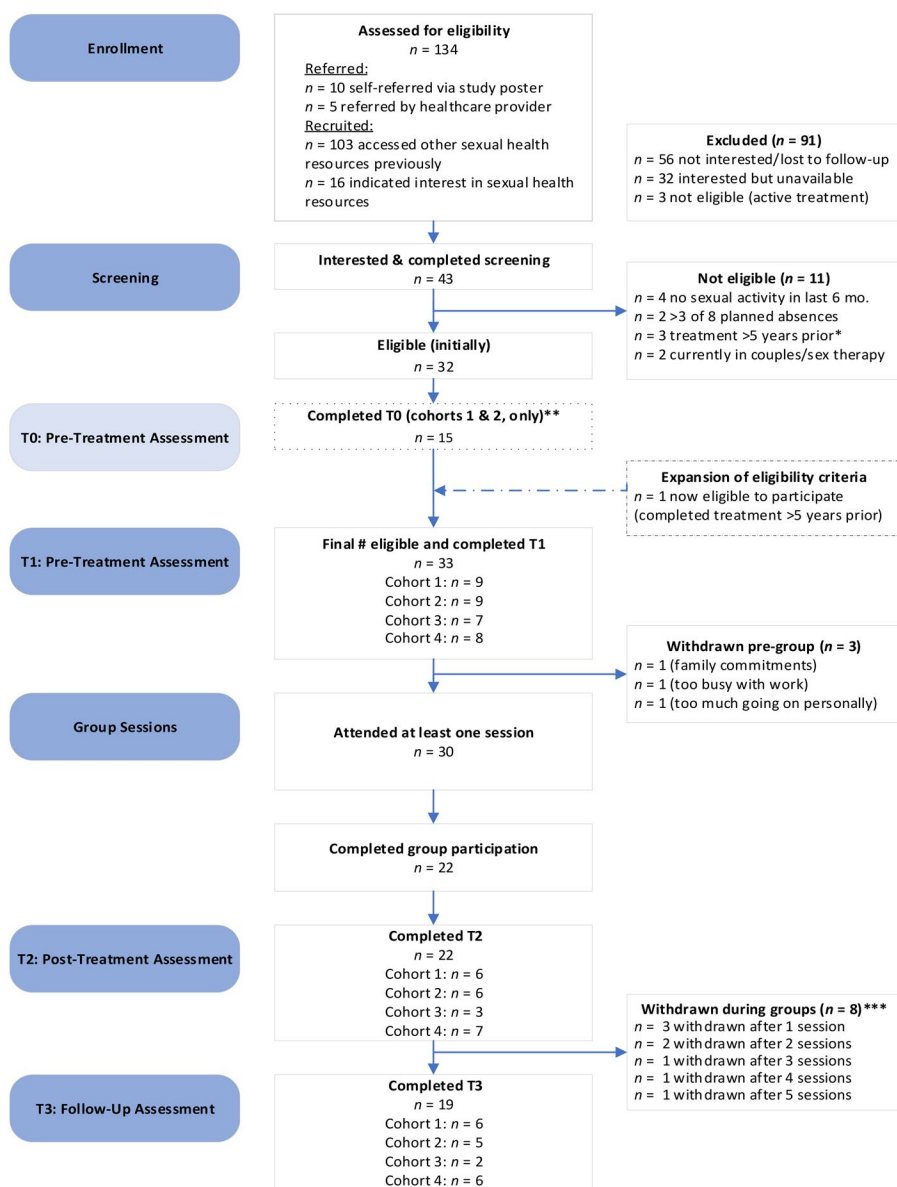


Figure 1. CONSORT diagram.*Eligibility requirements were adapted following recruitment of cohorts 1 and 2 to include those who completed treatment within approx. the past 10 years.**T0 was dropped part-way through the study due to feasibility concerns.***Reasons for withdrawal: fatigue; missed sessions due to travel plans; relationship difficulties; unable to continue due to poor health; missed sessions due to family commitments; overwhelm related to work and other commitments.

Attrition ranged from 33% (for 3 of 4 groups) to 57% (for 1 of 4 groups), which is higher than other recent trials of mindfulness for SIAD (Paterson et al., 2017). Of the 30 women who initially consented to participate, 63% ($n=19$) completed both the post-treatment and follow-up assessments. The current drop-out rate of 37% is consistent with rates observed in past studies of MBCT-based interventions among women with a history of cancer, which range from 18% (Brotto et al., 2012) to 37% (Brotto et al., 2008). When comparing those who dropped out versus those who completed the program, no significant differences were observed in terms of anxiety, time since treatment completion, type of cancer treatment(s) completed, sexual activity status, previous treatment for sexual difficulties, or total FSFI score. Significant differences between groups were found for age ($t(28) = 2.871$, $p = .008$) and relationship duration ($t(26) = 2.608$, $p = .015$). The same 8 variables were assessed when comparing participants who were waitlisted (cohorts 1 & 2) versus those who

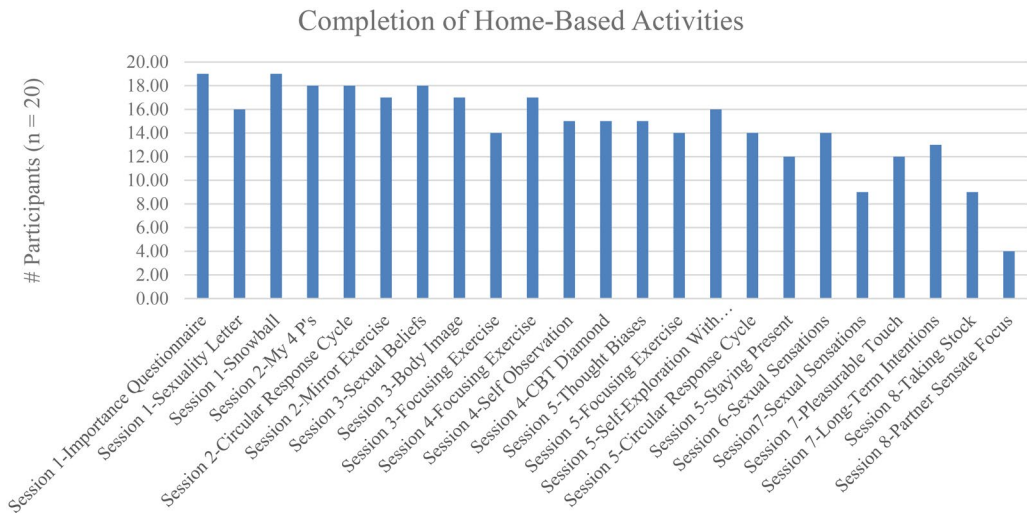


Figure 2. Number of participants who completed each home-based activity ($n=20$).

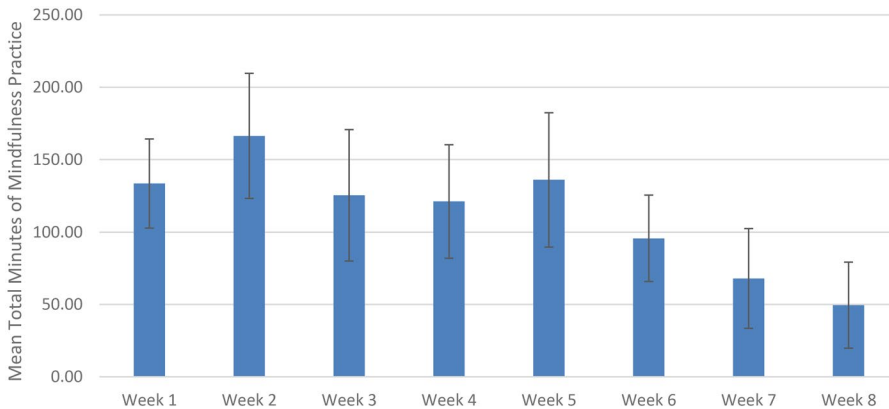


Figure 3. Average number of minutes per week of mindfulness practices ($n=20$ participants).

were not (cohorts 3 & 4). A greater number of waitlisted participants ($n=14$) versus non-waitlisted participants ($n=7$) reported a history of chemotherapy ($X^2(1, N=30) = 5.00, p = .046$). No other statistically significant differences between groups were found.

Changes in sexual distress and sexual interest/desire

A one-way repeated measures MANOVA revealed a significant effect of time on sexual distress scores and sexual interest/desire and arousal scores ($F=9.792(4), p < .001$), with large effect size ($\eta^2_p = .352$) (Table 2). Follow-up univariate ANOVAs showed that there was a statistically significant effect of time on sexual distress ($F=13.086(2, 36), p < .001$), with a large effect size ($\eta^2_p = .421$). Sexual distress significantly declined from pretreatment ($M=25.16, SD=11.12$) to post-treatment ($M=18.04, SD=11.66, p < .001$) but did not continue to significantly decline between post-intervention and 8-week follow-up ($M=16.74, SD=10.23, p = .360$) (Figure 4). There was a statistically significant effect of time on sexual interest/desire scores ($F=15.878(2, 36), p < .001$), with a large effect size ($\eta^2_p = .469$). Sexual interest/desire scores significantly improved from pretreatment ($M=21.75, SD=7.37$) to post-treatment ($M=29.77, SD=8.35; p=0.001$) (Figure 4). Scores declined between post-treatment and 8-week follow-up ($M=26.11, SD=7.75; p < .001$), but continued to remain higher than pretreatment scores ($p = .007$).

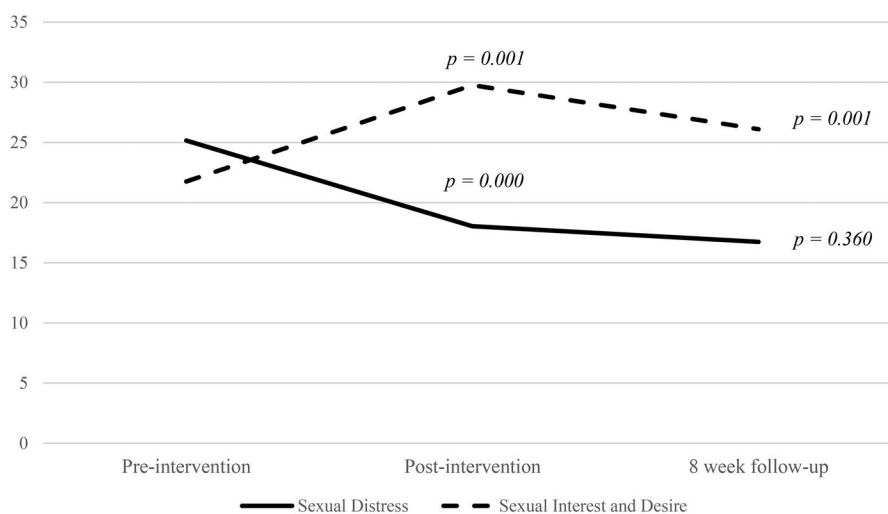


Figure 4. Changes in sexual distress and sexual interest/desire from pretreatment to 8-week follow-up.

Table 2. Multivariate analysis of variance results for sexual distress and sexual desire/interest.

Variable/Time	Mean	SD	Test type	F (df)	p	η_p^2
			Multivariate	9.792 (4)	<.001	.352*
Sexual Distress			Univariate	13.086 (2, 36)	<.001	.421*
Time 1 (T1)	25.16	11.12	T1 v. T2		.000	
Time 2 (T2)	18.04	11.66	T2 v. T3		.360	
Time 3 (T3)	16.74	10.23				
Sexual Desire/Interest			Univariate	15.878 (2, 36)	<.001	.469*
Time 1 (T1)	21.75	7.37	T1 v. T2		0.001	
Time 2 (T2)	29.77	8.35	T2 v. T3		<.001	
Time 3 (T3)	26.11	7.75	T1 v. T3		.007	

*Note: According to guidelines for the interpretation of effect sizes using partial eta squared (η_p^2), where small = .010 - .039, intermediate = .060 - .110, and large = .140 - .200, the results presented here are indicative of large effect sizes.

Two paired t-tests were conducted to compare baseline waitlist scores for the proportion of the group that waited 8 weeks before participating in the intervention. Baseline scores were compared to pretreatment scores. A significant reduction in sexual distress ($p = .037$) was noted between baseline ($M = 31.33$, $SD = 7.60$) and pretreatment scores ($M = 29.53$, $SD = 9.28$), with a small effect size ($\eta_p^2 = .0111$). No significant changes were observed in sexual interest/desire ($p = .604$) between baseline ($M = 20.05$, $SD = 7.23$) and pretreatment scores ($M = 20.68$, $SD = 7.74$), which indicated no effect ($\eta_p^2 = .0018$).

Analysis of post-treatment feedback

Following the final group session, participants were invited to provide written feedback about the group experience and content, as well as their thoughts on the application of MBCT specifically for women with a history of BrCa (Table 3). Responses were received from 18 participants and ranged in length from one half to one full hand-written page, providing a moderate amount of data for thematic content analysis. Themes relating to relevance of the group to breast cancer, satisfaction with the program and suggested changes were coded and are presented in Table 3.

Table 3. Participant written responses to post-intervention feedback questions.

Theme
<p>Breast cancer and changes in sexuality</p> <p>"My experience with breast cancer I felt like I lost a part of me. There is me before breast cancer and me after breast cancer. There are powerful judgmental thoughts, that snowball into worse thoughts. I didn't feel sexy. I had no desire to even touch myself."</p> <p>"Instead of stressing over lack of desire and decreased response, I am more willing to go ahead and see what happens this time. I don't have to want to do it; being willing to do it is enough."</p> <p>"In my case I feel I need [to] integrate the "losses" that come with aging with the changes that have resulted from cancer therapy."</p> <p>Re-discovering sense of self & sexuality</p> <p>"I feel like I'm finding myself again and it feels pretty great."</p> <p>"I feel like I'm going to be heading toward a place where I'm at peace with it. I'm comfortable with it. We can have that intimacy again. I feel lighter in my step. It feels like I'm running to the end of this course."</p> <p>Managing judgemental thoughts</p> <p>"Learning to meditate and accept the thoughts that come to mind, acknowledge them and let them go – without judgment – was great. I learned that thoughts come as one meditates – I'm not doing it wrong. I'm now aware of my thoughts while in meditation but can let them be – and continue to focus on my breath to come back to the present. Very good exercise for me – I judge myself a lot. Thoughts are not fact. Another thing I learned in group."</p> <p>"I have learned about "thoughts of judgment" while in meditation practice or looking at my body. I have noticed when my thoughts turn toward judgment and being aware of that and letting it go. [It's been] very freeing."</p> <p>Acceptance of post-cancer changes</p> <p>"I am less anxious about trying to recapture what has been lost and more willing to press on even if it takes longer or is less likely to result in orgasm. I figure if my husband can accept these changes then I can too – I don't have to feel bad about what is gone, I just have to carry on and appreciate what is."</p> <p>"Knowing that this [loss of desire] is common after breast cancer makes it easier to accept that my life and body have changed."</p> <p>"I enjoyed the group and although my sexual interest hasn't increased, I am more accepting of it and more willing to act "as if" I had some interest. Knowing that this is common after breast cancer makes it...easier to accept that my life and body have changed."</p> <p>Modifications to tailor the intervention more to breast cancer populations</p> <p>"I'm curious about the five-year window after treatment and what expectations we realistically should put on ourselves as we are sorting out a "new normal"</p> <p><i>Volume of information and homework & practices</i></p> <p>"Too much homework!"</p> <p>"I wish we had started with shorter meditations rather than jumping into 30-minute ones."</p> <p>"There was a lot of information. I was unable to complete all the exercises required during the sessions. I felt bad for not doing the exercises but learned to do my best."</p> <p><i>Need for information specific to cancer-related changes</i></p> <p>"...more discussion on the effect of the long-term drugs most breast cancer patients are on."</p> <p>"...could there be an added topic of dealing with the pain that is new since chemo?"</p> <p><i>Addressing diverse sexual concerns</i></p> <p>"It is also good to have options made available, in terms of mind set, lubrication and other sexual aides."</p> <p>"I'm glad exercises in body image and self-esteem were included. Suggestions on how to alleviate pain, like lubes, dilators, and moisturizers, were also appreciated. Free samples are great!"</p> <p>Importance of the shared experience and normalization of concerns</p> <p>"It's nice to know I'm not by myself. Because for a while I thought something was wrong with me. In the group, with eight of us sitting here, I felt like I'm not alone. It's just such a relief to know that there are other people going through this."</p> <p>"The information normalized my experience and took a bunch of guilt and weight off my shoulders."</p> <p>"It was oddly comforting as there was a feeling of camaraderie knowing other women were struggling and concerned about their lack of desire despite being in loving relationships."</p> <p>Benefits of mindfulness</p> <p>"...using mindfulness, meditation to get back in touch with one's sexual desire is brilliant."</p> <p>"Mindfulness has allowed me to slow the "noise" in my head thus allowing me to concentrate on more important areas in my life."</p> <p>"And knowing how mindfulness and the power of the mind has so much effect not just on sexual issues but on many things."</p> <p>Psychoeducation</p> <p>"It was so helpful to learn that spontaneous desire is not necessarily the starting point for arousal."</p> <p>Professional facilitation of the group</p> <p>"I appreciate that the program facilitators created a comfortable space so that anything was okay to discuss. This allowed for informative sharing."</p> <p>"The experience and most of all both instructors were very well trained and made it a very positive experience that will stay with me."</p> <p>"It was an open and safe place to discuss issues."</p>

(Continued)

Table 3. (Continued).**Communication with a partner**

"It has made a significant difference in my understanding and ability to reenter into a sexual relationship with my friend-with-benefits (I had stopped pre-group) and almost even more importantly – to feel that these issues are normal and to open up the lines of communication and closeness (emotionally) with my partner. He really appreciates what we learned as well. Sexual health is so important!"

"As much as this is an individual journey it is also a couple's journey."

"I'm have gratitude because it's opened up communication between my husband and myself. I go home after each group and talk about what we've done, and what I've learned. I'm actually comfortable talking to him about it, and that's a huge step. I mean, if you can't even talk about sex, then how are you going to actually perform sex?"

Comments reflected the importance of comprehensively addressing diverse post-cancer sexual concerns. An array of difficulties were reported, including negative or judgmental thoughts, body image concerns, a sense of grief and loss, disconnect from sexuality, and coping with forced menopause. Information about vaginal health treatments (e.g., moisturizers and lubricants), though only briefly presented in the intervention, was identified as a valuable aspect. Comments also indicated that normalization of post-cancer sexual concerns helped to minimize distress and promote a sense of acceptance.

Some participants suggested further adaptations of program content to best suit the needs of BrCa patients. Participants described difficulties related to the volume of content and time commitment required for home-based activities. Some participants also expressed value in additional information on cancer-related fatigue and suggestions for self-pacing and managing expectations for completing home activities. A couple of participants also suggested the addition of content related to other areas of concern for BrCa patients (e.g., information on tamoxifen/aromatase inhibitors and post-chemotherapy pain).

Several benefits were associated with the intervention, including a new sense of hopefulness, openness, and acceptance about changes in sexual desire, as well as a new-found understanding that enjoyable sexual experiences are still possible in the context of reduced sexual desire. Both the mindfulness practices and sex education were described as helpful aspects in changing expectations and awareness of sexual desire. As expressed by many participants, MBCT content and practices were impactful and extended into other areas of life, promoting a sense of presence during daily activities, and increasing "awareness of stress before it grows out of control". When describing their experiences with the group program, several participants emphasized the value of social support provided within the group context and how this resulted in feeling less alone. Participants also noted the importance of the open, safe, and supportive space fostered by the group facilitators.

Discussion

This study involved the novel application of an 8-week MBCT program, specifically adapted to address the unique concerns of women with SIAD following BrCa treatment. To account for BrCa-related sequelae, the duration of group sessions and assessments was reduced, and intervention content was modified to include discussion of the effects of cancer treatment. This pilot intervention study sought to build upon the promising results found in previous research involving MBCT-based programs for sexual difficulties (Brotto et al., 2012, 2021; Brotto & Basson, 2014; Paterson et al., 2017). This study is among the first to assess the use of MBCT for sexual concerns, specifically in women with SIAD following BrCa. As such, we aimed to determine feasibility and acceptability of the MBCT intervention in this context. Given findings of high group attendance, good completion rates of weekly home activities/mindfulness practices, as well as attrition rates that largely paralleled those of similar studies, MBCT can be considered a feasible and acceptable intervention among BrCa patients. Secondary objectives included examination of post-intervention changes in sexual distress and desire, the results of which demonstrate post-intervention improvements in both outcomes.

Prior to participating in the 8-week group intervention, all 30 women met criteria for SIAD and 90% of participants met criteria for clinically significant levels of sexual distress at baseline. While the MBCT intervention was specifically targeted toward BrCa patients with low sexual desire, the types of sexual concerns reported by participants were varied. Given the diversity of sexual symptoms reported, an expansion of program content to address other types of sexual concerns is pertinent and appropriate. For example, evidence suggests that in addition to sexual desire, sexual pain can be managed using mindfulness approaches (Brotto et al., 2021; Guillet, Cirino, Hart, & Leclair, 2019; Paterson et al., 2017).

Patient population & acceptability

Good attendance and adherence to weekly homework and mindfulness practices suggests this MBCT program is feasible and acceptable among a group of women with SIAD following breast cancer. Most participants were able to attend a minimum of 6/8 group sessions and to complete at least 50% of daily home activities. Despite patient reports of too much homework, the average self-reported time devoted to weekly at-home mindfulness practices was relatively consistent with previous research among women with SIAD in the general population. However, rates of mindfulness practice completion decreased substantially from weeks 6-8, with the average number of minutes per week reduced by nearly 2/3 at the end of week 8 versus week 1. Indeed, participant feedback indicated challenges associated with completing weekly at-home activities which may have had a cumulative effect in later weeks of the intervention.

Participant feedback about the intervention

According to written responses provided at post-intervention follow-up assessments, participants found the MBCT intervention to be relevant and helpful for addressing their sexual health concerns. Participants' responses affirmed that cancer-related impacts on sexual desire manifest in concert with other changes to sexual response and physiology (e.g., vulvo-vaginal health). Although the central focus of the intervention was management of low sexual desire, participants acknowledged the usefulness of comprehensively addressing a range of concerns related to the BrCa experience, including body image considerations, feelings of disconnect from sexuality, coping with forced menopause, and managing negative self-directed thoughts and difficult emotions including a sense of grief and loss. Participants reported benefits associated with normalization of their concerns.

While the MBCT program was described as beneficial, adjustments to content and structure were suggested to further tailor the intervention for women with a history of BrCa. The time and energy required to complete weekly home activities and mindfulness practices posed a significant challenge, particularly if cancer-related fatigue was also present. In spite of the endorsed difficulties, participants still managed to complete a fair amount of home activities, averaging 112 minutes per week of mindfulness practice, with 95% completing over half of the home activities. Minimizing the number or duration of weekly home-based practices may increase program acceptability and adherence. Comments indicated diverse impacts of cancer on sexual wellbeing beyond the loss of desire (e.g., vulvo-vaginal dryness and pain, changes in sensation, body image concerns). Accordingly, participants suggested integrating additional group content for managing these topics.

Comments also highlight two key aspects of the MBCT intervention that were of particular benefit: the group setting (e.g., professional facilitation and social support), and learnings related to mindfulness theory and practice. Participants expressed appreciation for the comfortable, supportive group environment fostered by facilitators and noted the importance of a sense of camaraderie amongst group members. Participants also described wide-reaching benefits of learning mindfulness concepts and practices.

Changes in sexual distress and sexual interest/desire

Our focus was on effect sizes and preliminary efficacy of outcomes. Results of pre-post assessments indicated significant reductions in sexual distress and improvements in sexual interest/desire immediately following intervention completion and at the 8-week follow-up, with high effect sizes. This is consistent with previous trials in which MBCT interventions were implemented among women with a history of gynecological cancer (Brotto et al., 2021) and among otherwise healthy women with SIAD (Paterson et al., 2017), and provides preliminary evidence of efficacy. Improvements in sexual distress and sexual interest/desire plateaued after the immediate post-group assessment, suggesting that regular, professionally-facilitated group support may itself play a particularly important role in regulation of distress and desire. It has been proposed that rumination and negative affectivity about sex may be key to the persistence of sexual distress and SIAD; moreover, decreases in rumination and negative thinking are associated with mindfulness-based interventions (Brotto et al., 2021; Pascoal, Raposo, & Roberto, 2020). A larger, controlled trial with longer follow-up periods is warranted and would offer insights into potential factors affecting post-intervention levels of distress and interest/desire.

For the subset of the sample that were on a waitlist prior to starting the intervention, sexual distress decreased, and sexual interest/desire remained the same, during this 8-week pretreatment period. It is possible that the very idea of potentially receiving support was associated with a decrease in distress.

Strengths & limitations

This is one of the first trials in which an 8-week MBCT intervention has been assessed for treatment of SIAD in the BrCa population. The use of clinical assessment of SIAD rather than self-reported sexual symptoms is a strength. This pilot study demonstrated feasibility and acceptability of the MBCT intervention; moreover, findings offer insights about further adaptations to best meet the needs of the BrCa population that could be incorporated into a future larger trial. Feedback indicates that in-person assessments and the volume of home activities was onerous. Therefore, future offerings may benefit from reducing requirements related to assessments and home activities to account for cancer-related fatigue.

An additional limitation was that dropouts were high; however, a comparison of those who dropped out versus those who completed the program revealed that only age and relationship duration were significantly different. Moreover, across all 4 cohorts, participants made clear efforts to engage in the program. For example, although only 2 participants from cohort 3 completed all 3 assessments, 5 participants attended at least one group session, 4 attended at least 4 group sessions, and 3 completed make-up sessions. Participants in this feasibility trial were predominantly high SES, white, and highly educated. Future efforts to implement the MBCT intervention may consider factors related to accessibility (e.g., offering the program after work hours, providing virtual sessions for rural participants). Despite endorsing low sexual desire and high sexual distress, several women were initially excluded from the study due to sexual activity status. Importantly, one might argue that these women had an even greater need for the intervention, as symptoms may have prevented them from being sexual.

Certainly, a weakness of this study was the lack of an active treatment control. This study was intentionally designed without a control group to focus on feasibility and acceptability, and to determine effect sizes to inform a future larger, controlled trial. Additional efforts were made to provide some degree of assessment of waitlist effects, with an additional waitlist time-point collected for roughly half the sample. Real-world implementation challenges led to the abandonment of this extra timepoint halfway through the study.

Additionally, while recruitment was demonstrated to be feasible according to predetermined targets, obtaining sufficient numbers to run groups required effortful engagement from the study team (e.g., direct-to-patient phone calls). To address recruitment barriers, a modification of

inclusion criteria was implemented part-way through recruitment to allow for the inclusion of BrCa patients who had completed primary cancer treatment >5 years prior. Recruitment outcomes may therefore not be generalizable to the context of real-world implementation in a cancer center, in an exclusively clinical setting where active recruitment is not feasible.

Conclusion

A novel 8-session mindfulness-based intervention to treat SIAD was applied to women with a history of BrCa, thus extending the small body of research testing briefer mindfulness interventions in other populations of cancer patients with sexual concerns. These preliminary studies employed strict inclusion criteria which ultimately posed a barrier to recruitment and feasibility, as was the case in the current study. Our exploration of referral pathways revealed a need for active recruitment (i.e., contacting potential participants directly), as referrals from healthcare providers were insufficient to fill groups. Our preliminary findings suggest that an 8-week MBCT intervention is associated with reductions in sexual distress and improvements in sexual interest/desire. Future studies involving assessment of potential mediators, including mindfulness-related mechanisms, are warranted. To address barriers to participation and to increase feasibility, an expansion of inclusion criteria and an exploration of healthcare provider referral pathways are needed.

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