A randomized comparison of online mindfulness-based group sex therapy vs supportive group sex education to address sexual dysfunction in breast cancer survivors

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Abstract

Background. Sexual difficulties and vaginal pain are common following treatment for breast cancer.
Aim. The goal of this study was to evaluate an online mindfulness-based group sex therapy vs an online supportive sex education group therapy to address these sexual difficulties.
Methods. Breast cancer survivors (n = 118) were randomized to 1 of the 2 arms; 116 provided informed consent and completed the time 1 assessment. Treatment included 8 weekly 2-hour online group sessions. Those randomized to the mindfulness group completed daily mindfulness exercises, and those in the comparison arm read and completed exercises pertaining to sex education.
Outcomes. Assessments were repeated at posttreatment and 6 months after the completion of the group.
Results. There was a main effect of treatment on primary endpoints of sexual desire, sexual distress, and vaginal pain, with all outcomes showing significant improvements, with no differential impact by treatment arm. Secondary endpoints of interoceptive awareness, mindfulness, and rumination about sex also significantly improved with both treatments, with no group-by-time interaction.
Conclusion. Both mindfulness-based sex therapy and supportive sex education delivered in group format online are effective for improving many facets of sexual function, vaginal pain, rumination, mindfulness, and interoceptive awareness in breast cancer survivors.
Strengths and Limitations. We used a randomized methodology. Future studies should seek to diversify participants.
Clinical Implications. These findings highlight the need to offer similar treatments to more breast cancer survivors immediately after and in the years following cancer treatment as a means of improving survivorship quality of life.

Keywords: breast cancer; survivorship; sexual desire; sexual dysfunction; mindfulness; sex education.

Introduction

Globally, there are approximately 2.3 million women diagnosed with breast cancer (BrCa) every year, and of those, 685 000 will succumb to their illness.[1] As survival rates have been increasing due to advances in treatment, this has resulted in prioritization of survivorship concerns. Chief among the difficulties faced by survivors are issues of sexual dysfunction, which begin during treatment and persist long into survivorship.[2-5] The prevalence of sexual concerns after BrCa treatment is high, with up to 86% of survivors experiencing difficulties.[3,5,6] The most prevalent concerns include decreased sexual desire, arousal, lubrication, anorgasmia, and sexual pain.[5,7,8] Women younger than 50 years of age have the highest rates of sexual difficulties, which are often compounded by reproductive concerns including fertility potential after chemotherapy.[9,10]

Between 42% and 86% of BrCa survivors experience low sexual interest,[6,11] and 48% to 74% experience difficulties with vaginal lubrication.[12,13] Chronic low sexual desire associated with significant personal distress is formally classified as sexual interest/arousal disorder (SIAD), and a diagnosis requires 3 of 6 criteria for a period of 6 months.[14] Pain with sexual activity is also common following treatment for BrCa due to vaginal dryness,[10-12] and can reduce or altogether eliminate sexual activities due to fear of pain[15] and also negatively influence sexual desire. Symptoms of low desire and vaginal pain typically persist if left untreated[15] and can drastically impact quality of life,[8,16] identity, self-image, confidence, social roles, and intimate relationships.[2,17] Most women suffer in silence without receiving adequate treatment.

Pharmacological interventions targeting low desire (eg, flibanserin) have limited applications in this population due to modest efficacy, high side-effect profiles, and low consumer uptake.[18-21] However, 2 small studies funded by the makers of flibanserin found statistically significant benefits to sexual desire and reduced distress among BrCa survivors.[22,23] While promising, patients may prefer nonpharmaceutical treatments.

Despite solid evidence supporting psychological treatments for sexual concerns,[24-26] the literature evaluating psychological treatments for sexualodifficulties after BrCa

is much more limited. A Cochrane review published in 2016 found that although there was some support for the efficacy of psychological treatments (mostly cognitive behavioral and psychoeducational) in improving sexual function after BrCa, many of these reviewed studies lacked methodological detail on the interventions delivered.[27] More recently, a randomized trial of Internet-delivered cognitive behavioral therapy (which lasted up to 24 weeks) for BrCa survivors with sexual dysfunction showed significant improvements in desire, arousal, lubrication, pleasure, and pain compared with a control group.[28] Apart from these effective cognitive behavioral treatments, in women without a history of cancer, there is considerable evidence specifically that mindfulness meditation-based interventions are effective in treating low sexual desire and arousal.[29-31] Mindfulness approaches aim to cultivate present-moment attention to sexual experiences in an accepting and nonjudgmental manner.[32] Delivered in 4-session[30] and 8-session[31] formats, mindfulness-based cognitive group therapy for sexual desire and arousal concerns demonstrates significant improvements in sexual desire, overall sexual function, and sexual distress. Compared with a psychoeducational supportive-expressive group, the 8-session mindfulness group led to significantly greater improvements in sexual distress, rumination, and relationship satisfaction, all retained 1 year later.[29] When a similar 8-session mindfulness group intervention was compared with cognitive behavioral therapy for women with vaginal pain (provoked vestibulodynia),[33] the former led to significantly greater improvements in pain associated with vaginal insertion, also maintained 1 year later.[34]

Given the prominence of sexual desire/arousal symptoms and persistent vulvovaginal pain in BrCa survivors,[3,5,35] these studies suggest that mindfulness may be a particularly promising approach to address BrCa-associated sexual concerns, which often include both sexual desire and sexual pain difficulties.[36,37] An existing efficacious mindfulness-based treatment for low desire[29] and for genital pain[34] in noncancer survivors was adapted to BrCa survivors specifically by including information about cancer-associated sexual difficulties, survivorship symptoms that impact attention, energy, and mood, and in turn sexual health, and cancer-specific beliefs that could be the target in mindfulness exercises. A pilot study evaluating this 8-week group mindfulness treatment for BrCa survivors who met criteria for SIAD (many of whom also experienced vulvovaginal pain)[38] found that sexual distress significantly decreased from pre- to posttreatment, with an observed large effect size. Importantly, effects remained stable at 8-week follow-up.[38] Sexual desire also significantly improved from pre- to posttreatment, with a demonstrated large effect size, but scores decreased somewhat at the 8-week follow-up time point.[38] Another study evaluated standard mindfulness-based stress reduction in BrCa survivors, without adaptation for sexual concerns, and found that participants experienced improvements in sexual desire and sexual arousal but not sexual pain.[39]

In qualitative responses provided by BrCa survivors who participated in a pilot study of this 8-session mindfulness intervention, participants reported that the mindfulness provided tools for them to address their body image, feelings of disconnect from sexuality, menopausal symptoms, and negative and judgmental thoughts pertaining to grief and loss.[38] Despite their significant improvements in sexual desire (the main outcome), participants also proposed a number of improvements to the intervention that they suggested be

incorporated before it was subjected to a larger clinical trial. Their feedback was incorporated into the present mindfulness-based cognitive therapy for sexual concerns after BrCa (MBCT-Br) intervention.

The goal of this study was to evaluate an online mindfulness-based group sex therapy to address sexual difficulties (low desire and vaginal pain) in BrCa survivors. We chose to include supportive-expressive sex education as our comparison group for a few reasons: (1) the mindfulness group comprised mindfulness plus sex education, and therefore having an education-only comparison group allowed for a pure test of the effects of mindfulness skills; (2) compared with a supportive sex education, group mindfulness in non-BrCa survivors has shown superiority of mindfulness for sexual distress, but not for sexual desire, and as such, this study allowed for a replication of that design but in BrCa survivors; and (3) education alone is often the only treatment available to generalists or family physicians without specialized training, and thus the present analysis of the effect of sex education would have implications for generalist healthcare providers. Our 3 co-primary endpoints included sexual desire, sexual distress, and vaginal pain. Leveraging the finding that online delivery of mindfulness and other sex therapies can be as effective as face-to-face treatments,[40] combined with the fact that this study began in early 2020 when COVID-19 safety measures prevented in-person psychological therapy, both treatments were administered entirely online.

We hypothesized that compared with baseline, the mindfulness group vs the sex education group would have significantly greater posttreatment as well as 6-month follow-up improvements in primary outcomes of (1) sexual desire, (2) sexual distress, and (3) sexual pain. We assessed 3 secondary outcomes based on the findings of the same mindfulness intervention in noncancer survivors, which found significant beneficial effects of mindfulness on (4) rumination about sex, (5) mindfulness, and (6) interoceptive awareness. We predicted stronger effects for the mindfulness group compared with the sex education group for each of these primary and secondary outcomes. A number of additional variables were assessed as potential mediators (acceptance, pain catastrophizing, depression) and moderators (type of cancer treatment), and those will be the subject of a separate article. These hypotheses were preregistered at ClinicalTrials.gov (NCT04472104).

Methods
Study design

This study was designed as a randomized, unblinded 2-site clinical trial to evaluate mindfulness-based cognitive therapy for sexual concerns in BrCa survivors (MBCT-Br) vs supportive-expressive psychoeducation for BrCa (STEP-Br). Assessments were conducted at baseline (t1), 1 to 2 weeks after completion of the eighth session (t2), and 6 months after completion of the eighth session (t3). Participants were recruited from 2 sites (Vancouver, Canada and Calgary, Canada). The trial protocol was preregistered at ClinicalTrials.gov (NCT04472104) and was approved by the Behavioural Research Ethics Board at the University of British Columbia (H19-02480) and the Health Research Ethics Board of Alberta Cancer Committee (HREBA.CC-19-0320).

Participants

Inclusion criteria were: identification as a woman, 19 years of age or older, history of BrCa treatment, minimum 3

months following treatment completion, fluent in English, and a sexual distress score exceeding the clinical cutoff (11 or higher on the Female Sexual Distress Scale–Revised).[41] Participants were eligible regardless of relationship status but were required to have engaged in sexual activity either alone or with a sexual partner in the past 6 months, or to indicate willingness to engage in sexual activity (alone or partnered) during the study period. Exclusion criteria included: active cancer treatment (eg, chemotherapy or radiation, not including consistent endocrine or maintenance therapy), or scheduled breast reconstruction during the study period. Participants who expressed characteristics that might preclude their ability to fully participate in the online group sessions (eg, stating that they would not interact in a group setting) were also excluded. In order to determine whether any changes in symptoms were a result of participation in the intervention, participants must also have agreed to (1) not make changes to or commence vaginal interventions (eg, vaginal hormone treatments, moisturizing, dilation) or (2) engage in other treatments for sexual difficulties (eg, sex therapy) for 2 weeks prior to the baseline assessment until 2 weeks following the final intervention session. Although we did not exclude on the basis of current anxiety or depressive symptoms, any prospective participant who declared a negative impact of their mental health symptoms on daily functioning during the telephone screen was excluded from participating, and provided mental health resources.

Group assignment

Due to the scheduling demands and considerable investment of time associated with weekly participation in group sessions we first grouped participants according to their availability and then we randomized groups into the treatment rather than individual participants. Groups ranged in size from 4 to 9 participants, with 80% of groups having 6 to 8 members.

Treatments

Both treatments were delivered over 8 weekly group sessions, 2 hours in length, by 2 PhD-level clinical psychologists or registered clinical counselors (or PhD senior trainees) with specialized training in sex therapy, mindfulness, and previous facilitation experience. The Vancouver site had 6 facilitators, all of whom were dually trained in both intervention arms. One facilitator was an upper-level PhD student who was directly supervised by L.A.B. There were 2 group facilitators at the Calgary site only. In addition to their attendance at the 8 group sessions, participants were asked to complete weekly homework assignments (eg, self-reflection exercises, worksheets, meditation for the MBCT-Br condition). As is customary in mindfulness-based interventions, participants were invited to practice mindfulness and associated homework exercises for up to 60 minutes per day (comprising a variety of different mindfulness practices). As the STEP arm did not have any mindfulness instruction, homework was estimated at 10 minutes per day. Participants received handouts specific to their treatment arm at the conclusion of every session.

The MBCT-Br protocol was previously pilot tested[38] and underwent further revision based on qualitative feedback from BrCa survivors who participated in the pilot study. As detailed in Supplementary Table 1, the MBCT-Br treatment integrated education, mindfulness skills, daily mindfulness practice, and sex therapy exercises. Factoring in that many BrCa survivors may experience fatigue as well as cognitive impacts due to chemotherapy, the exercises were delivered at a manageable pace and described in plain language. The STEP-Br protocol contained the same sexuality education as that provided in the MBCT-Br arm (eg, on the prevalence and etiology of SIAD as well as vaginal pain following BrCa, illustration of the sexual response cycle and how cancer treatment may impact it) but without elements of mindfulness theory or practice. In other words, the STEP-Br group contained all of the same educational elements as the MBCT-Br group except the mindfulness exercises. Group facilitators encouraged participants to discuss their concerns and provide peer support by helping participants express their emotions, and by modeling empathy and validation toward group members.

Procedures

We recruited participants through (1) recruitment flyers placed at BC Cancer (British Columbia) and Tom Baker Cancer Centre (Alberta) follow-up BrCa clinics; (2) flyers at the After Breast Cancer (ABC) clinic designed for women after primary BrCa treatment, located at a tertiary care women's hospital (British Columbia), as well as the Breast Cancer Supportive Care Clinic (Alberta); (3) British Columbia and Alberta cancer registries, which distributed study information to all patients recently treated for BrCa; (4) advertisements on social media (Instagram, Facebook, and Twitter) using the authors' existing social media accounts; (5) direct referrals from oncology and psychosocial oncology clinicians (AB); and (6) previous attendees of the Tom Baker Cancer Centre's OASIS (Oncology and Sexuality, Intimacy and Survivorship) program.

Interested candidates contacted the study coordinator at each site via telephone or email. A detailed phone screen was used to assess eligibility and explain study methods. Consenting participants completed a phone interview with one of the group facilitators to assess fit for the group. The interviewer asked potential participants about the history of their current sexual concerns, and in particular its relation to BrCa diagnosis and treatment. The interviewer also asked prospective participants about their trauma history, and evaluated current symptoms of dissociation and trauma. While these symptoms were not used as a basis for exclusion, the interviewer did explain that some participants who are randomized to the mindfulness arm might have unique experiences with mindfulness (of note, these were described as neither positive nor negative). The interviewer also informally observed any traits that would make participation in a group challenging (eg, tendency to repeatedly interrupt, unwillingness to turn camera on, etc.). Finally, they asked about current treatments received for their sexual concerns, and emphasized that enrolled participants would need to agree to put all treatments on hold until they reached their 6-month posttreatment time point. Enrolled participants chose a time availability and were assigned to a group of other participants with matching schedules. Those groups were then randomized to 1 of the 2 conditions (MBCT-Br or STEP-Br). Participants received a unique Qualtrics link to complete their pretreatment questionnaires (t1).

Study participants each received a small vaginal insert (dilator), a few single-use lubricant packages, a small vibrator, and instructions for logging on to the online platform. Sessions were audio-recorded for training purposes (in the case of 1 trainee serving as a group facilitator). For these sessions, L.A.B. listened to the recordings and provided clinical supervision and guidance to the trainee/facilitator. Participants were

Table 1. Demographic characteristics of participants randomized to the sex education (STEP-Br) and mindfulness-based cognitive therapy (MBCT-Br) treatment arms.

Measure	STEP-Br	MBCT-Br	Total
Number of participants	56	60	116
Age, y	50.9 ± 7.5	49.0 ± 11.0	49.9 ± 9.5
Relationship status			
Single	7 (12.5)	8 (13.3)	15(12.9)
Short-term relationship	1 (1.8)	1 (1.7)	2 (1.7)
Long-term relationship	48 (85.7)	50 (83.3)	98 (84.5)
Missing values	0	1	1
Length of current relationship, y	20.3 ± 10.8	19.8 ± 10.7	20.1 ± 10.7
Missing values	6	9	15
Ethnicity			
Arabic	2 (3.6)	0 (0)	2 (1.7)
Black	0 (0)	1 (1.7)	1 (0.9)
Chinese	6 (10.7)	1 (1.7)	7 (6.0)
Filipino	3 (5.4)	2 (3.3)	5 (4.3)
Hispanic	1 (1.8)	0 (0)	1 (0.9)
Indigenous	4 (7.1)	0 (0)	4 (3.4)
Japanese	0 (0)	2 (3.3)	2 (1.7)
White	39 (69.6)	53 (88.3)	92 (79.3)
Other	1 (1.8)	1 (1.7)	2 (1.7)
Sexual orientation			
Asexual	2 (3.6)	1 (1.7)	3 (2.6)
Bisexual	4 (7.1)	2 (3.4)	6 (5.2)
Heterosexual	49 (87.5)	54 (91.5)	103 (89.6)
Lesbian	1 (1.8)	1 (1.7)	2 (1.7)
Pansexual	0 (0)	1 (1.7)	1 (0.9)
Missing values	0	1	1
Education			
Graduated high school or earned GED	2 (3.6)	1 (1.7)	3 (2.6)
Attended some college	12 (21.4)	7 (11.9)	19 (16.5)
Graduated college	37 (66.1)	30 (50.9)	67 (58.3)
Postgraduate degree	5 (8.9)	21 (35.6)	29 (22.6)
Missing values	0	1	1
Significant medical history[a]	28 (50.9)	35 (58.3)	63 (54.3)
Missing values	1	0	1
Number of months with current sexual concerns, mean $\pm$ SD	48.7 ± 39.5	47.6 ± 40.9	48.1 ± 40.0
Missing values	1	0	1
Report a history of sexual assault			
As an child	7 (13.5)	13 (23.2)	20 (18.5)
As an adult	10 (19.2)	8 (14.3)	18 (16.7)
As a child and as an child	4 (7.7)	4 (7.1)	8 (7.4)
Missing values	4	4	8
Ever treated by a professional for sexual dysfunction	4 (7.3)	6 (10.2)	10 (8.8)
Missing values	1	1	2

Values are n, mean $\pm$ SD, or n (%). Abbreviations: MBCT-Br, mindfulness-based cognitive therapy for sexual concerns after breast cancer; STEP-Br, supportive-expressive psychoeducation for sexual concerns after breast cancer. [a]Reported based on participants endorsing 1 or more of the following: diabetes, heart attack, stroke, asthma, emphysema, breathing problems, stomach ulcer, irritable bowel syndrome, other gastrointestinal issues, kidney disease, depression, anxiety, seizures, drug problems, alcohol problems, or other health condition.

advised that if they missed a group session, a one-on-one make-up session with one of the facilitators would be strongly encouraged and was scheduled accordingly.

After completing the first of 8 sessions, participants completed a measure of treatment expectations. They were also asked to complete a genital pain rating activity, which involved inserting the lubricated vaginal insert into their vagina and self-reporting their level of vulvovaginal pain from 0 (no pain) to 10 (highest level of pain imaginable). Following session 4, participants completed anxiety (Generalized Anxiety Disorder-7)[42] and depression (6-item version of the Hamilton Depression Rating Scale)[43] measures, which were used to assess possible mediating effects on primary outcomes (data not discussed). Two weeks after the final session (t2), participants repeated the outcome measures administered at t1 as well as the vaginal pain rating. These same measures were assessed 6 months after the final session (t3).

Outcome measures

The following demographic variables were assessed: age, relationship status, education, income, disease characteristics, sexual health characteristics (eg, menopausal status, severity of sexual symptoms, history of having sought treatment for a sexual difficulty), and history of sexual abuse.

Treatment credibility

All participants were asked, "To what extent do you think the treatment you will receive is logical in terms of alleviating your sexual concerns?" (rated from 0 [not at all] to 10 [completely]) and "To what extent do you expect improvement in your sexual response/function as a result of this treatment?" (rated from 0 [no improvement] to 10 [complete improvement]). Treatment credibility was assessed after the first of the 8 sessions so participants had some information about the

treatment, allowing them to form an opinion about how well it would work.[44] A mean score of the 2 questions was computed and ranged from 0 to 10.

Primary outcomes

The primary outcome, sexual desire, was assessed with the 13-item Sexual Interest and Desire Inventory–Female total score.[45] Possible total scores range from 0 - 51, with higher scores indicating higher levels of sexual desire. In this sample, Cronbach's alpha at pretreatment was 0.81. The second co-primary outcome, sexual distress, was assessed with the Female Sexual Distress Scale–Revised.[41] This 13-item self-report measure can discriminate women with sexual dysfunction from healthy controls. Scores range from 0 to 52. In this sample, Cronbach's alpha at pretreatment was 0.92. The third co-primary outcome was vaginal pain. Consistent with the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendations,[46] vaginal pain was assessed using a Numeric Rating Scale of 0 to 10 (from no pain to worst possible pain).

Secondary outcomes

The 3 secondary outcomes included rumination, mindfulness, and interoceptive awareness. Rumination was assessed with the Rumination-Reflection Questionnaire.[47] Rumination is defined as "self-attentiveness motivated by perceived threats, losses, or injustices to the self"; reflection is defined as "self-attentiveness motivated by curiosity or epistemic interest in the self." The rumination subscale of the questionnaire was previously adapted to reflect ruminations about sex and was found to yield very high reliability.[29] For example, item 1, "My attention is often focused on aspects of myself I wish I'd stop thinking about," was adapted to "My attention is often focused on aspects of my sexuality or sex life I wish I'd stop thinking about." The total mean score ranges from 1 to 5, and higher scores indicate more rumination. In this sample, Cronbach's alpha at pretreatment was 0.94. The second secondary outcome was mindfulness, measured with the 15-item Five Facet Mindfulness Questionnaire[48] total mean score, which ranged from 1 to 5, with higher scores indicating greater mindfulness. The Five Facet Mindfulness Questionnaire has been found to have adequate to good internal consistency, with alphas ranging from 0.72 to 0.92. In this sample, Cronbach's alpha at t1 was 0.57. The final co-secondary outcome was interoceptive awareness, measured with the 32-item Multidimensional Assessment of Interoceptive Awareness.[49] Questions were answered on a 6-point Likert scale ranging from 0 (never) to 5 (always). The Multidimensional Assessment of Interoceptive Awareness measures 8 dimensions of interoceptive awareness: noticing, not-distracting, not-worrying, attention regulation, emotional awareness, self-regulation, body listening, and trusting. We computed mean scores of all 8 scales and then computed a mean of those as the total Multidimensional Assessment of Interoceptive Awareness score used in the present analyses. In this sample, Cronbach's alpha at pretreatment for the total score was 0.76.

Data analysis

A power analysis was calculated using G∗Power for a 2×3 mixed analysis of variance with a power of 0.9, alpha of 0.05, and a small-to-medium effect size (Cohen's $f = 0.15$) for the primary outcomes (based on the pilot study).[38] It was estimated that 96 participants would be needed (48 per treatment group). We planned for 20% attrition, and thus sought to recruit a total of 60 women per group (N = 120).

Analysis of primary and secondary outcomes

Effects of treatment were analyzed using a multilevel mixed model analysis with random intercept, which tested main effects of within-subject time factor consisting of 3 measurement points (t1, t2, t3) and the between-subject factor comparing 2 treatments (STEP-Br vs MBCT-Br), as well as the interaction of time and treatment. Therefore, changes from pretreatment to posttreatment time points were compared between the 2 groups. Since the randomization was conducted at the study group level, the Initial models included 2-level nesting (time points nested within participants and participants nested within study groups) and contained 2 random effects. However, the study group clusters accounted for a very minimal amount of variance, and in some cases the variance associated with study group was so small that it prevented model convergence. Therefore, all finally reported models were run with only 1 random effect of participant intercept. Six models were examined, one for each primary and secondary outcome. In addition to main and interaction effects, effect sizes and confidence intervals were also computed. If no significant interaction effects were observed, the main effects were reported from models without interaction term.

Missing data

This study used an intention-to-treat approach, a method that is more conservative and does not compromise the comparability of groups achieved through randomization.[50] Little's test[51] of missing completely at random assumption for all outcome variables was not significant; therefore, the analysis was conducted on complete cases. However, sensitivity analysis was also conducted using multiple imputation (10 samples) and pooled estimates. The pattern of significant results from those analyses was identical to the analyses on complete cases. Additionally, a comparison of participants who dropped out of the study by t2 vs those who remained found no significant differences on any baseline participant characteristic variables or outcomes.

Results
Participant characteristics

As shown in the CONSORT diagram (Figure 1), of the original 164 women who were assessed for eligibility, 46 did not meet the study criteria and 118 were randomized to either the MBCT-Br or STEP-Br group. Of these, 60 provided informed consent and completed the t1 assessment in the MBCT-Br group and 56 did so in the STEP-Br group. Attrition at t2 (posttreatment) was 15% for the MBCT-Br group and 10.7% for the STEP-Br group. Further attrition at t3 (6-month follow up) compared with t2 was 17.6% for the MBCT-Br group and 4% for the STEP-Br group. Participant demographic characteristics are presented in Table 1. All demographic characteristics were equivalent in the 2 groups, except ethnicity ($P = .046$; more non-White participants in STEP-Br) and education ($P = .016$; higher level of education in MBCT-Br). Less than 10% of participants in each arm had previously received treatment for a sexual difficulty; these proportions across the

Figure 1. CONSORT diagram for participants (n = 118) randomized to either mindfulness-based cognitive therapy (MBCT-Br) or supportive-expressive psychoeducation (STEP-Br).

2 groups did not differ. Cancer and cancer treatment–related characteristics are presented in Table 2.

Session attendance and homework completion

A total of 70% of women in the MBCT-Br group and 73.2% women in the STEP-Br group attended all 8 sessions (whether scheduled sessions or make-up sessions), and 83.7% of women in the MBCT-Br group and 87.5% of women in the STEP-Br group completed 6 or more sessions.

There was no significant difference in the completion of sexuality-related homework exercises between groups, with the average homework completion being 76% for the MBCT-Br group and 82% for the STEP-Br group. Posttreatment, the MBCT-Br group participants practiced mindfulness on average 2 to 3 days a week for 22 minutes per day.

Treatment credibility

Mean treatment credibility (measured after the first session) was 6.60 out of 10 (SD = 1.77) for the MBCT-Br group,

and was significantly higher in the STEP-Br arm (7.37 out of 10; $t_{110} = -2.45$, $P = .016$, Cohen's $d = 0.46$), indicating a moderate-to-high level of treatment credibility in both groups.

Effects of treatment on primary outcomes of sexual desire, sexual distress, and vaginal pain

Table 3 contains means and standard deviations for each outcome variable by treatment arm and time of assessment. Results for random coefficient analyses are reported in Table 4 along with Cohen's ds. Because of the baseline group differences on ethnicity and education, all models were first run with ethnicity and education as covariates. Because all the pattern of results was unchanged, the models without covariates are reported for clarity.

Analysis of sexual desire, as measured by the Sexual Interest and Desire Inventory, showed an increase in desire from t1 to t2, as well as from t1 to t3, with large and medium effect sizes ($d = 0.95$ and 0.59, respectively). Sexual distress, as measured by the Female Sexual Distress Scale–Revised total score,

Table 2. Cancer diagnosis and treatment characteristics of participants randomized to the supportive-expressive sex education (STEP-Br) and mindfulness-based cognitive therapy (MBCT-Br) treatment arms.

Measure	STEP-Br	MBCT-Br	Total
Time since diagnosis, mo	58.7 ± 44.2	48.8 ± 41.1	53.6 ± 42.7
Duration of treatment, mo	3.6 ± 2.9	3.6 ± 2.9	3.6 ± 2.8
Missing values	4	3	7
Chemotherapy before t1			
Yes	36 (67.9)	39 (67.2)	75 (67.6)
No	17 (32.1)	19 (32.8)	36 (32.4)
Missing values	3	2	5
Radiation before t1			
Yes	42 (80.8)	49 (89.5)	91 (82.7)
No	10 (19.2)	9 (15.5)	19 (17.3)
Missing values	4	2	6
Surgeries undergone before t1			
None	5 (10.0)	4 (7.8)	9 (8.9)
Lumpectomy	12 (24.0)	14 (27.5)	26 (25.7)
Mastectomy	25 (50.0)	27 (52.9)	52 (51.5)
Multiple breast cancer surgeries	8 (16.0)	6 (11.8)	14 (13.9)
Missing values	6	9	15
Breast reconstruction			
Yes	25 (56.8)	20 (46.5)	45 (51.7)
No	19 (47.5)	23 (57.5)	41 (48.3)
Missing values	12	17	29
Currently taking antiestrogen therapy			
Yes	38 (70.4)	47 (83.9)	85 (77.3)
No	16 (29.6)	9 (16.1)	25 (22.7)
Missing values	2	4	6
Cancer recurrence after enrollment			
Yes	1 (1.8)	2 (3.4)	3 (2.7)
No	54 (98.2)	56 (96.6)	110 (97.3)
Missing values	1	2	3
Menopause status			
Premenopausal	8 (14.5)	4 (6.9)	12 (10.6)
Perimenopausal	13 (23.6)	10 (17.2)	23 (20.4)
Postmenopausal	34 (61.8)	44 (75.9)	78 (69.0)
Missing values	1	2	3

Values are mean ± SD, n, or n (%). Abbreviations: MBCT-Br, mindfulness-based cognitive therapy for sexual concerns after breast cancer; STEP-Br, supportive-expressive psychoeducation for sexual concerns after breast cancer; t1, pretreatment.

showed significant improvement (scores decreased) from t1 to both posttreatment time points (between medium and large effect sizes: $d = -0.69$, and -0.76, respectively). Vaginal pain, as assessed with at-home vaginal insertion using a dilator, showed significant improvement with a decrease in scores from t1 to both posttreatment points and medium effect sizes ($d = -0.45$, and -0.46, respectively). The interactions of time by group were nonsignificant for all 3 primary outcomes.

Effects of treatment on secondary outcomes of rumination, mindfulness, and interoceptive awareness

Rumination about sex, as measured by the Rumination-Reflection Questionnaire, significantly improved for all participants from t1 to both t2 and t3 time points (small effect sizes: $d = -0.18$ and -0.31, respectively). The interactions of time by group were nonsignificant, indicating similar improvements in rumination with both treatments.

Participants' mindfulness scores, as measured by Five Facet Mindfulness Questionnaire total score, improved significantly from t1 to t2 and t3, with small effect sizes ($d = 0.20$ and 0.22, respectively). There was no significant interaction between time and treatment, indicating similar improvements in both treatments.

On interoceptive awareness, as assessed with the total Multidimensional Assessment of Interoceptive Awareness scale averaged across 8 dimensions, there was a significant main effect of time, but no significant interaction, revealing that for all participants there was significant improvement between t1 and t2 as well as between t1 and t3 in interoceptive awareness.

Discussion

Overall, we found that online group sex therapy adapted for sexual concerns in BrCa survivors—both mindfulness based and psychoeducation based—led to significant improvements, compared with baseline, in sexual desire, sexual distress, vaginal pain, rumination, mindfulness, and interoception, with effects maintained at 6 months posttreatment. Effect sizes for these improvements were in the moderate-to-high range for sexual desire and distress, medium for improvements in vaginal pain and interoceptive awareness, and small for all other endpoints. We found no differences between the 2 treatment modalities, suggesting that both the supportive sex education and mindfulness interventions can be considered as equally effective for addressing the main outcomes of sexual dysfunction in BrCa survivors.

On the primary outcome of sexual desire, these findings mirror what was found recently in a face-to-face delivery

Table 3. Primary and secondary outcomes by time of assessment and treatment group.

Outcome and group	Baseline	Posttreatment	6-mo follow-up
Sexual desire (SIDI)[a]			
STEP-Br	18.01 ± 8.22	25.76 ± 9.10	22.90 ± 9.51
MBCT-Br	15.71 ± 7.67	23.07 ± 8.73	20.31 ± 9.19
Score (n, %) ≤33[d]	104 (96.3)	77 (82.8)	76 (90.5)
Sexual distress (FSDS-R)[c]			
STEP-Br	30.45 ± 9.09	24.11 ± 10.25	23.52 ± 9.79
MBCT-Br	29.60 ± 10.54	21.85 ± 10.78	22.23 ± 12.85
Score (n, %) ≥11[d]	113 (98.3)	86 (86.9)	75 (85.2)
Pain with dilator insertion			
STEP-Br	2.15 ± 2.22	1.13 ± 1.83	1.09 ± 1.61
MBCT-Br	3.41 ± 2.82	2.07 ± 2.10	1.71 ± 1.58
No pain (n, %)	32 (28.8)	40 (43.5)	39 (47.0)
Rumination about sex (RRQ)[e]			
STEP-Br	2.64 ± 0.83	2.40 ± 0.86	2.31 ± 0.75
MBCT-Br	2.51 ± 0.78	2.39 ± 0.87	2.26 ± 0.86
Mindfulness (FFMQ)[e]			
STEP-Br	3.25 ± 0.43	3.36 ± 0.49	3.39 ± 0.51
MBCT-Br	3.37 ± 0.49	3.47 ± 0.49	3.41 ± 0.47
Interoceptive Awareness (MAIA)[b]			
STEP-Br	2.79 ± 0.57	2.98 ± 0.59	3.05 ± 0.58
MBCT-Br	2.81 ± 0.68	3.14 ± 0.57	3.00 ± 0.55

Values are mean ± SD or n (%). Abbreviations: FFMQ, Five Facet Mindfulness Questionnaire; FSDS-R, Female Sexual Distress Scale–Revised; MAIA, Multidimensional Assessment of Interoceptive Awareness; MBCT-Br, mindfulness-based cognitive therapy for sexual concerns after breast cancer; RRQ, Rumination-Reflection Questionnaire; SIDI, Sexual Interest and Desire Inventory; STEP-Br, supportive-expressive psychoeducation for sexual concerns after breast cancer. [a] Possible range: 0-51. [b] Possible range: 0-5. [c] Possible range: 0-52. [d] Respondents who meet the clinical cutoff score for a sexual desire disorder and sexual distress. [e] Possible range: 1-5.

of a very similar 8-session in-person group mindfulness program for women with low sexual desire unrelated to BrCa.[29] In that study, group mindfulness also produced statistically significant and clinically meaningful improvements in sexual desire, and effects were maintained at a 6- and 12-month follow-up. That the present study also showed large effect sizes for desire at posttreatment, and medium effect sizes at 6-month follow-up suggest that group mindfulness previously found effective for sexual desire in noncancer survivors may also be clinically recommended among BrCa survivors seeking treatment for sexual dysfunction. A meta-analysis of mindfulness-based interventions for cancer survivors shows such interventions to be effective for addressing psychological distress, anxiety, depression, fear of recurrence, pain, and sleep disturbance[52]—even when not adapted to specific health issues. The present findings (showing improvements to sexual desire, sexual pain, and sexual distress) suggest that benefits of mindfulness can also be extended to sexual dysfunction when mindfulness-based interventions are adapted specifically for sexual concerns.

Vaginal pain, assessed by having participants self-insert a vaginal dilator at home, significantly decreased in both treatment arms, and showed a medium effect size. This finding is similar to the improvements in self-reported pain when 8 sessions of group mindfulness was evaluated among women with provoked vestibulodynia.[34] In that study, decreases in pain catastrophizing and self-criticism, and increases in pain acceptance and mindfulness, mediated these improvements in vaginal pain intensity.[53] Although mediators were not assessed in the present study, it is indeed possible that changes in these variables account for survivors' perceived decrease in vaginal pain. Interestingly, these improvements in vaginal pain intensity were also seen in the supportive sex education group, which did not deliver any mindfulness skills. Although one might not expect that supportive sex education would lead to improvements in pain catastrophizing, self-criticism, pain acceptance, and mindfulness, it is entirely possible (even likely) that delivering sex education pertaining to cancer survivorship in a supportive group environment, comprising other women with BrCa, may indeed elicit improvements in these domains, which in turn may account for the improvements in vaginal pain. Anecdotal feedback from participants in the STEP-Br arm, who regularly noted during their sessions how useful and supportive they found the group to be, would support this speculation that being in a validating and nonjudgmental group with survivors who experienced something similar to oneself may have created a cascade of changes that ultimately resulted in improved sexual functioning and vaginal pain.

Considering our finding that the supportive sex education group was as effective for our primary outcomes as the mindfulness group, it is worth noting that past studies have also found comparability in efficacy between these treatments. For example, an 8-week MBT was equally effective to a supportive-expressive comparison group on symptoms of mood.[54] Our study showed similar effectiveness of mindfulness and supportive sex education in sexual desire, sexual distress, and sexual pain, suggesting that these treatments may have similar mechanisms of action. A future publication will assess a priori mediators in order to explore this possibility. Given that few BrCa survivors receive any kind of treatment to address their sexual health issues during cancer,[3,5,7-10] it may be that both approaches were experienced as novel and effective. The moderately high degree of treatment credibility in our sample supports this assertion that survivors valued both treatment approaches and believed that both may help alleviate their sexual symptoms.

The moderate-to-high effect sizes on the endpoints of sexual desire and sexual distress suggest that either of these treatments—mindfulness or supportive sex education—might be

Table 4. Time and group comparisons and interaction effects from random coefficient analysis models for the outcome measures at t1, t2, and t3.

Variable	b	SE	P	d	95% CI for b
Model for sexual desire: SIDI					
Constant	15.698	1.099	<.001[a]	—	13.53 to 17.87
Time (t2-t1)	7.569	0.828	<.001[a]	0.95	5.94 to 9.20
Time (t3-t1)	4.753	0.857	<.001[a]	0.59	3.06 to 6.44
Group	2.402	1.417	.093	0.30	−0.41 to 5.21
Time (t2-t1) × group	0.260	1.655	.875	0.03	−3.01 to 3.53
Time (t3-t1) × group	−0.006	1.719	.997	0.00	−3.40 to 3.39
Model for sexual distress: FSDS-R					
Constant	29.560	1.338	<.001[a]	—	26.91 to 32.21
Time (t2-t1)	−6.791	0.824	<.001[a]	−0.69	−8.42 to −5.17
Time (t3-t1)	−7.382	0.861	<.001[a]	−0.76	−9.08 to −5.68
Group	0.926	1.761	.600	0.09	−2.56 to 4.41
Time (t2-t1) × group	0.739	1.645	.654	0.08	−2.51 to 3.98
Time (t3-t1) × group	−0.610	1.723	.724	−0.06	−4.01 to 2.79
Model for pain with dilator insertion					
Constant	2.269	0.275	<.001[a]	—	1.73 to 2.81
Time (t2-t1)	−1.184	0.196	<.001[a]	−0.45	−1.57 to −0.80
Time (t3-t1)	−1.209	0.204	<.001[a]	−0.46	−1.61 to −0.81
Group	1.022	0.355	.005[b]	0.39	0.32 to 1.73
Time (t2-t1) × group	−0.418	0.390	.286	−0.16	−1.19 to 0.35
Time (t3-t1) × group	−0.488	0.406	.231	−0.19	−1.29 to 0.31
Model for rumination about sex: RRQ					
Constant	2.528	0.107	<.001[a]	—	2.32 to 2.74
Time (t2-t1)	−0.146	0.060	.015[c]	−0.18	−0.26 to −0.03
Time (t3-t1)	−0.251	0.062	<.001[a]	−0.31	−0.37 to −0.13
Group	0.097	0.142	.496	0.12	−0.18 to 0.38
Time (t2-t1) × group	−0.107	0.119	.371	−0.13	−0.34 to 0.13
Time (t3-t1) × group	−0.007	0.125	.954	−0.01	−0.25 to 0.24
Model for mindfulness: FFMQ					
Constant	3.271	0.062	<.001[a]	—	3.15 to 3.39
Time (t2-t1)	0.095	0.035	.008[b]	0.20	0.03 to 0.16
Time (t3-t1)	0.101	0.037	.006[a]	0.22	0.03 to 0.17
Group	0.081	0.083	.329	0.17	−0.08 to 0.25
Time (t2-t1) × group	−0.021	0.070	.768	−0.05	−0.16 to 0.12
Time (t3-t1) × group	−0.121	0.073	.101	−0.26	−0.26 to 0.02
Model for Interoceptive Awareness: MAIA					
Constant	2.785	0.080	<.001[a]	—	2.63 to 2.94
Time (t2-t1)	0.276	0.042	<.001[a]	0.44	0.19 to 0.36
Time (t3-t1)	0.243	0.044	<.001[a]	0.39	0.16 to 0.33
Group	0.048	0.103	.639	0.08	−0.16 to 0.25
Time (t2-t1) × group	0.132	0.083	.113	0.21	−0.03 to 0.30
Time (t3-t1) × group	−0.060	0.087	.487	−0.10	−0.23 to 0.11

Group refers to STEP-Br (reference) vs MBCT-Br. All models had random intercepts. Abbreviations: CI, confidence interval; FFMQ, Five Facet Mindfulness Questionnaire; FSDS-R, Female Sexual Distress Scale–Revised; MAIA, Multidimensional Assessment of Interoceptive Awareness; MBCT-Br, mindfulness-based cognitive therapy for sexual concerns after breast cancer; RRQ, Rumination-Reflection Questionnaire; SIDI, Sexual Interest and Desire Inventory; STEP-Br, supportive-expressive psychoeducation for sexual concerns after breast cancer; t1, pretreatment; t2, posttreatment; t3, 6-month follow-up. [a] $P < .001$. [b] $P < .01$. [c] $P < .05$.

considered as first-line options for BrCa survivors experiencing sexual dysfunction, and that effects (as indicated by effect sizes) are larger than with pharmacological approaches.[22,23] Moreover, offering patients the option of selecting which approach—mindfulness or supportive sex education—they would prefer is aligned with efforts in patient-oriented clinical practice and shared decision making. For example, a patient who has experience with mindfulness for managing mood or anxiety and experienced benefits may prefer the current mindful sex approach. On the other hand, a patient who prefers to have information and knowledge may benefit more from a supportive sex education approach. Future studies may offer such an option to participants and measure the impact of choosing treatment, vs randomization, on outcomes. Indeed, there is evidence that when patients are empowered to share treatment decision making with their clinicians, that they may experience better outcomes.[55] Because mindfulness and supportive sex education do not have (known) side effects, indeed we recommend that these be offered to all BrCa survivors to address and mitigate their sexual issues.

There are limitations to the study design that need to be considered. For example, our method of randomization in which participants first chose a time slot based on their availability, and then the entire cohort was randomized to treatment type, may be seen as a limitation, in that individual factors may be less controlled. However, in order to account for the lack of randomization by individual, and instead by group, and the group differences at baseline on ethnicity, education, and treatment credibility, all longitudinal models were re-analyzed with each of these 3 variables as covariates. The patterns of significant results were identical; the models without the covariate are thus reported for clarity.

Another limitation to the study pertains to the lack of a no-treatment control group. As argued by Pyke and Clayton,[56]

no-treatment control groups are important in the evaluation of psychological treatments for sexual dysfunction, as they allow one to control for nonspecific effects such as time, discussion about sex, prioritization of attending sessions, etc. As such, we cannot rule out entirely the positive impact of these domains on the outcomes measured.

Although our interventions were delivered online, and therefore accessible to women who lived even in rural and remote regions, another limitation of the study is that only participants who could commit to attending all the group sessions were eligible. This excludes BrCa survivors who may face other barriers related to their personal, social, or financial situation that impede their ability to seek care. We also acknowledge the limitations inherent to using a vaginal insert to measure pain. Even though it has been widely used as a diagnostic tool for assessing pain associated with penetrative sex,[57] its generalizability to partnered sexual activity may be seen as questionable.

Both treatment arms had similar improvements in overall interceptive awareness, suggesting that providing evidence-based information in a supportive environment led to similar improvements in awareness of internal bodily sensations as mindfulness training did, even without specific training in paying attention to the body. This finding deserves further study in order to understand the mechanisms by which education alone leads to enhanced body awareness.

In conclusion, we found that both group mindfulness-based cognitive therapy and group supportive sex educations for sexual concerns after breast cancer are effective for improving sexual desire, sexual distress, vaginal pain, rumination, mindfulness, and interoceptive awareness for BrCa survivors experiencing sexual dysfunction. We recommend that cancer treatment centers consider providing such interventions during and following cancer treatment and that patients be empowered to engage in shared decision making regarding the treatment option that may best address their sexual health difficulties.

Author contributions

L.A.B., L.W., and R.M. designed the study and obtained funding. L.A.B., L.W., C.S., S.W., and R.M. collected the data. S.W. and B.Z. cleaned the dataset. B.Z. carried out all statistical analyses. All authors wrote, edited, and approved the final manuscript.

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