THE JOURNAL OF
SEXUAL MEDICINE

ORIGINAL RESEARCH

PSYCHOLOGY

A Comparison of Mindfulness-Based Cognitive Therapy Vs Cognitive Behavioral Therapy for the Treatment of Provoked Vestibulodynia in a Hospital Clinic Setting

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ABSTRACT

Introduction: Chronic and distressing genito-pelvic pain associated with vaginal penetration is most frequently due to provoked vestibulodynia (PVD). Cognitive behavioral therapy (CBT) significantly reduces genital pain intensity and improves psychological and sexual well-being. In general chronic pain populations, mindfulness-based approaches may be as effective for improving pain intensity as CBT.

Aim: To compare mindfulness-based cognitive therapy (MBCT) with CBT in the treatment of PVD.

Methods: To ensure power of 0.95 to find medium effect size or larger in this longitudinal design, we enrolled 130 participants. Of these, 63 were assigned to CBT (mean age 31.2 years), and 67 to MBCT (mean age 33.7 years). Data from all participants who completed baseline measures were analyzed, with intent-to-treat analyses controlling for years since diagnosis.

Main Outcome Measures: Our primary outcome was self-reported pain during vaginal penetration at immediate post-treatment and at 6 months' follow-up. Secondary endpoints included pain ratings with a vulvalgesiometer, pain catastrophizing, pain hypervigilance, pain acceptance, sexual function, and sexual distress.

Results: There was a significant interaction between group and time for self-reported pain, such that improvements with MBCT were greater than those with CBT. For all other endpoints, both groups led to similar significant improvements, and benefits were maintained at 6 months.

Clinical Implications: Mindfulness is a promising approach to improving self-reported pain from vaginal penetration and is as effective as CBT for several psychological endpoints.

Strength & Limitations: A strength of the present study was the robust sample size (n = 130 women) who had received confirmed clinical diagnoses of PVD.

Conclusion: The present study showed mindfulness to be as effective for most pain- and sexuality-related endpoints in the treatment of PVD. **Brotto LA, Bergeron S, Zdaniuk B, et al. A Comparison of Mindfulness-Based Cognitive Therapy Vs Cognitive Behavioral Therapy for the Treatment of Provoked Vestibulodynia in a Hospital Clinic Setting. J Sex Med 2019;16:909–923.**

Key Words: Provoked Vestibulodynia; Mindfulness; Cognitive Behavior Therapy; Clinical Trial; Genital Pain

INTRODUCTION

Chronic and distressing genito-pelvic pain from vaginal penetration is often due to provoked vestibulodynia (PVD), which affects approximately 8% of women.[1,2] Although there may be many reasons for pain with sexual activity, PVD has received considerable research attention. The associated symptom of chronic dyspareunia poses a significant health, emotional, and economic burden.[1,3–5]

The psychological correlates of PVD are well established. Women with PVD have increased rates of anxiety, fear of pain,

Received January 8, 2019. Accepted April 1, 2019.

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https://doi.org/10.1016/j.jsxm.2019.04.002

sex-related distress, hypervigilance to pain, and pain catastrophizing—the latter being significantly correlated with pain intensity during intercourse.[6,7] Furthermore, a history of depression or anxiety significantly increases vulnerability to developing PVD.[8] Like other chronic pain syndromes,[9] pharmaceutical treatments for PVD are minimally effective.[10,11]

Neuroimaging evidence that simply expecting pain produces a neural pattern of activation similar to experiencing pain [12] provides a strong foundation for psychological approaches such as cognitive behavioral therapy (CBT), aimed at challenging maladaptive pain-related thoughts, teaching relaxation skills, targeting avoidance behavior,[13] and restoring sexual function.[14] Controlled studies find CBT as effective as pelvic floor physiotherapy and surgical approaches, both in the short term [15–18] and in the long term.[19] A more-recent study was completed evaluating CBT for women with PVD vs a topical steroid (consisting of 1% hydrocortisone cream) for 13 weeks for the primary outcome of pain during intercourse.[16] Whereas participants in both conditions improved, women in the CBT group reported greater reduction in pain with intercourse, greater improvement in sexual function at the 6-month post-treatment time point, greater improvement in pain catastrophizing, and greater treatment satisfaction, but similar pain self efficacy as compared with women receiving the topical steroid.[16] The CBT intervention for PVD has been described at length in the literature.[20]

Whereas CBT is aimed at challenging and changing thoughts, mindfulness-based cognitive therapy (MBCT) aims to increase awareness of pain-related thoughts,[21] while not identifying with their content, and neither engaging with nor changing them. Focused attention and acceptance of all sensations is fundamental to the skill of mindfulness, and acceptance is a concept central to coping for women with PVD.[22]

Limited research has compared the 2 therapies for chronic pain conditions. Mindfulness led to significantly greater reductions in pain catastrophizing and stress-related affect compared with CBT in patients with rheumatoid arthritis,[23] but similar improvements in disability symptoms and pain bothersomeness in patients with chronic low back pain.[24] Given that women with PVD have premorbid symptoms of anxiety and depression more frequently than control subjects,[8] high pain sensitivity,[25] and pain catastrophizing, fear of pain, and hypervigilance,[6] mindfulness is an appropriate treatment choice, and there is preliminary evidence of benefit.[26,27] In light of findings that group MBCT benefits sexual function [28,29] and preliminary support for MBCT for women with PVD,[26,27] we created a group MBCT for women with PVD and compared it with CBT, given that this is the treatment for PVD with an extensive body of literature supporting its efficacy.

If found to be as effective as CBT, mindfulness may be an alternative option for those with chronic pain who do not respond to conventional treatments.[21,30–33] Women with PVD report that anticipated sex triggers distressing catastrophic thoughts, a ruminative tendency to anticipate painful sex, hypervigilance to pain, feelings of anxiety, guilt, and sadness, and significant partner-related worries.[4] Therefore, psychological techniques that train women to shift attention away from cognitive processes such as rumination, tolerate distressing symptoms, and remain non-judgmentally in the present moment may be especially worthwhile to pursue.[34]

The purpose of this study was to carry out a non-inferiority comparison in which we hypothesized that MBCT would be comparable to CBT for addressing the primary outcome of self-reported pain intensity with sex in women with PVD. CBT was implemented as our comparison group, given that it has already been established as an effective treatment for PVD and it has the ability to target multiple dimensions of vaginal pain beyond the pain itself, including sexual, relationship, and psychological distress. In addition to self-reported pain intensity, we measured provoked vulvar pain intensity using a vulvalgesiometer as a secondary treatment outcome. Other secondary outcomes focused on overall sexual function and sex-related distress, and psychological endpoints of pain catastrophizing, pain hypervigilance, and pain acceptance. We also administered a measure of global satisfaction with treatment. The study was powered to detect improvements to the 6-month post-treatment follow-up, allowing us to examine whether any improvements were maintained.

METHODS

Participants

Participants comprised a total of 130 women diagnosed with PVD by a physician from an original sample of 153 women who had a diagnosis of PVD and were invited to contact the study coordinator. Participants were recruited from 2 tertiary care academic health centers specializing in sexual medicine. Of note, all women were seeking treatment, and, thus, this was a clinical hospital-based sample. In the first center, every woman who received a diagnosis of PVD was informed about the study by the physician who carried out an extensive intake assessment, which involved a clinical history, as well as physical examination with a cotton swab to confirm the diagnosis of PVD. Those women who expressed an interest were introduced to the on-site study coordinator, who provided additional study details. In the second center, all women who attended an introductory multidisciplinary program for women with PVD received a description of the study via email, and women who wanted more information were invited to contact the study coordinator. Women wanting to pursue study participation then received the same detailed clinical assessment as women recruited from the first center before study enrollment. We have compared the women who did and those who did not receive past treatment on our primary outcomes.

Inclusion criteria were (i) a diagnosis of PVD confirmed by both clinical history and by a cotton-swab test carried out by a physician; (ii) duration of PVD of at least 6 months; (iii) ability to attend 8 weekly treatment sessions; (iv) age 19 years or older;

(v) fluent in English; and (vi) willingness to not begin any new treatments for PVD for the duration of the study until the 6-month follow-up point. Exclusion criteria were as follows: (i) unprovoked vulvovaginal pain; (ii) pelvic pain; (iii) a vulvar skin condition (eg, lichen sclerosus); and (iv) significant symptoms of dissociation (which would make participation in mindfulness-based therapy challenging). We did not exclude participants with symptoms of anxiety or depression.

As shown in the participant CONSORT diagram (Figure 1), 23 women who were assessed for eligibility were excluded from participating: 18 did not meet the study criteria, and 5 declined to participate after receiving more information about the procedures. The study was approved by the Clinical Research Ethics Board at the University of British Columbia, #H12-02358, as well as the Vancouver Coastal Health Hospital Research Ethics Board, and all participants provided written consent. This project was registered with clinicaltrials.gov, NCT01704456 and funded by the Canadian Institutes of Health Research Operating Grant MOP-123271 to the first author. The original project was powered to evaluate outcomes to the 6-month follow-up time point. The project was independently peer reviewed, and the funder played no role in the study or the writing.

Procedure

The first participant consented on October 2, 2012, and the student ended in March 2016. Women who consented to participate took part in a standardized vulvar pain assessment with an instrument known as the *vulvalgesiometer*.[35] In a private room, with the woman on an examination table with her legs supported by footrests, a trained clinician exerted a standardized 30 g of pressure at the 1-, 3-, 4-, 6-, 8-, 9-, and 11-o'clock positions (randomly) around the vulvar vestibule and recorded

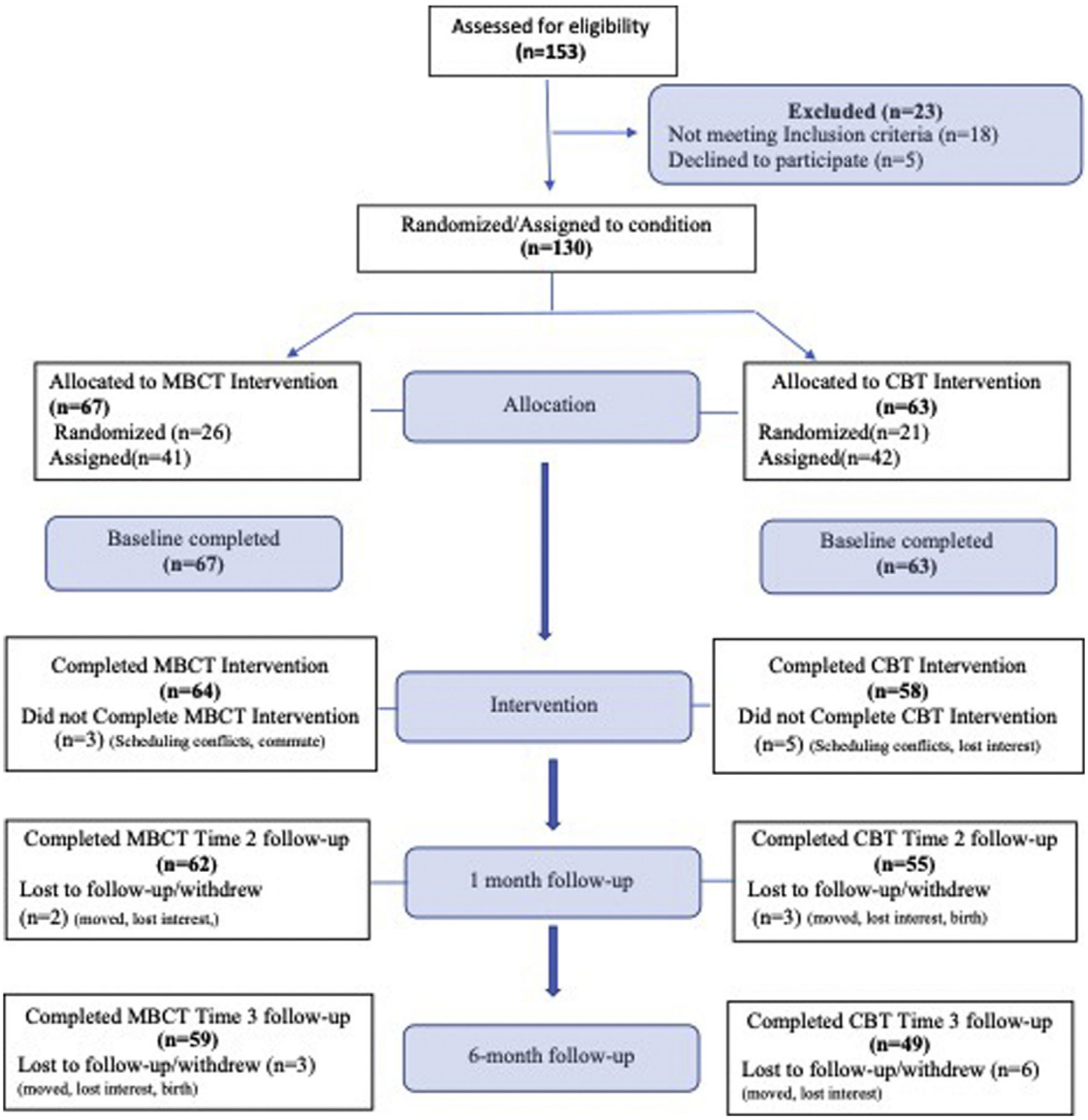

Figure 1. CONSORT diagram for participants in mindfulness-based cognitive therapy (MBCT) and cognitive behavior therapy (CBT).

the woman's numeric rating of pain from 0 (no pain)−10 (worst pain ever) at each position. An average pain rating across these 7 sites was then computed for analyses.

All women completed a battery of questionnaires online, at least 1 week before treatment began. They were e-mailed an individualized link to the questionnaire battery, which was administered and stored in SurveyMonkey. Reminder e-mails or telephone calls were sent up to 3 times for any participant who did not complete these baseline measures.

A total of 22 women took part in an additional assessment and formed the wait-list subgroup. These 22 women completed 2 pretreatment baseline questionnaire batteries, which were separated by ≥2 months (ie, the duration of the 8 weeks of treatment) before treatment onset. Their treatment data were included in the present analyses of treatment and were intended to examine the impact of passage of time without treatment.

Although this study was originally designed as a randomized clinical trial, the setting was a hospital clinic with a requirement to provide care without undue delay. Given significant wait-lists in this academic health care setting, this sometimes necessitated assigning women to the next available group without formal randomization. Thus, 47 of the 130 participants (36.1%) were strictly randomized to group; the remaining participants were assigned to a group non-randomly, but the assignment was based strictly on scheduling logistics and never on participant or clinician preference for treatment modality. Randomization for those 47 participants was carried out by the study coordinator, who was not involved in any aspect of treatment. We tested extensively for any potential effect of non-randomization, and these tests are described at the beginning of the Results section. A remuneration of $25 for each assessment point (≤5 assessments) was provided.

Treatments

Both treatments were delivered over 8 weekly sessions, 2.25 hours in length, by clinicians who had specialized training in group therapy (either CBT or MBCT or both), and who had considerable expertise in the diagnosis and management of sexual disorders and PVD. Facilitators for the MBCT groups also had additional workshop training in mindfulness, had attended, at a minimum, a monthly mindfulness group for clinicians, and each had a personal ongoing mindfulness practice. The original developer of the CBT manual (Bergeron) that was adapted for this study [15,16,19,20] provided extensive supervision to the team of facilitators who carried out the first CBT groups. Any facilitator who was delivering 1 treatment was not permitted to simultaneously deliver the other treatment so as to allow the facilitator to remain fully aligned to that particular treatment for the full duration of the group. If a woman missed a session, she was encouraged to let the facilitators know and schedule an individual make-up session.

Cognitive Behavioral Therapy (CBT)

The CBT intervention was adapted from a 10-session group CBT for PVD that was developed and tested by Bergeron and colleagues.[15,16,19,20] The goal of the CBT group was to provide psychoeducation on how PVD affects women's sexual desire, motivation, and function and the role of stress in chronic pain and PVD; behavioral skills training (eg, progressive muscle relaxation, diaphragmatic breathing, vaginal inserts, or challenging avoidance behavior); cognitive techniques (eg, rehearsal of self-statements to cope with pain or cognitive restructuring); and communication skills training, which included addressing ways a woman might speak to a current or future partner about her pain. We took a well-established group intervention based on CBT [15,16,19,20] and adapted it to 8 sessions. We developed a treatment manual for the facilitator and an accompanying guide for the participant that contained detailed descriptions of the exercises, diaries, and places to document homework activities (S. Bergeron et al, unpublished manual, 2012).

Mindfulness-based Cognitive Therapy (MBCT)

The MBCT intervention was developed over 4 years before the current study began, with extensive input provided by 2 mindfulness experts. Given the known significant impact of PVD on sexual functioning, the adapted intervention included psychoeducation about sexual activity, and discussed the known literature of mindfulness as it pertains to sexual response. We elected to use an adapted MBCT, as opposed to mindfulness-based stress reduction, given that the former included elements of cognitive therapy already and, thus, allows for a clearer examination of the effects when mindfulness is added to CBT. We pilot tested the intervention on 2 groups of women with PVD and solicited their feedback before further revising the treatment manual to use in the current project. The resulting treatment manual (R. Basson et al, unpublished manual, 2012) and participant guide contained mindfulness exercises such as mindful eating, the body scan, mindfulness of breath, mindfulness of sounds and thoughts, and a loving-kindness self-compassion practice. In addition, some of the meditations involved provoking a mild (non-genital) pain in session, which was done by asking participants to mindfully observe an existing pain elsewhere in their body, or to elicit a pain by holding their arm in the air for 15 minutes. For homework they were asked to provoke vestibular pain using their finger and touching the opening of the vagina while observing sensations mindfully. A full 1 hour of each session was spent engaging in a guided mindfulness practice plus inquiry on practice. Women also learned how PVD affects sexual desire, motivation, and function and about the role of stress in chronic pain and PVD (which was identical to the information provided in the CBT arm); development of metacognitive awareness (eg, noticing biased and unbiased thoughts and simply allowing their existence but not engaging with them or necessarily believing their content); and communication skills training. Participants were sent Dropbox links after each session to the audio-recorded mindfulness practice (which ranged from 20−45 minutes daily) that was encouraged to be practiced daily at home before the next session. Participants were also encouraged to document their observations

from a variety of at-home exercises in their participant manuals. Immediately after their last session, and again at the 6- and 12-month time points, all participants were asked to self-rate their degree of homework completion. Only the 6-month data are included in this article.

20% of all group sessions were audio-recorded, as is considered standard in treatment adherence coding in psychological treatment studies; half of these sessions were then coded for treatment adherence by 2 trained research assistants who were not involved in the study. The coders were trained by 1 of the group facilitators by selecting 5 random recordings that the coders and the facilitator all coded separately. Feedback from the facilitator to the coders allowed them to reach 100% agreement on the coding by the fourth session recording. We used a modified version of the MBCT Adherence Scale and CBT Adherence Scales,[36] with 7 items focused on group cohesion, provision of treatment rationale, adherence to skills, home practice setting, home practice review, adherence to treatment modality, and commitment to practice. This 7-item scale was scored on a 0−2 scale by each independent coder, with a possible total score range of 0−14.

Measures

The battery of questionnaires was administered at pretreatment (and twice at pretreatment for the 22 wait-list participants), then again at 2−4 weeks after the last session, and at 6 and 12 months' follow-up. Data from the 12-month assessment point are not included in the present article, given that they were not part of the primary goals of this study. They are the subject of another article.

Demographic and Clinical Characteristics

At the baseline assessment, we administered a variety of demographic questions (eg, age, ethnicity, education, sexual orientation, and relationship status and duration) and clinical questions (eg, duration of PVD, whether the PVD was lifelong or acquired, past treatments tried, and medications).

Pain During Intercourse/Other Sexual Vaginal Entry

Pain was measured in 2 ways: (i) the primary outcome was a Numeric Rating Scale that asked participants to rate the "intensity of pain during vaginal penetration attempts with sexual intercourse or penetration over the past 4 weeks." This question was rated on a 0−10 scale from no pain to worst possible pain. Women who did not engage in vaginal penetration over the past 4 weeks received a not applicable score (n = 66) for this question at baseline and were not included in follow-up analyses. Of note, we did not expect all participants to provide a score for this measure, given that our experience with a tertiary care hospital setting is that many women may have been experiencing longstanding PVD. As a result, (ii) a secondary outcome of pain was assessed with the vulvalgesiometer. The vulvalgesiometer is an instrument that provides a measure of pain/sensitivity. It exerts standardized amounts of pressure ranging from 3−1,000 grams. An advantage of the vulvalgesiometer is that it can be standardized across time points and with different clinicians administering the pressure, given that it exerts known amounts of pressure. The vulvalgesiometer has been validated and reliably documents changes in pain.[35] As the study clinician palpated 7 different locations around the vulvar vestibule using 30 g of pressure at each site, women self-reported their level of pain from 0 (no pain)−10 (worst pain ever). An average score across the 7 points (in some cases, <7 if the woman reported severe pain during the test) was calculated.

Sexual Function

We used the Female Sexual Function Index (FSFI) [37] to measure overall sexual function. This validated, 19-item scale asks about the frequency and intensity of a variety of domains of sexual response and generates a total score. The FSFI has good discriminant validity, correctly identifying 70.7% of women with sexual dysfunction, using a cut-off score of 26.55.[38] Any woman who did not engage in sexual activity during the preceding 4 weeks, which again we had predicted given the longstanding nature of their PVD, was coded as not applicable and her FSFI total score was missing (n = 32). Total score was computed by adding scores for six FSFI subscales with mean replacement for up to one missing subscale. Given that FSFI items asked about sexual activity or intercourse, this meant that women engaging in sexual activity that did not include intercourse could still have scores on most items. Moreover, women who did not experience vaginal penetration but engaged in other sexual activity could have a valid FSFI score if their only missing score was for the penetration related Pain subscale. In this sample, Cronbach's α at pretreatment was 0.81.

We also administered the 13-item Female Sexual Distress Scale-Revised (FSDS-R),[39] which measures a woman's distress associated with her sexual functioning. Total scores range from 0−52, with higher scores indicating greater distress. The FSDS-R has been found to have excellent discriminant validity, correctly identifying 92.7% of women with sexual dysfunction using a cut-off score of 11. In this sample, Cronbach's α at pretreatment was 0.93.

Psychological Function

3 different domains of psychological function were measured. We administered the (i) Pain Catastrophizing Scale (PCS),[40] a 13-item self-report measure that asks participants to indicate the degree to which they have certain thoughts or feelings when experiencing pain and that includes the following 3 subscales: rumination (eg, inability to keep pain out of mind), magnification (eg, fear pain will worsen), and helplessness (eg, feeling overwhelmed by pain). We specifically asked participants to complete the PCS in relation to their vestibular pain. Items were rated on a scale from 0 (not at all) to 4 (all the time), with higher

scores indicating higher levels of catastrophizing. In the current sample, Cronbach's α was 0.94 for the PCS; the (ii) Pain Vigilance and Awareness Questionnaire (PVAQ) [41] was used to measure awareness of and attention to vulvar pain. The PVAQ is a self-report measure of attention to pain that assesses pain awareness, consciousness, vigilance, and observation. Respondents are asked to consider their pain experiences, if applicable, over the previous 2 weeks and to indicate the frequency with which each item describes their response to pain. The PVAQ contains 16 items rated on a 0 (never)−5 (always) scale, with higher scores indicating higher levels of attention to pain. The PVAQ demonstrates good internal consistency and evidence of validity. In the current sample, Cronbach's α was 0.91 at the pretreatment assessment; and (iii) the Chronic Pain Acceptance Questionnaire (CPAQ),[33] which measures the extent to which one tries to avoid or control pain and the extent to which one participates in valued activities despite living with pain. 2 subscales of the questionnaire were used: the Activities Engagement subscale, which measures pursuit of life activities regardless of pain, and the Pain Willingness subscale, which recognizes that avoidance and control are not adaptive means of coping with pain. We elected to examine these subscales given the possibility that mindfulness might impact activity engagement more than CBT, whereas the 2 treatments may impact pain willingness equally. The 11 items of the Activities Engagement subscale had a total score range from 0−66, and the 9 items of the Pain Willingness subscale had a total score range from 0−54, with higher scores on both domains indicating higher levels of pain acceptance. Baseline Cronbach's α was 0.86 for the Activities Engagement subscale and 0.81 for the Pain Willingness subscale.

Global Impression of Change

The Patient Global Impression of Change assesses the extent to which one's pain during sexual penetration and overall quality of sexual life have changed after the 8-session group treatment; additionally, this questionnaire assesses patient satisfaction toward the treatment received. The Patient Global Impression of Change questionnaire used in this study is based on items used in a previous RCT that assessed treatment, including group CBT, for women with PVD.[15]

Treatment Credibility

Immediately after their first treatment session, participants in both groups were asked, "To what extent do you think the treatment you will receive is logical in terms of alleviating your PVD?" This item was rated on a 0 (not at all logical)−10 (completely logical) scale.

Homework Completion

Participants were asked 2 questions about their homework completion: (i) overall, to what degree were you able to complete your homework assignments? and (ii) overall, since the last group session, to what degree have you been able to practice the skills and exercises you learned in group. Each item was scored on a 5-point Likert scale from 0 (not at all) to 4 (high degree).

Data Analysis Plan

Power Analysis

The pre-study power analysis calculated for a 2-factor mixed design ANOVA (1 within and 1 between-subject factor) and medium effect size based on past studies,[7,16] power = .95 and alpha = .05 called for $n = 46$ per group.[42] Given that our final sample size was n = 130, our study was fully powered to test our hypotheses. For the pain outcome associated with intercourse, we expected a likelihood $\leq$50% of the participants not providing the data due to abstaining from intercourse as per instructions during the treatment arms. Even with such a considerably smaller sample, this study still had an acceptable power (0.83) of finding a medium effect size.

Analysis of Primary and Secondary Outcomes

Longitudinal effects of treatment were analyzed using multilevel mixed model analysis evaluating main effects of the within-group factor based on 3 measurement points (pretreatment to post-treatment and pretreatment to 6 months' follow-up) and between-group factor comparing 2 treatments (CBT vs MBCT), as well as the interaction of the within and between subject factors (pretreatment group difference was compared with post-treatment and 6-month follow-up difference). 8 models were examined, 1 for each primary and secondary outcome. Length of time between PVD diagnosis and participation in this study was included as a covariate in each model, because the 2 treatment groups significantly differed on this variable at pretreatment. In addition to main and interaction effects, effect sizes and CIs were also calculated. Analysis of the primary outcome of vaginal intercourse/penetration pain with the numeric rating scale was performed on a subset of 64 women who reported vaginal penetration 4 weeks before data collection. Analysis of FSFI total scores was conducted on a subset of 98 women who were sexually active 4 weeks before data collection because sexual inactivity precludes responses to several FSFI items. The whole sample was included for the analysis of other outcomes.

Missing Data

This study used an intent-to-treat approach, a method that is more conservative and does not compromise the comparability of groups achieved through randomization.[43] Multilevel modeling analyses used full-information maximal likelihood estimation technique to deal with missing data at post-treatment and follow-up, which is considered a "state-of-the-art" method of modern missing data approaches.[44] Additionally, a comparison of participants who dropped out of the study by 6 months' follow-up to those who stayed found no significant differences on any of the characteristics listed in Table 1 or any of the outcomes at baseline.

Table 1. Baseline demographic and clinical characteristics of women assigned/randomized to CBT (n = 63) and those assigned/randomized to MBCT (n = 67)

Measure	CBT	MBCT	Total
Age in years, mean (SD)	31.24 (8.99)	33.72 (7.48)	32.35 (8.21)
Relationship status, N (%)			
Married/common-law	41 (66.1)	45 (67.2)	86 (66.7)
Dating	13 (21)	11 (16.4)	24 (18.6)
Single	8 (12.9)	11 (16.4)	19 (14.7)
Length of relationship in years, mean (SD)	7.56 (6.79)	7.77 (6.16)	7.67 (6.5)
Satisfaction with relationship closeness (/10), mean (SD)	7.79 (1.99)	7.26 (2.29)	7.52 (2.15)
Ethnicity, N (%)			
Euro-Canadian	38 (62.3)	46 (70.8)	84 (66.7)
South/East Asian	11 (18)	10 (15.4)	21 (16.7)
Other	12 (19.7)	9 (13.8)	21 (16.7)
Education, N (%)			
High school	2 (3.6)	1 (1.7)	3 (2.6)
Some college	17 (30.4)	10 (16.9)	27 (23.5)
University degree	24 (42.9)	31 (52.5)	55 (47.8)
Post-graduate	13 (23.2)	17 (28.8)	30 (26.1)
Level of typical pain (/10), mean (SD)	5.96 (2.11)	6.04 (1.82)	6.00 (1.96)
Level of worst pain (/10), mean, (SD)	8.23 (1.32)	8.23 (1.10)	8.23 (1.21)
Years since diagnosis,* mean (SD)	6.02 (4.72)	9.85 (7.72)	7.95 (6.67)
PVD history, N (%)			
Lifelong	37 (58.7)	43 (64.2)	80 (61.5)
Acquired	26 (41.3)	24 (35.8)	50 (38.5)
Received past treatments for PVD, N (%)	29 (46.0)	36 (53.7)	65 (50.0)
Receiving medication to treat PVD at baseline, N (%)	11 (17.5)	8 (11.9)	19 (14.6)

CBT = cognitive behavioral therapy; MBCT = mindfulness-based cognitive therapy; PVD = provoked vestibulodynia.
*Significant difference between the groups ($P < .01$). Years since diagnosis was controlled for in all analyses involving between-group comparisons.

Wait-List Analysis

Analyses on the change from baseline period 1 to baseline period 2 allowed us to examine the effects of waiting (potential maturation effect) for treatment for the 22 women assigned to a wait-list group before receipt of treatment.

RESULTS

Non-Randomization and Previous Treatment Check

Randomization status was evenly distributed between the 2 treatments: 43 non-randomized vs 20 randomized participants in CBT condition and 41 vs 26, in MBCT condition ($\chi^2(1) = 0.72$, $P = .400$). Randomized participants did not differ from the non-randomized ones on any of the demographic characteristics or on any of the baseline outcome scores. All the analyses described below were first conducted, including each participant's randomized vs assigned-to-condition status as an additional factor. Randomization status did not significantly alter any of the findings and was subsequently dropped from the models reported below.

We also examined potential impact of participants' experience with previous treatments for their PVD. The status of having or not having experienced previous treatments was added as an additional factor to all analyses described below. Previous treatment status did not alter any of the finding and was dropped from the models described below.

Participant Recruitment

As shown in Figure 1, 130 women were either randomized or assigned to a treatment arm, and this formed the analytic sample. Participant demographic characteristics are presented in Table 1. The treatment groups were similar, with the exception of the mean length of time since PVD diagnosis ($t[128] = -3.3$, $P = .001$), indicating that women in the MBCT group had a diagnosis of PVD for significantly more years than women in the CBT group. We, therefore, included this variable as a covariate in all analyses examining effects of MBCT vs CBT treatment. 65 women (50% of the sample) reported engaging in vaginal penetration in the preceding 3 months; among the remaining 50%, most reported not engaging in penetration due to pain (22.3% of total sample), 10.8% reported having been advised not to by a health care provider, 9.2% reported not having a partner, and the remaining women (7.7% of total sample) said they were not engaging in vaginal penetration for other reasons.

Session Attendance and Homework Completion

51 of 63 (81.0%) women in the CBT group and 50 of 67 (74.6%) women in the MBCT group attended all 8 sessions.

Overall session attendance was very high, with 92% of women in the CBT group and 94.1% of women in the MBCT group completing ≥6 sessions.

The average rating for ability to complete homework was 2.76/4.0 for the CBT group and 2.49/4.0 for the MBCT group, with no significant differences between the groups ($t[70] = 1.70$, $P > .05$); these values reflect a moderate to high degree of homework completion. The average rating for amount of practice of the skills and exercises since group ended was 2.21 of 4.0 for the CBT group and 2.0 of 4.0 for the MBCT group, with no significant group differences ($t[69] = 0.38$, $P > .05$); these scores reflect a slightly higher level than moderate practice of learned skills. Overall, these scores correspond to a moderate to high-moderate degree of skill practice.

Treatment Manual Adherence and Treatment Credibility

12 random MBCT group sessions were selected to be the focus of treatment manual adherence. The average score was 13 of 14, indicating an extremely high degree of facilitator adherence to the manual. Among the 10 CBT group sessions that were randomly selected to analyze for therapist adherence, the average adherence score was 13.6, indicating near-perfect adherence to the manual. Mean treatment credibility, which was measured after the first session, was 7.40 of 10 (SD = 1.87) for the CBT group and 7.12 of 10 (SD = 1.92) for the MBCT group, indicating a high level of credibility in treatment.

Effects of Wait-List Condition

No significant changes were found between the baseline 1 and baseline 2 scores for any of the primary or secondary outcomes for the 22 women who comprised the wait-list subsample, with t values ranging from 0−1.96, P values from 1.00−.064, and effect sizes from 0−0.34.

Effects of Treatment on Primary and Secondary Outcomes

Table 2 contains means and SDs for each pain, sexual function, and psychological function outcome by treatment and time of assessment. Results for random coefficient analyses are reported in Table 3, along with measures of effect sizes using Cohen's d notation for small, medium, and large effect sizes. In all analyses, t_1 corresponds with pretreatment, t_2 corresponds with post-treatment, and t_3 corresponds with the 6-month follow-up assessment point.

Analysis of pain outcomes showed a decrease in pain between pretreatment and post-treatment, as well as between pretreatment and 6-month follow-up for both the numeric self-report of pain during sexual intercourse/penetration (large effect sizes) and vulvalgesiometer ratings (large effect sizes). In addition, there was a significant Time × Group interaction for the primary outcome (numeric rating scale of pain intensity with intercourse/penetration; n = 64), indicating that MBCT participants reported significantly more pain reduction both between t_1-t_2 and t_1-t_3 than those in the CBT condition.

Sexual function as measured by the FSFI total score (n = 98) showed significant improvement for t_1 and t_2 comparison (small/medium effect size) and for t_1 and t_3 comparison (large effect size). The interaction of Time × Group from t_1-t_3 did not reach statistical significance ($P = .088$).

Participants also reported significant improvements in sexual distress, as measured by the FSDS-R, both between t_1-t_2 (medium/large effect size) and t_1-t_3 (large effect size). No significant Time × Group interaction was found, indicating similar reduction in sexual distress in both treatment groups.

With regard to psychological function outcomes, pain catastrophizing significantly improved for all participants from pretreatment to post-treatment (large effect size) and from pretreatment to 6 months' follow-up (very large effect size). There was no Time × Group interaction, indicating that both groups improved to the same degree. Participants also significantly improved on pain vigilance, as measured by PVAQ, between pretreatment and 6 months' follow-up only (small effect size), whereas the change from t_1-t_2 was not significant. There was no significant difference between the groups.

Significant improvements with treatment were also found on both subscales of chronic pain acceptance (CPAQ Activities Engagement and CPAQ Pain Willingness) between t_1-t_2 and between t_1-t_3 (medium to large effect sizes). There were no significant Time × Group interactions on these measures.

Patient Global Impression of Change and Treatment Satisfaction

Women's ratings of global pain improvement, improvement in quality of sexual life, and overall satisfaction with the treatment was assessed after treatment and at 6 months' follow-up. There were no group differences on any of these measures (Table 4). Participants in both treatment groups reported improvements in pain and sexual life quality at post-treatment and 6 months' follow-up. Overall, 43% reported moderate or great improvement in pain (51% in the CBT group and 35% in the MBCT group) at post-treatment and 63% at 6 months' follow-up (68% in CBT group and 58% in MBCT group). In terms of sex life quality, 43% reported moderate or great improvement at post-treatment (48% in the CBT group and 38% in the MBCT group), and, at 6 months' follow-up, 59% of participants reported moderate or great improvement (60% in the CBT group and 59% in the MBCT group). There were no group differences in the above percentages for any of the analyses (χ^2 tests not significant).

Table 2. Pain, sexual function and distress, and psychological function outcomes by time of assessment and treatment group

Outcome and group	Before treatment, mean (SD)	After treatment, mean (SD)	6 months' follow-up, mean (SD)
Pain during intercourse rating scale*,†			
CBT	5.86 (2.13)	4.65 (2.21)	4.03 (2.11)
MBCT	6.69 (1.91)	4.34 (2.22)	3.39 (1.89)
Vulvalgesiometer pain rating			
CBT	6.62 (2.19)	3.60 (2.14)	2.86 (1.89)
MBCT	6.66 (2.17)	3.21 (1.96)	2.92 (2.31)
Sexual function FSFI total‡			
CBT	21.18 (6.10)	23.41 (5.72)	23.20 (5.45)
MBCT	19.57 (6.29)	21.79 (6.83)	24.75 (5.62)
Sexual distress, FSDS-R			
CBT	35.68 (10.43)	24.93 (9.31)	23.77 (9.61)
MBCT	34.28 (11.18)	26.60 (13.35)	22.81 (12.98)
Pain catastrophizing, PCS			
CBT	25.62 (11.97)	12.57 (8.13)	10.83 (7.66)
MBCT	26.92 (12.86)	15.64 (12.54)	11.55 (9.91)
Pain vigilance, PVAQ			
CBT	42.46 (12.12)	40.32 (14.19)	38.76 (14.47)
MBCT	43.24 (14.67)	39.74 (13.72)	38.50 (13.88)
Chronic pain acceptance, CPAQ Activities Engagement			
CBT	42.39 (10.14)	46.63 (9.34)	47.83 (8.70)
MBCT	42.40 (10.91)	47.97 (10.26)	49.24 (9.29)
Chronic pain acceptance, CPAQ Pain Willingness			
CBT	22.91 (8.05)	29.20 (8.42)	31.29 (8.51)
MBCT	23.99 (9.29)	29.34 (10.07)	33.72 (8.80)

CBT = cognitive behavioral therapy; CPAQ = chronic pain acceptance questionnaire; FSFI = Female Sexual Function Index; FSDS-R = Female Sexual Distress Scale-Revised; MBCT = mindfulness-based cognitive therapy; PCS = pain catastrophizing scale, PVAQ = pain vigilance and awareness questionnaire.
*"Rate the intensity of pain during vaginal penetration attempts with sexual intercourse or penetration over the past 4 weeks."
†Based on n = 64 women.
‡Based on n = 98 women.

DISCUSSION

Main Findings

The aim of this study was to compare group MBCT vs CBT for women with PVD. Overall, we found that group MBCT was superior to group CBT for the primary outcome of pain intensity with sexual intercourse/penetration. MBCT was as effective as CBT on all other pain-related, sexual function—related, and psychological secondary outcomes. Importantly, participants rated a high level of overall satisfaction with both treatments, and all effects were maintained at 6 months. These novel findings contribute significantly to the literature on evidence-based treatments for a distressing and prevalent genital pain condition. Because the study was adequately powered, we posit that the findings are unlikely to be due to chance.

Participants demonstrated a high degree of compliance with session attendance, with 81.0% of participants in the CBT arm and 74.6% of the participants in the MBCT arm completing all 8 sessions, and 93.8% of all participants completing ≥6 of the 8 sessions. In addition, the average amount of homework completion during the sessions was moderate to high, and women continued to complete their homework at the 6-month follow-up.

There was also a very high level of adherence by facilitators to the treatment manual. This suggests that the treatment was delivered as intended and that women found the treatment credible.

Interpretation

Consistent with a body of research showing the beneficial effects of CBT for reducing pain in PVD,[15–19] we found a significant positive effect of CBT on all pain, sexual, and psychological outcomes measured. These findings further strengthen recommendations by international guidelines that CBT is an excellent treatment option for addressing pain intensity with PVD.[45]

Mindfulness, however, was more effective than CBT for self-reported pain with intercourse. The effect sizes associated with this finding were in the strong range, at both immediate post-treatment and 6 months' follow-up. Although the exact

Table 3. Random coefficient analysis models for the outcome measures before treatment, after treatment, and at 6 months' follow-up; group comparison and interaction effects

Variable	b	SE	*P*	*d*	95% CI
Model for pain rating scale of vaginal intercourse/penetration*					
Constant	6.797	0.431	<.001		[5.94, 7.65]
Time ($t_1 - t_2$)	−2.173	0.365	<.001	−1.13	[−2.90, −1.45]
Time ($t_1 - t_3$)	−2.979	0.366	<.001	−1.46	[−3.70, −2.25]
Group	−0.764	0.494	.123	−0.39	[−1.74, 0.21]
Time ($t_1 - t_2$) × Group	1.152	0.538	.034	0.60	[0.09, 2.22]
Time ($t_1 - t_3$) × Group	1.276	0.543	.020	0.63	[0.20. 2.35]
Model for vulvalgesiometer pain rating					
Constant	7.056	0.344	<.001		[6.38, 7.73]
Time ($t_1 - t_2$)	−3.381	0.284	<.001	−1.27	[−3.94, −2.82]
Time ($t_1 - t_3$)	−3.730	0.300	<.001	−1.63	[−4.32, −3.14]
Group	−0.191	0.376	.613	−0.05	[−0.93, 0.55]
Time ($t_1 - t_2$) × Group	0.396	0.412	.337	0.08	[−0.42, 1.21]
Time ($t_1 - t_3$) × Group	−0.002	0.431	.996	−0.05	[−0.85, 0.85]
Model for sexual function: FSFI†					
Constant	20.618	1.138	<.001		[18.37, 22.87]
Time ($t_1 - t_2$)	2.206	0.905	.016	0.36	[0.42, 3.99]
Time ($t_1 - t_3$)	4.782	0.941	<.001	0.77	[2.92, 6.64]
Group	0.697	1.209	.565	0.11	[−1.69, 3.08]
Time ($t_1 - t_2$) × Group	0.457	1.282	.722	0.07	[−2.07, 2.99]
Time ($t_1 - t_3$) × Group	−2.295	1.337	.088	−0.37	[−4.94, 0.345]
Model for sexual distress: FSDS-R					
Constant	33.043	1.892	<.001		[29.31, 36.78]
Time ($t_1 - t_2$)	−7.960	1.301	.001	−0.74	[−10.52, −5.40]
Time ($t_1 - t_3$)	−11.358	1.344	<.001	−1.05	[−14.01, −8.71]
Group	1.835	2.034	.368	0.17	[−2.18, 5.84]
Time ($t_1 - t_2$) × Group	−2.878	1.875	.126	−0.27	[−6.57, 0.82]
Time ($t_1 - t_3$) × Group	−0.659	1.946	.735	−0.06	[−4.50, 3.18]
Model for pain catastrophizing: PCS					
Constant	27.376	1.818	<.001		[23.79, 30.96]
Time ($t_1 - t_2$)	−11.265	1.308	<.001	−0.91	[−13.84, −8.69]
Time ($t_1 - t_3$)	−15.286	1.352	<.001	−1.23	[−17.95, −12.62]
Group	−1.466	1.963	.456	−0.12	[−5.34, 2.41]
Time ($t_1 - t_2$) × Group	−1.818	1.880	.334	−0.15	[−5.52, 1.89]
Time ($t_1 - t_3$) × Group	0.965	1.952	.622	0.08	[−2.88, 4.81]
Model for pain hypervigilance: PVAQ					
Constant	40.726	2.298	<.001		[36.19, 45.27]
Time ($t_1 - t_2$)	−2.806	1.441	.053	−0.21	[−5.65, 0.03]
Time ($t_1 - t_3$)	−4.163	1.490	.006	−0.31	[−7.10, −1.23]
Group	0.113	2.442	.963	0.01	[−4.70, 4.93]
Time ($t_1 - t_2$) × Group	0.163	2.078	.938	0.01	[−3.93, 4.26]
Time ($t_1 - t_3$) × Group	0.287	2.152	.894	0.02	[−3.95, 4.53]
Model for pain acceptance subscale: CPAQ Activities					
Constant	40.164	1.687	<.001		[36.83, 43.50]
Time ($t_1 - t_2$)	5.284	1.105	<.001	0.50	[3.11, 7.46]
Time ($t_1 - t_3$)	6.321	1.153	<.001	0.60	[4.05, 8.59]
Group	−0.578	1.796	.748	0.05	[−2.96, 4.12]
Time ($t_1 - t_2$) × Group	−1.700	1.590	.286	−0.16	[−4.84, 1.44]
Time ($t_1 - t_3$) × Group	−1.317	1.649	.425	−0.13	[−4.57, 1.93]
Model for pain acceptance subscale: CPAQ Willingness					
Constant	22.677	1.484	<.001		[19.75, 25.61]
Time ($t_1 - t_2$)	5.094	0.997	<.001	0.58	[3.13, 7.06]

(continued)

Table 3. Continued

Variable	b	SE	P	d	95% CI
Time ($t_1 - t_3$)	9.482	1.032	<.001	1.09	[7.45, 11.52]
Group	−0.694	1.588	.662	−0.08	[−3.83. 2.44]
Time ($t_1 - t_2$) × Group	1.512	1.430	.292	0.17	[−1.31, 4.33]
Time ($t_1 - t_3$) × Group	−1.460	1.483	.326	−0.17	[−4.38. 1.46]

All models had random intercepts. Effect sizes were calculated using random coefficient analysis estimates presented in this table.
CPAQ Activities = Chronic Pain Acceptance Questionnaire − Activities Engagement scale; CPAQ Willingness = Chronic Pain Acceptance Questionnaire − Pain Willingness scale; FSDS-R = Female Sexual Distress Scale-Revised; FSFI = Female Sexual Function Index; group = mindfulness-based cognitive therapy (reference) vs cognitive behavioral therapy; PCS = Pain Catastrophizing Scale; PVAQ = Pain Vigilance and Awareness Questionnaire; SE = standard error; t_1 = before treatment; t_2 = after treatment; t_3 = 6 months' follow-up.
*Based on n = 64 women.
†Based on n = 98 women.

mechanisms underlying pain relief were not evaluated here and are the subject of another article focused on mediators, whereas both therapies target pain-related thoughts, unique to mindfulness practice is the enhancement of intensity of all sensations—sexual and non-sexual. Research confirms MBCT to heighten sexual sensations to increase desire and arousal in women,[29,46] possibly contributing to the improvement in total sexual function scores. It is also possible that cultivating a more mindful, non-evaluative approach learned in the non-sexual areas of life generalizes to their sexual encounters. The MBCT intervention specifically included exercises in learning a new way to experience physical discomfort by bringing attention to sensations with attitudinal qualities of receptivity and equanimity instead of evaluating them. This new way of experiencing pain sensations may have directly contributed to the improvements seen with MBCT. The fact that we did not see any changes in self-reported pain among the subset of women who completed 2 baseline assessments before beginning treatment suggests that treatment-related improvements are unlikely to be due to the passage of time.

Overall improvement in sexual function was similar with both MBCT and CBT; the latter findings were consistent with previous RCTs of CBT that evaluated sexual functioning as an endpoint.[15,16] That sexual function was also found to be improved in the MBCT arm is consistent with a growing body of literature showing effects of group mindfulness-based interventions for low sexual desire among non-PVD samples.[29,46] Although mechanisms of action were not analyzed here, it is possible that mindfulness reduces the tendency to follow non-erotic distracting thoughts—a major factor identified as limiting women's sexual function[47]—and enhances relationship intimacy.[48,49] It is also possible that the known effects of mindfulness on reducing anxiety [50] may have contributed to the observed improvements in sexual function for women with PVD.[51] Sexual distress significantly decreased in both treatment groups, consistent with previous studies in women with PVD [26,27] and with sexual dysfunction.[29,46]

Catastrophizing dramatically decreased equally in the CBT and MBCT groups. Whereas CBT directly addresses irrational and catastrophic thoughts and replaces them with more balanced

Table 4. Satisfaction and treatment evaluations by time of assessment and treatment group

Measure and group	Post-treatment, mean (SD)	Follow-up, mean (SD)	Group		Group × Time	
			t	P	t	P
Satisfaction*			−0.73	.467	1.02	.313
CBT	7.46 (1.70)	7.48 (1.74)	d = −0.14		d = 0.16	
MBCT	7.53 (2.15)	7.88 (1.75)				
Pain improvement†			−0.83	.409	−0.19	.850
CBT	3.47 (0.89)	3.11 (0.89)	d = −0.17		d = −0.04	
MBCT	3.67 (1.10)	3.27 (1.22)				
Sexuality improvement‡			0.23	.821	−1.19	.236
CBT	2.48 (1.01)	2.30 (0.83)	d = 0.05		d = −0.23	
MBCT	2.70 (1.01)	2.27 (1.09)				

Higher scores indicate more satisfaction and less improvement.
CBT = cognitive behavioral therapy; MBCT = mindfulness-based cognitive therapy.
*Maximum possible score is 10.
†Maximum possible score is 5.
‡Maximum possible score is 4.

thoughts, mindfulness is intended to help an individual recognize catastrophic thoughts as simply being mental events, without attempting to change them. In contrast to our findings, some studies have found mindfulness to produce stronger effects.[23,52,53] The discrepancy between our observed equivalency of CBT and MBCT on pain catastrophizing compared with other patient populations deserves further study.

Pain hypervigilance also decreased to a similar degree in both the CBT and MBCT groups, but only when assessed at 6 months' follow-up, and, compared with the magnitude of effects for pain catastrophizing, the effect sizes for pain hypervigilance were small. It may be that ongoing mindfulness training is necessary to reduce anxiety—key to reducing pain hypervigilance [54]—and greater improvements might be seen at the 12-month follow-up (the subject of a future article). However, there is an apparent paradox given that mindfulness can reduce hypervigilance to visceral sensitivity,[55] but it can also increase interoception [56] so that the person is more aware of bodily sensations. The extent to which the increased awareness in physical sensations is matched with increased ability to accept them without reactivity may have contributed to an overall weak effect of MBCT on hypervigilance.

Because mindfulness enhances the ability to accept all that each moment brings, it is not surprising that MBCT increased pain acceptance. Interestingly, CBT also had a similar beneficial effect on pain acceptance, an effect consistent with that found among chronic low back pain sufferers.[52] Although the mechanisms by which CBT and MBCT both decrease the threat value of pain are different, these strategies appear to cultivate pain acceptance to a similar degree

Participants were overall very satisfied with treatment, remaining so 6 months later. Global ratings of overall improvement in pain and in sexuality were both in the modest range after treatment without significant change at 6 months post-treatment. Despite this, women still reported high levels of satisfaction with treatment. This finding suggests that their evaluations of satisfaction may be based on aspects of their experience beyond the pain intensity itself.

Strengths and Limitations

Given the hospital-based context of our study, and the fact that women were recruited from a population of women seeking treatment for PVD, timely patient care took priority, and this meant that we were only able to randomize one-third of our participants to treatment arm. Future studies should aim to replicate the current design using strict randomization. Although the lack of complete randomization may be taken as a weakness, this also speaks to the clinical context of the tertiary care sexual medicine center in which the study was conducted, as well as to the ability of our findings to be generalized to other similar clinical contexts. However, patients were not permitted to express any preference for 1 arm over the other, and study personnel performing the randomization and group assignment were not involved in the treatment itself. Further contributing to the generalizability of our sample to the larger population of treatment-seeking women with PVD, at baseline, participants' mean level of pain was rated as high, comparable to levels of pain seen in clinical settings, and to other studies of women with PVD.[15,16,57–59] Their ratings of credibility were the same as those in another study of CBT for PVD.[49]

Also, our primary treatment outcome, self-reported pain with sexual intercourse/penetration, was completed by only one-half of the sample, given that it required women to have engaged in penetrative sexual activity in the previous 4 weeks—the absence of which may not have been to do with residual pain. This finding was expected, given that both treatment arms had instructed women to abstain from sexual activity that elicited pain for them (although, in the CBT arm, women were also taught to challenge avoidance behavior and engage in vaginal penetration using vaginal inserts). The possibility that women were not engaging in sexual activity (as evidenced also by the finding that 50% of the women at study entry had not engaged in vaginal sexual activity in the preceding 3 months) also justifies our inclusion of other measures of sexual and psychological function, which were not dependent on sexual activity. In addition, pain reduction may not be the most relevant factor in women's sexual satisfaction [60,61] with PVD, as supported by recent research emphasizing the importance of multiple measures of pain and affect in treatment outcome studies with PVD.[62]

Implications

Integrating 8 session group therapy programs into the clinical management of PVD has proven to be effective, feasible, and satisfying to patients. This was true for both CBT and MBCT approaches. In many respects, benefit was comparable between the 2 programs: reduction of pain during vaginal penetration was greater with MBCT. Our findings support recent international guidelines endorsing the use of CBT for women with PVD.[45]

This is the first empirical test of an 8-session group MBCT for women with PVD and suggests that health care providers should consider the use of mindfulness-based approaches for women seeking care. In the future, it may be important to develop online adaptations of these interventions to allow women living in geographically remote areas to access these therapies.

CONCLUSIONS

Our findings support recent international guidelines endorsing the use of CBT for women with PVD at a level 2 grade of evidence.[45] Moreover, we have shown that integrating 8-session group mindfulness therapy programs into the clinical management of PVD is effective, feasible, and satisfying to patients. Future studies should aim to replicate the current study using a strict randomization protocol.

ACKNOWLEDGMENTS

We wish to acknowledge the assistance of Adrienne Marsh, Robyn Jackowich, and Yvonne Erskine.

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Conflicts of Interest: The authors report no conflicts of interest.

Funding: Operating Grant MOP-123271 from the Canadian Institutes of Health Research was awarded to L. Brotto as Principal Investigator, and the co-authors as Co-Investigators.

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