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Mindfulness and Cognitive Behavior Therapy for Provoked Vestibulodynia: Mediators of Treatment Outcome and Long-Term Effects

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Objective: Provoked vestibulodynia (PVD) is a chronic vulvo-vaginal pain condition affecting 8% of premenopausal women. Cognitive–behavioral therapy (CBT) is effective in managing pain and associated sexual and psychological symptoms, and a recent study found group mindfulness-based cognitive therapy (MBCT) to be equivalent. Our goal was to examine the long-term outcomes of these treatments and to explore mediators of change. ***Method:*** Participants were 130 women diagnosed with PVD who had participated in a clinical trial comparing 8 weeks of group CBT to 8 weeks of group MBCT. Data were collected at pretreatment, posttreatment, and at 6- and 12-month follow-up periods. Outcomes focused on (a) pain with vaginal penetration, (b) pain elicited with a vulvalgesiometer, and (c) sex-related distress. Mediators of interest included pain acceptance (both pain willingness and activities engagement), self-compassion, self-criticism, mindfulness, decentering, and pain catastrophizing. ***Results:*** All improvements in the 3 outcomes were retained at 12-month follow-up, with no group differences. Pain catastrophizing, decentering, and chronic pain acceptance (both scales) were mediators of improvement common to both MBCT and CBT. Changes in mindfulness, self-criticism, and self-compassion mediated improvements only in the MBCT group. ***Conclusions:*** Both MBCT and CBT are effective for improving symptoms in women with PVD when assessed 12 months later. The findings have implications for understanding common and potentially distinct pathways by which CBT and MBCT improve pain and sex-related distress in women with PVD.

What is the public health significance of this article?
This study strongly suggests that the benefits of both mindfulness-based therapy and cognitive–behavioral therapy for provoked vestibulodynia are maintained a year after treatment. The finding that there were several mediators associated with improvements in both these treatments suggests common underlying mechanisms in MBCT and CBT. That mindfulness, self-criticism, and self-compassion mediated improvements only with MBCT suggests unique properties of mindfulness that should be considered when selecting treatments for women with PVD seeking care.

Keywords: provoked vestibulodynia, mindfulness-based therapy mediators, cognitive behavior therapy mediators, treatment outcomes, pain catastrophizing

Provoked vestibulodynia (PVD) is the most common explanation for women's experience of chronic and distressing vulvo-vaginal pain. PVD affects approximately 8% of premenopausal women (Harlow et al., 2014; Pukall & Cahill, 2014; Reed et al., 2012) with a similar prevalence across ages among sexually active women (Reed et al., 2012). The diagnostic hallmark of PVD is the triggering of pain in response to a nonpainful stimulus applied to the vulva (otherwise known as *allodynia of the vestibule*). Women also have varying degrees of heightened pelvic muscle contraction. When the pain symptoms last 6 months or more, PVD is classified under genito-pelvic pain/penetration disorder in the 5th edition of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM–5*; American Psychiatric Association, 2013). Although genito-pelvic pain/penetration disorder and PVD are sometimes used interchangeably to refer to the same condition, we will refer to it as PVD given that the predominance of the literature uses this terminology.

Women's pain with sexual intercourse or other forms of penetrative sexual activities poses a significant health burden, and negatively impacts personal relationships, emotional function (mood), sexual function (including sexual desire, arousal, and

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orgasm), sexual satisfaction, and other domains of well-being (Pukall et al., 2016; Sadownik, 2014). The economic burden of PVD is high with 60% of women consulting at least three physicians prior to receiving an accurate diagnosis (Harlow et al., 2014). The emotional costs can be staggering for women and form the basis of the current study.

Psychological Aspects of PVD

The psychological correlates of PVD are well established (Benoit-Piau et al., 2018). Women experiencing chronic PVD have increased rates of anxiety, fear of pain, sex-related distress, hypervigilance to pain, fear of negative evaluation by others, and pain catastrophizing, many of which are significantly correlated with pain intensity during intercourse (Basson, 2012; Brotto, Basson, & Gehring, 2003; Desrochers, Bergeron, Khalifé, Dupuis, & Jodoin, 2009; Goldstein et al., 2016; Pukall et al., 2016). A history of depression and/or anxiety markedly increases vulnerability to developing chronic genito-pelvic pain (Khandker et al., 2011). Similar to other frequently associated chronic pain syndromes (Lester, Brotto, & Sadownik, 2015), there has been much interest in establishing effective psychological treatment approaches.

Two psychological approaches, namely cognitive–behavioral therapy (CBT) as well as mindfulness-based cognitive therapy (MBCT), have been found to be effective in the management of PVD. In the context of PVD, CBT aims at challenging maladaptive pain-related thoughts, emotions, behaviors, and couple interactions; teaching relaxation skills; targeting avoidance; and restoring sexual function (Dunkley & Brotto, 2016). *Mindfulness*, on the other hand, is a meditative practice defined as non-judgmental, present-moment awareness (Bishop et al., 2004), which, in the context of PVD, aims to increase awareness of pain-related thoughts and physical sensations with equanimity and without the intention of controlling or changing them. Whether CBT is administered individually (Goldfinger, Pukall, Thibault-Gagnon, McLean, & Chamberlain, 2016; Masheb, Kerns, Lozano, Minkin, & Richman, 2009), to couples (Corsini-Munt, Bergeron, Rosen, Mayrand, & Delisle, 2014), or to groups (Bergeron et al., 2001; Bergeron, Khalifé, Dupuis, & McDuff, 2016), it has been found to lead to both short-term and lasting improvements in genital pain intensity, overall sexual function, and pain catastrophizing in women with PVD.

Mindfulness-based therapy has only more recently been applied to and studied as a treatment for PVD, compared to CBT. An initial study comparing four biweekly sessions of mindfulness against a wait-list control group in 85 women with PVD found significant reductions in genital pain intensity, pain catastrophizing, pain hypervigilance, sexual distress, and negative mood, and an increase in feelings of self-efficacy for managing pain (Brotto, Basson, Smith, Driscoll, & Sadownik, 2015). Qualitative interviews revealed that pain acceptance was a vehicle for producing improvements in mood and anxiety (Brotto, Basson, Carlson, & Zhu, 2013).

Efficacy of Psychological Treatments for PVD

Recently, CBT has been compared to an equal duration MBCT intervention in a head-to-head trial focused on women with PVD (Brotto et al., 2019). Treatment consisted of eight 2-hr weekly group sessions led by professional facilitators, with expertise in mindfulness-based interventions, CBT, and managing PVD. Duration of sessions, assessments, and educational information about PVD were the same in both arms. The primary endpoint focused on vaginal pain intensity using a numeric rating scale (Farrar, Young, LaMoreaux, Werth, & Poole, 2001) and vulvo-vaginal pain assessed with a vulvalgesiometer (Pukall, Binik, & Khalifé, 2004; Pukall, Young, Roberts, Sutton, & Smith, 2007) designed to administer a fixed amount of pressure to the vulva. In addition, several secondary endpoints focused on sexual functioning, sex-related distress, and various psychological outcomes used in studies of chronic pain. Both treatments led to similar significant improvements in ratings of provoked vulvar pain; overall sexual function; pain catastrophizing; pain hypervigilance; and sex-related distress. MBCT, however, had a comparatively larger effect size for the outcome of self-reported pain with vaginal penetration, compared to CBT, suggesting potentially different mechanisms underlying these two treatments. All effects were in the moderate to very strong clinically meaningful range when assessed both 2–4 weeks after treatment and at the 6-month follow-up period (Brotto et al., 2019).

Putative Mediators of Improvement With CBT

Little research has focused on identifying mediators of pain outcomes in women with PVD. According to the fear-avoidance model of pain (Norton & Asmundson, 2003; Vlaeyen, Crombez, & Linton, 2009), when pain is viewed as threatening there is an ensuing fear reaction that contributes to avoidance behavior in an attempt to minimize or avoid the pain. The interference in one's life as a result triggers negative affect which can directly contribute to the pain intensity. From a fear-avoidance model of pain adapted to women with PVD, catastrophizing in particular is found to contribute a significant amount of unique variance to pain intensity given that catastrophizing about pain leads directly to avoidance behavior (Desrochers et al., 2009). In a comparison of CBT versus a topical treatment for PVD, baseline levels of catastrophizing significantly predicted pain intensity levels after treatment (Desrochers, Bergeron, Khalifé, Dupuis, & Jodoin, 2010).

Vaginismus is a separate but often co-occurring women's sexual dysfunction characterized by variable degrees of pelvic floor dysfunction and inability to permit vaginal penetration. Three studies have evaluated CBT for vaginismus, with each of them exploring potential mediators of treatment improvement. In a comparison of 10 weekly group CBT sessions versus a minimal-contact CBT bibliotherapy for vaginismus, a total of 33% of participants achieved full vaginal penetration after treatment, and improvements were partially mediated by fear of penetration and by more noncoital penetration behavior (ter Kuile et al., 2007). Therapist-aided exposure for vaginismus, which included three 2-hr sessions at a hospital where the woman inserted a vaginal dilator in the presence of a therapist and her partner, resulted in 89% of treated couples successfully achieving vaginal penetration with a partner (ter Kuile, Melles, Tuijnman-Raasveld, de Groot, & van Lankveld, 2015). Changes in catastrophic pain penetration beliefs significantly mediated improvements in vaginismus symptoms, coital frequency, and coital pain (ter Kuile, Melles, de Groot, Tuijnman-Raasveld, & van Lankveld, 2013). Changes in perceived control over penetration also mediated improvements in outcomes. In the

more general chronic pain literature, mediators found to predict improvements in pain-related outcomes 18 months later after CBT (plus exercise) included improvements in negative emotional cognitions, perceived control, coping, and catastrophizing (de Rooij et al., 2014). Taken together, these findings provide support for the fear avoidance model of maintaining symptoms in PVD (as well as vaginismus) and suggest that pain catastrophizing is likely a mediator of improvements following treatment with CBT.

Putative Mediators of Improvement With MBCT

Because earlier work applying mindfulness to women with PVD found that there were changes in catastrophizing, but that those changes did not mediate improvements in the primary outcome of pain (Brotto et al., 2015), we did not expect catastrophizing to mediate changes in the MBCT arm.

Instead, given past qualitative findings that changes in pain acceptance may underlie improvements in genital pain after mindfulness for PVD (Brotto et al., 2013), and given findings from a cross-sectional study of women with PVD that found that a woman's level of pain acceptance was associated with her own levels of pain as well as her own and her partner's level of sexual satisfaction (Boerner & Rosen, 2015), we elected to examine chronic pain acceptance as a mediator of outcomes. Among cancer survivors, there is evidence that responding to neuropathic pain with acceptance may lead to reduced rumination about pain, and this may explain the observed negative association between pain intensity and a self-report measure of "non-judgement" (Poulin et al., 2016). Acceptance was also found to mediate improvements in pain intensity among a general chronic pain sample (Samwel, Kraaimaat, Crul, van Dongen, & Evers, 2009). However, the mediating role of pain acceptance has not yet been unequivocally established. In a comparison of 8 weeks of acceptance and commitment therapy, a type of mindfulness-based intervention, versus CBT in the treatment of chronic pain (Wetherell et al., 2011), pain acceptance failed to mediate outcomes. The authors attributed the lack of mediation by chronic pain acceptance to the likelihood that participants had learned active methods of coping, which translated into improvements in sense of control over pain that may have masked mediated effects of acceptance. Given that the two dimensions of pain acceptance—willingness to accept pain and reduce efforts to avoid or control it and engagement in activities despite feeling pain—have been found to be somewhat related but also associated with different pain-related disability and distress outcomes (see McCracken, Vowles, & Eccleston, 2004), we examined both of these acceptance dimensions as potential mediators after MBCT.

Self-compassion has also been described as a possible mediator of the benefits of mindfulness treatment and can be defined as being open to one's own suffering, not avoiding or disconnecting from it, and generating desire to alleviate suffering with kindness (Neff, 2003b). Self-compassion appears to be an important target of treatment in PVD given evidence that this population of women experience guilt, shame, and self-blame (Shallcross, Dickson, Nunns, Mackenzie, & Kiemle, 2018)—constructs that are relevant to the scale of self-criticism. Changes in self-compassion have been found to mediate improvements in self-perceived stress among health care providers following mindfulness training (Shapiro, Astin, Bishop, & Cordova, 2005; Van Dam, Sheppard, Forsyth, & Earleywine, 2011). Furthermore, a cross-sectional study of women with PVD and their partners found that self-compassion was associated with lower levels of anxiety and depression, and a partner's self-compassion predicted a woman's level of sex-related distress (Santerre-Baillargeon et al., 2018). Kindness toward oneself rather than blame and judgment may interrupt the vicious cycle of stress speculated to underlie the chronicity of PVD (Basson, 2012). Specifically, a circular model of PVD maintenance has been postulated that suggests that the sexual dysfunction secondary to painful sex combined with preexisting emotional symptoms as well as current cognitions such as feeling "sexually substandard" collectively lead to neuroplastic changes in the brain that give rise to central sensitization. Cognitive changes can further interfere with processing sexual stimuli and further hamper motivation for sex, above and beyond the effects of pain. Exacerbating this cycle is the impact of stress on skin sensitivity. Basson's (2012) model of the perpetuation of vaginal pain in women with PVD posits that women's tendency to be overly self-critical was an important target for PVD management that could be addressed with mindfulness-based interventions. As such, we hypothesized that improvements in pain intensity with penetration would be mediated by changes in self-compassion in the MBCT arm but not in the CBT arm.

Another hypothesized mediator following MBCT was changes in the level of mindfulness itself, which we measured with two different instruments. One of the core skills taught in the mindfulness intervention was to focus on the physical sensations of pain, letting go of the tendency to focus on the emotional aspects of pain, including suffering. With repeated practice, participants could focus on describing the pain qualities and sensations and let thoughts with a strong emotional tone become less prominent. As a result of this practice, we hypothesized that improvements in self-reported pain with penetration in the mindfulness arm only would be mediated by changes in general mindfulness. Also given that the mindfulness intervention included training in metacognitive awareness and experiencing thoughts as mental events, we included a measure of decentering that tapped into having a decreased attachment to one's thoughts and emotions (Fresco et al., 2007; Shapiro, 2009; Shapiro, Carlson, Astin, & Freedman, 2006), which allows one to remain with or tolerate negative emotional states (Simons & Gaher, 2005) and to distance themselves from thoughts of evaluation and reaction. The literature interchanges the terms *metacognitive awareness* and *decentering*, with both referring to the ability to observe thoughts and feelings as temporary events of the mind (Teasdale et al., 2002) and, as such, ours was a measure of decentering. Because only the MBCT arm trained participants to observe mindfully and without emotional attachment, we predicted that changes in mindfulness and decentering would mediate improvements in pain in the mindfulness but not in the CBT arm.

Long-Term Effects of Treatment

What happens to improvements in pain over time? In a different long-term analysis of women with PVD who were randomized to receive treatment with either CBT, vestibular surgery, or biofeedback, pain with sexual intercourse continued to improve between the 6-month and the 2.5 year follow-up time periods after CBT (Bergeron, Khalifé, Glazer, & Binik, 2008). On overall sexual

function, women in the CBT group showed no loss of improvement from 6 months to 2.5 years after treatment. Nevertheless, the sample size for each arm of this study was relatively small (range between $n = 22$ to $n = 28$ across the three arms) and hence results require replication. Further, there are no published data on the long-term (12 months or longer) effects of MBCT for PVD. There is thus a need to examine the long-term effects of CBT and MBCT, and to compare them directly, in the maintenance of improved pain, and in ongoing improvements with sexual distress—a major aspect of quality of life impacted by PVD. Given evidence that pain intensity tends to improve among women with PVD even in the absence of treatment (Davis, Bergeron, Binik, & Lambert, 2013), it is especially important to determine the degree of improvement with each of these treatments over the long-term.

Goals of the Study

The psychological mechanisms by which MBCT and CBT may improve pain outcomes in women with PVD are largely unknown and form the basis for the current study. We also examined changes in pain acceptance, self-compassion, mindfulness, decentering, and pain catastrophizing as mediators of our three outcomes. Second, we report on the long-term outcomes of pain with vaginal penetration, pain provoked with a vulvalgesiometer, and sex-related distress at the 12-month point after receiving CBT or MBCT. We examined these three outcome variables given evidence that self-reported pain with penetration and vulvalgesiometer-elicited pain represent two unique aspects of the pain experience (Aerts, Bergeron, Pukall, & Khalifé, 2016; Wammen Rathenborg, Zdaniuk, & Brotto, 2019), and sex-related distress given it is frequently identified in the clinical setting, and has been included as a primary outcome in treatment outcome studies of PVD (Brotto et al., 2019).

Method

Participants

Participants were 130 women diagnosed with PVD. Inclusion criteria were (a) having a diagnosis of PVD that was confirmed by both clinical history as well as by a cotton-swab test carried out by a physician; (b) a duration of PVD that was at least 6 months; (c) ability to attend eight weekly treatment sessions; (d) age 19 years or older; (e) fluent in English; and (f) a 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 (a) unprovoked vulvovaginal pain; (b) pelvic pain; (c) a vulvar skin condition (e.g., lichen sclerosus); and (d) significant symptoms of dissociation (which would make participation in mindfulness-based therapy challenging). Additional recruitment details are provided in Brotto et al. (2019).

Procedure

An emailed link to the online battery of questionnaires was administered at pretreatment (T1), then again at 2–4 weeks after the eighth session of treatment (T2), and at 6- and 12- month follow-up (T3 and T4). In the present article, the follow-up analyses compare T2 and T4 data whereas the mediation analyses examined T1 and T4 data. Measures included pain, sexual functioning, and psychological symptoms. Immediately after completing the baseline battery of questionnaires, participants attended 8 weeks of CBT or MBCT group treatment. All participants provided written consent, and the study was approved by both the University of British Columbia Clinical Research Ethics Board and the associated Vancouver Coastal Health Research Ethics Board (for detailed description of all the procedures, please see Brotto et al., 2019).

Treatments. Some participants were randomized to treatment and others were allocated due to scheduling logistics (see Figure 2). Potential impact of nonrandomization was methodically examined and no effect was found, as discussed in Brotto et al. (2019). Both treatments were delivered over eight weekly sessions, 2.25 hr in length, by clinicians with training in group therapy (either CBT or MBCT or both), and with considerable expertise in the diagnosis and management of sexual disorders and PVD. Facilitators for the mindfulness 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. There were two facilitators for every group, and the maximum number of participants in each group was eight. Any given facilitator did not lead a CBT and MBCT group at the same time, to adhere to the theoretical orientation of that group only. All facilitators were considered experts in the delivery of the treatment modality, and there was a very high level of adherence to the treatment manuals, as measured by having two independent coders listen to 20% of all recorded sessions and rate adherence on a modified version of the MBCT Adherence Scale and CBT Adherence Scales (Segal, Teasdale, Williams, & Gemar, 2002).

CBT. The CBT intervention was adapted from a 10-session group CBT for PVD that was developed and tested by Bergeron et al. (Bergeron et al., 2001, 2016) to an 8-week group format. 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 (e.g., progressive muscle relaxation, alone and then paired with vaginal penetration exercises done with progressively increasing sizes from a cotton swab to two fingers; diaphragmatic breathing; challenging avoidance behavior); cognitive techniques (e.g., rehearsal of self-statements to cope with pain; cognitive restructuring); and communication-skills training, which included addressing ways a woman might speak to a current or future partner about her pain. We developed a treatment manual for the facilitator and an accompanying guide for the participant which was adhered to closely by the facilitators. Home activities were up to 45 min/daily, and of the same duration as exercises prescribed in the MBCT arm.

MBCT. The MBCT intervention (Basson et al., 2012) taught women 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 (nongenital) pain in session and provoking vestibular pain at home using the woman's own finger at the entrance of the vagina. A full 1 hr of each session was spent engaging in a guided mindfulness practice plus inquiry on practice. The treatment also focused on development of metacognitive awareness (e.g., noticing biased and unbiased thoughts and simply allowing their existence but not following them or

necessarily believing them). Participants were sent Dropbox links after each session to the audiorecorded mindfulness practice (which ranged from 20 to 45 min daily) that was encouraged to be practiced daily at home prior to the next session. Participants were also encouraged to document their observations from a variety of at-home exercises in their participant manuals.

Psychoeducational material common to both arms. There was common psychoeducational material in both the CBT and MBCT arms, which included (a) learning how PVD affects sexual desire, motivation, and function; (b) information on the role of stress in chronic pain and PVD; and (c) communication skills training. Immediately after their eighth (last) session, and again at the 6-month time point, participants were asked to self-rate their degree of homework completion since their last assessment.

As reviewed in the article describing the primary outcomes of the study (Brotto et al., 2019), participant attendance was excellent (92% of women in the CBT group and 94.1% of women in the MBCT group completed six or more sessions). Homework compliance scores reflected a moderate degree of homework completion both at the end of treatment and when women were assessed in follow-up. Importantly, women found the treatments to be highly credible (when assessed after the first group session).

Measures

Pain and sexual distress outcomes. We had three main outcomes in this study. Given that there is only modest overlap between different measures of pain (Wammen Rathenborg et al., 2019), we included two different measures of pain as endpoints. Sexual distress was included as an additional outcome given strong evidence of high levels of distress in women with PVD, and its association with depressive symptoms and anxiety in both women and their partners (Pâquet et al., 2018). First, we included the self-rated Numeric Rating Scale as a measure of vaginal pain intensity, which 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 0 (*no pain*) to 10 (*worst possible pain*). Women who did not engage in vaginal penetration over the past 4 weeks received a *not applicable* score for this question at baseline and were not included in follow-up analyses. A secondary outcome of pain was assessed with the vulvalgesiometer and provided a standardized measure of pain that was intended to resemble the cotton swab test, considered part of a gold-standard method of diagnosing PVD (Friedrich, 1987). The vulvalgesiometer is an instrument that provides a measure of pain/sensitivity by exerting a standardized amount of pressure. The vulvalgesiometer has been validated and reliably documents changes in pain (Pukall et al., 2007). As the study clinician palpated seven 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*) to 10 (*worst pain ever*). An average score across the seven points (in some cases, fewer than seven if the woman reported severe pain during the test) was calculated. The third outcome of interest was *sexual distress* and was measured by the 13-item Female Sexual Distress Scale—Revised (FSDS-R; DeRogatis, Clayton, Lewis-D'Agostino, Wunderlich, & Fu, 2008), which measures a woman's distress associated with her sexual functioning. Total scores range from 0 to 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 (DeRogatis et al., 2008). In this sample, Cronbach's alpha at pretreatment was .93.

Mediators. We assessed pain catastrophizing with the Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995). It is a 13-item self-report measure that asks participants to indicate the degree to which they have certain thoughts or feelings when experiencing 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. Total scores which range from 0 to 52, with higher scores indicating greater pain catastrophizing, were used. In the current sample, Cronbach's alpha was .94 for the PCS total scale.

Pain acceptance was measured with the Chronic Pain Acceptance Questionnaire (CPAQ; McCracken et al., 2004), 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. Two scales recommended by the authors of the questionnaire were used: the Pain Willingness Scale, which recognizes that avoidance and control are not adaptive means of coping with pain, and the Activities Engagement Scale, which measures pursuit of life activities regardless of pain. We elected to examine these scales given the possibility that they might mediate changes with MBCT more than CBT, whereas the two treatments may impact pain willingness to the same degree. The nine items of the Pain Willingness Scale had a total score range from 0 to 54 and the 11 items of the Activities Engagement Scale had a total score range from 0 to 66, with higher scores on both domains indicating higher levels of pain acceptance. Baseline Cronbach's alpha was .81 for the Pain Willingness Scale and .86 for the Activities Engagement Scale.

Three mindfulness-related constructs and two dimensions of psychological functioning were examined as potential mediators of treatment effected change. The first mindfulness related mediator was self-compassion tested using the 26 item Self-Compassion Scale (Neff, 2003a), which measures different aspects of compassion and kindness toward oneself. Whereas the original measure produced six subdomains of self-compassion the subsequent research failed to confirm the higher-order single factor structure and provided robust evidence for two domains of self-compassion and self-criticism (Costa, Marôco, Pinto-Gouveia, Ferreira, & Castilho, 2016; Neff, 2016), and these two scales were used in this study. Higher scores indicate greater self-compassion and lower self-criticism and both scale scores range from 1 to 5. In this sample, Cronbach's alpha at pretreatment was .92 for self-compassion and .91 for the self-criticism scale.

The second mindfulness measure relied on a total score from the 39-item Five Facet Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006), which measures different aspects of attentiveness. Total scores range from 39 to 195, with higher scores indicating greater mindfulness. The FFMQ has been found to have adequate to good internal consistency with alphas ranging from 0.72 to 0.92 (Leitenberg & Henning, 1995). In this sample, Cronbach's alpha at pretreatment was .89. A third mindfulness related mediator was "decentering," assessed using the Experiences Questionnaire (Fresco et al., 2007), which measures one's ability to observe thoughts and feelings. It taps into the

degree to which people can separate themselves from the temporary nature of their thoughts. It originally was designed to measure two domains, decentering and rumination, but only one factor, decentering, persevered after performing exploratory and confirmatory factor analysis. The final measure consisted of 11 items. The score range is from 11 to 55, and the higher the score, the greater the ability to decenter (a goal of mindfulness). Internal consistency measured by Cronbach's alpha on the current sample was .90.

Data Analysis Plan

Longitudinal effects of treatment were analyzed using a multilevel mixed model analysis evaluating main effects of the within group factor based on two measurement points (posttreatment and 12-month follow-up) and between group factor comparing two treatments (CBT vs. MBCT), as well as the interaction of the within and between subject factors. Three models were examined, one for each dependent variable (vaginal pain intensity; vulvalgesiometer rating of pain; and sexual distress). In addition to main and interaction effects, effect sizes and confidence intervals (CIs) were also calculated. Multilevel modeling analyses used full-information maximal likelihood estimation technique to accommodate missing data which is considered "state of the art" method of modern missing data approaches (Coady, Futterman, Harris, & Coleman, 2015).

In light of our prediction that different mechanisms may underlie positive changes following each of the two treatments, we tested a moderated mediation model (see Figure 1) described as Model 5 in Preacher, Rucker, and Hayes (2007) and presented in Figure 10.1C in Hayes (2013). We examined which variables mediated the treatment impact on PVD related outcomes and whether such mediation was moderated by the type of treatment (CBT vs. MBCT). We hypothesized that the type of treatment (moderator variable in Figure 1) may affect path a, path b, or both. Thus, our hypothesis assumes that the moderated mediation is present when either path a or path b or both are moderated.

Mediation was tested by a sequence of multilevel mixed models. The main predictor consisted of the four time points (baseline, posttreatment, 6-month, and 12-month follow-up) entered as a continuous time variable in order to test the impact of treatment over time on the three outcomes. The mediators comprised within-subject change scores across the four time points. Following the recommendations of Zhang, Zyphur, and Preacher (2009) on testing mediation in multilevel models, the approach of mediator being centered within context with reintroduction of the subtracted mean (CWC[M]) was used by entering person centered mediator variable (Wang & Maxwell, 2015). Thus, each person's average across four time points (person intercept) was included as well as the difference scores between each time assessment and the person average (within person change) which allows for examining impact of change in mediator on the change in outcome.

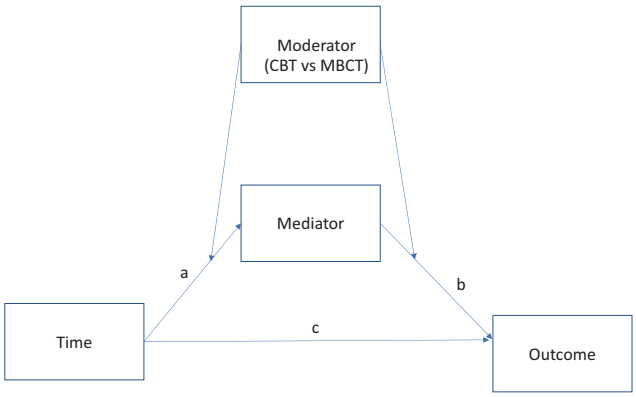

Figure 1. Model illustrating treatment type as a moderator of the mediated pathways (moderating either path a, path b, or both) from treatment to improvements in pain related outcomes. CBT = cognitive–behavioral therapy; MBCT = mindfulness-based cognitive therapy. See the online article for the color version of this figure.

The moderated mediation was tested by first fitting a model for moderated path a in which the change in the mediator is regressed on time, type of treatment (CBT vs. MBCT), and their interaction. Significant interaction term indicates that the impact of treatment on changes in the mediator is conditional on the type of treatment. Next, a model for moderated path b was fitted in which changes in the outcome were regressed on time, type of treatment (CBT vs. MBCT), mediator and the interaction of type of treatment and mediator. A significant interaction term indicates that the impact of the changes in the mediator on the changes in the outcome is conditional on the type of treatment. Finally, the conditional indirect effect was computed by multiplying path a and path b unstandardized coefficients separately for CBT and MBCT arms. The significance of those indirect effects was estimated using the bootstrap method (Hayes, 2013; MacKinnon, Lockwood, Hoffman, West, & Sheets, 2002). In this approach, which is considered superior to other methods (e.g., Sobel test) when evaluating the presence of mediation (MacKinnon et al., 2002), multiple samples (at least 5,000 are recommended) of N cases each are drawn with replication from the original sample of N cases. Next, the mediation models are conducted on each sample and the estimates and standard errors are averaged. The indirect effect is computed as the product of path a and path b unstandardized coefficients and the 95% CI for the values of this effect is established. It is assumed that the indirect effect is statistically significant if the CI does not include zero (Preacher et al., 2007). Statistically significant indirect effects indicate the presence of mediation. In the case of moderated mediation, the bootstrap analysis is performed separately for selected levels of the moderator (in our case, separately for CBT and MBCT participants).

Following the IMMPACT recommendations (Turk et al., 2008), we did not correct for multiple tests. The consortium recommends that when secondary endpoints are analyzed to better understand the mechanisms behind a treatment and such analysis is accompanied by significant effects of treatment for all primary endpoints (as is the case in our study) then the correction for multiple comparisons is not necessary and the prespecified alpha level ($p < .05$) can be used to avoid loss of power (D'Agostino, 2000; Turk et al., 2008).

The whole sample was used in the mediation analysis for vulvalgesiometer pain rating and sexual distress outcomes ($N = 130$ at baseline; Figure 2). However, for vaginal pain intensity, the proportion of participants for whom this outcome was unavailable (those who had not experienced intercourse or other vaginal penetration in the last four weeks) was 50% at baseline, 44% at posttreatment, 33% at 6-month, and 36% at 12-month follow-up. Overall, 109 participants reported this outcome at least at one of

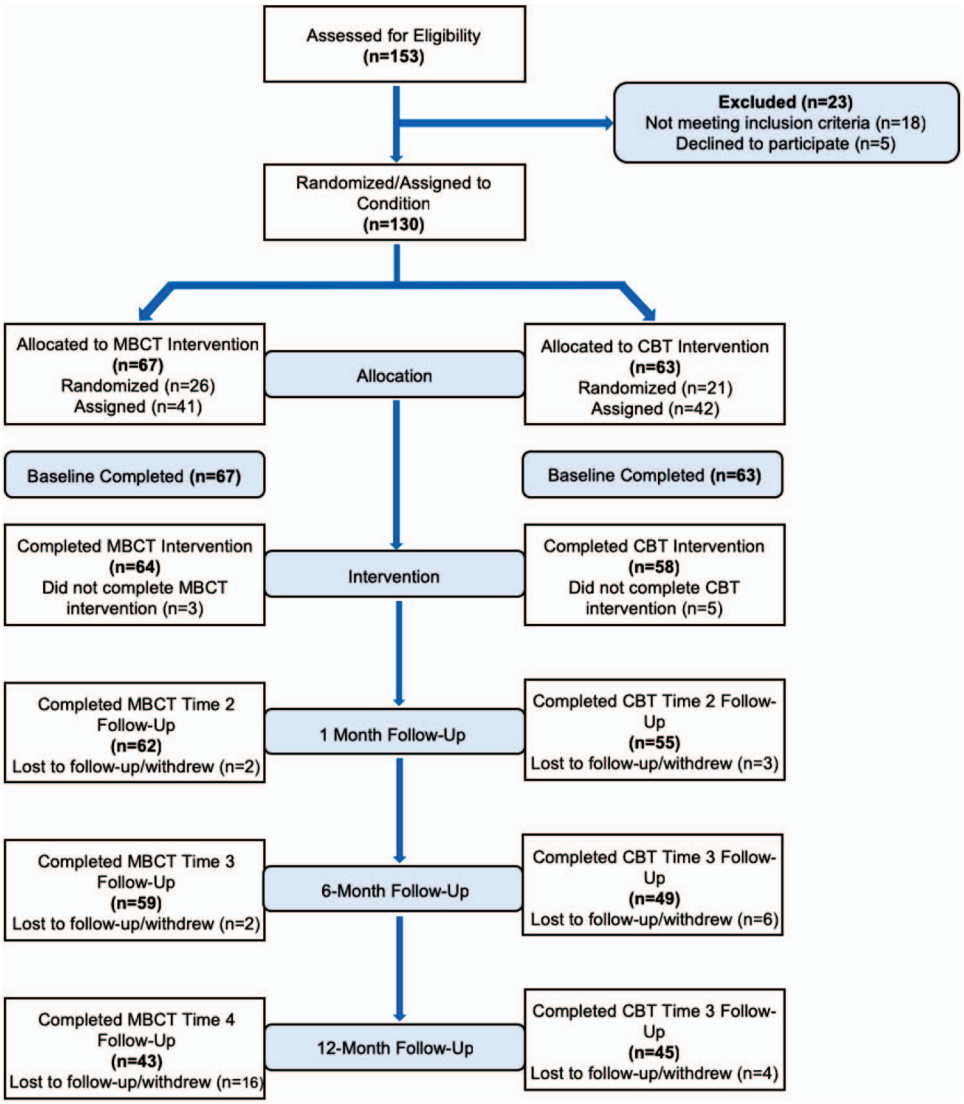

Figure 2. CONSORT diagram for participants in mindfulness-based cognitive therapy (MBCT) and cognitive–behavioral therapy (CBT). See the online article for the color version of this figure.

the four time points; therefore, they were included in the mixed model analysis, which uses estimation based on all available data.

The power estimate was conducted for the mixed model analysis with one between-subjects factor (treatment), one within-subject factor (four time points), and interaction using PASS software (PASS, 2019). The results indicated that a sample of $n = 50$ per group ($N = 100$ total) secures .87 power to find main group effect and .99 power to find main time effect and interaction. Thus, our study was adequately powered.

Results

Baseline Characteristics of Participants

A total of $n = 117$ women provided data at posttreatment, $n = 108$ provided data at 6-month follow-up, and $n = 88$ women provided data at 12-month follow-up. Baseline participant characteristics are included in Table 1. A diagram showing the flow of participants from recruitment through to each of the follow-up stages is included (see Figure 2). A comparison of participants who dropped out to those who stayed in the study found no significant differences on any of the characteristics listed in Table 1 or any of the baseline measures of outcomes or mediators.

Long-Term Effects of Treatment on Pain and Sexual Distress

Table 2 contains means and standard deviations for pain and sexual distress outcomes by treatment and time of assessment. Results for random coefficient analyses are reported in Table 3 along with measures of effect size using Cohen's d. In all analyses, T2 corresponds with posttreatment and T4 corresponds with 12-month follow-up assessment point.

Table 1
Baseline Characteristics of Participants in the Cognitive–Behavioral Therapy (CBT) and Mindfulness-Based Cognitive Therapy (MBCT) Treatment Arms

Measure	CBT	MBCT	Total
Number of participants	63	67	130
Age (years), *M* ± *SD*	31.2 ± 9.0	33.7 ± 7.5	32.4 ± 8.2
Relationship status, *N* (%)			
Married/common-law	41 (66.2)	45 (67.2)	86 (66.7)
Dating	13 (21.0)	11 (16.4)	24 (18.6)
Single	8 (12.9)	11 (16.4)	19 (14.7)
Length of relationship (years), *M* ± *SD*	7.6 ± 6.8	7.8 ± 6.2	7.7 ± 6.5
Satisfaction with relationship closeness (/10), *M* ± *SD*	7.8 ± 2.0	7.3 ± 2.3	7.5 ± 2.2
Ethnicity, *N* (%)			
Euro-Canadian	38 (62.3)	46 (70.8)	84 (66.7)
South/East Asian	11 (18.0)	10 (15.4)	21 (16.7)
Other	12 (19.7)	9 (13.8)	21 (16.7)
Sexual orientation, *N* (%)			
Heterosexual	57 (90.5)	58 (87.9)	115 (89.1)
Lesbian	1 (1.6)	1 (1.5)	2 (1.6)
Bisexual	5 (7.9)	7(10.6)	12 (9.3)
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), *M* ± *SD*	6.0 ± 2.1	6.0 ± 1.8	6.0 ± 2.0
Level of worst pain (/10), *M* ± *SD*	8.2 ± 1.3	8.2 ± 1.1	8.2 ± 1.2
Years since diagnosis, *M* ± *SD*	6.0 ± 4.7	9.9 ± 7.7	8.0 ± 6.7
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)

Note. PVD = provoked vestibulodynia.

Analysis of pain outcomes showed no change in pain between posttreatment and 12-month follow-up for vaginal pain intensity, and a continued significant decrease for vulvalgesiometer scores (medium effect size). There was no significant Time × Group interaction for either of these pain outcomes.

Participants also reported significant continued improvements in sexual distress (small effect size). There was no significant Time × Group interaction.

Correlations Between Outcome Measures and Mediators

The means and standard deviations for variables explored as potential mediators are included in Table 4. The observed means for chronic pain acceptance measures, self-compassion scales, and mindfulness measures (total mindfulness plus decentering) increased between baseline (T1) and 12-month follow-up (T4) whereas scores for pain catastrophizing decreased for both groups. Table 4 also provides correlations between mediators and outcomes. As expected, sexual distress correlated positively with pain catastrophizing and negatively with all other mediators at T1 (magnitudes of correlations were similar for both groups). At T4, sexual distress was no longer associated with decentering or self-compassion. Significant correlations between mediators and the measures of pain were less frequent. Scores on vaginal pain intensity were correlated negatively with self-compassion and general mindfulness at T1, and positively with pain catastrophizing at both time points. Vulvalgesiometer pain ratings were not correlated with any mediators.

Mediation of Treatment Effects

Table 5 presents the results of random coefficient analyses of moderated mediation and Table 6 presents bootstrap analyses testing significance and size of mediation effects. The results fall into one of three scenarios: no mediation, common mediation effect for both treatments, and moderated mediation in which mediation effect differs between the two treatments.

No mediation. There is no evidence of mediation if either path a or path b is not significant or if the indirect effect estimate is not significant. Thus, neither self-compassion nor mindfulness mediated changes in vulvalgesiometer pain scores (see Table 5). Bootstrap analysis further corroborated this lack of mediation—the confidence intervals for these two mediators for vulvalgesiometer ratings contained zero (see Table 6). Bootstrap analyses additionally indicated that changes in vulvalgesiometer ratings were also not mediated by activities engagement whereas changes in vaginal

Table 2
Pain and Sexual Distress Outcomes by Time of Assessment and Treatment Group

Outcome and group	Baseline *M* (*SD*)	Posttreatment *M* (*SD*)	12-month follow-up *M* (*SD*)
Vaginal pain intensity[a]			
CBT	5.86 (2.13)	4.65 (2.21)	3.97 (2.51)
MBCT	6.69 (1.91)	4.34 (2.22)	3.62 (3.09)
Vulvalgesiometer pain rating[a]			
CBT	6.62 (2.19)	3.60 (2.14)	2.52 (1.78)
MBCT	6.67 (2.17)	3.21 (1.96)	2.00 (1.66)
Sexual distress[b]			
CBT	35.68 (10.44)	24.93 (9.31)	20.89 (10.40)
MBCT	34.28 (11.18)	26.60 (13.35)	21.19 (11.57)

Note. Baseline data descriptives are included for reference only; they were not included in the follow-up comparisons reported in this paper. CBT = cognitive–behavioral therapy; MBCT = mindfulness-based cognitive therapy.
Possible range of scores: [a] 0 to 10. [b] 0 to 52.

Table 3
Random Coefficient Analysis Models for the Outcome Measures at Posttreatment (T2) and at 12-Month Follow-Up (T4); Group Comparison and Interaction Effects

Variable	*b*	*SE*	*p*	*d*	95% CI
Model for vaginal pain intensity					
Constant	4.38	.430	<.001		[3.52, 5.23]
Time (T4 − T2)	−.579	.552	.298	−.26	[−1.68, −.52]
Group	.384	.614	.533	.17	[−.83, 1.60]
Time (T4 − T2) × Group	−.174	.742	.816	−.08	[−1.66, 1.31]
Model for vulvalgesiometer pain rating					
Constant	3.213	.246	<.001		[2.73, 3.70]
Time (T4 − T2)	−1.138	.257	<.001	−.56	[−1.65, −.63]
Group	.402	.360	.265	.20	[−.31, 1.11]
Time (T4 − T2) × Group	−.031	.366	.934	−.02	[−.76, .70]
Model for sexual distress					
Constant	26.669	1.476	<.001		[23.75, 29.59]
Time (T4 − T2)	−4.306	1.375	.002	−.37	[−7.04, −1.58]
Group	−1.941	2.126	.363	−.17	[−6.14, 2.26]
Time (T4 − T2) × Group	.478	1.930	.805	.04	[−3.36, 4.31]

Note. T2 = posttreatment; T4 = 12-month follow-up; group = mindfulness-based cognitive therapy (reference) versus cognitive behavioral therapy; CI = confidence interval. All models had random intercepts.

pain intensity were not mediated by activities engagement, self-compassion, and decentering and changes in sexual distress were not mediated by mindfulness. This lack of mediation effects is visually summarized in Figure 3.

Common mediation. Presence of significant paths a and b and absence of significant interaction with treatment in either path model indicates potential presence of mediation that is common across both treatments. Significant and similar indirect effects in both treatments found in bootstrap analysis confirm presence of common mediation process. Results in Tables 5 and 6 reveal that improvements in willingness to accept pain, in decentering, and in pain catastrophizing mediated changes in vulvalgesiometer ratings and sexual distress uniformly across both treatments. Improvement in activities engagement was a common mediator for sexual distress improvements. Common mediation effects are visually summarized in Figure 3.

Moderated mediation. Significant path a and b and significant interaction with treatment in either path model indicated

Table 4
Means for Potential Mediator Variables, and Correlations Between Mediator and Outcome Variables at T1 (Baseline) and T4 (12-Month Follow-Up)

Measure	CPAQ Will T1	CPAQ Will T4	CPAQ Act T1	CPAQ Act T4	SCS Self-comp T1	SCS Self-comp T4	SCS Self-crit T1	SCS Self-crit T4	FFMQ T1	FFMQ T4	EQ T1	EQ T4	PCS T1	PCS T4
CBT														
M	22.9	32.9	42.4	48.9	3.0	3.2	2.9	3.1	125.0	131.1	32.7	38.1	25.6	9.6
SD	8.0	10.0	10.1	7.4	.7	.6	.8	.8	19.1	16.8	8.0	6.3	12.0	9.0
Correlations														
NRS T1	−.23	−.41	−.37*	−.38	−.41*	−.25	−.18	−.39	−.31	−.40	−.26	−.25	.53**	.57**
NRS T4	.05	−.17	.04	−.34	−.19	−.23	−.01	.00	.00	−.17	−.04	−.02	.06	.37*
VVG T1	−.22	−.18	−.14	−.28	−.13	−.12	−.13	−.10	−.18	−.20	.04	.07	.17	.21
VVG T4	.08	−.15	−.04	−.26	−.12	−.08	−.17	−.22	−.07	−.10	.03	−.05	−.03	.06
FSDS-R T1	−.39**	.00	−.20	−.14	−.28*	−.22	−.41**	−.11	−.28*	−.20	−.31*	−.03	.41**	.31*
FSDS-R T4	−.21	−.15	−.05	−.13	−.09	.00	−.29	−.20	−.34*	−.39**	−.25	−.05	.28	.54**
MBCT														
M	24.0	35.6	42.4	51.5	2.9	3.3	2.7	3.2	124.6	133.7	32.7	38.7	26.9	11.9
SD	9.3	8.8	10.9	8.6	.6	.7	.7	.8	15.9	16.9	6.8	6.2	12.9	12.0
Correlations														
NRS T1	.01	.29	.00	.10	−.29	−.21	−.15	−.04	−.37*	−.21	−.24	−.14	.43*	.07
NRS T4	−.04	−.20	.00	−.11	.12	−.12	.26	−.19	−.01	−.39	−.11	−.15	−.15	.31
VVG T1	−.12	−.12	−.04	−.05	.12	.05	−.18	.03	.01	−.10	−.02	.03	.10	.12
VVG T4	.05	.11	.06	−.25	.10	.03	.15	.03	.07	−.07	−.03	−.10	−.07	−.17
FSDS-R T1	−.36**	−.25	−.27*	−.14	−.15	−.17	−.46**	−.40**	−.19	−.22	−.22	−.15	.47**	.43**
FSDS-R T4	−.35*	−.34*	−.21	−.56**	.22	−.19	−.07	−.39*	.03	−.22	.06	−.14	.51**	.53**

Note. NRS = Numeric Rating Scale for vaginal pain intensity; VVG = vulvalgesiometer pain ratings; FSDS-R = Female Sexual Distress Scale—Revised; CPAQ = Chronic Pain Acceptance Questionnaire; Will = Pain Willingess Scale; Act = Activities Engagement Scale; SCS Self-comp = self-compassion subscale of the Self Compassion Scale; SCS Self-crit = self-criticism subcale of the Self Compassion Scale; FFMQ = Five Facet Mindfulness Questionnaire; EQ = Experiences Questionnaire; PCS = Pain Catastrophizing Scale; CBT = cognitive–behavioral therapy; MBCT = mindfulness-based cognitive therapy; T1 = pretreatment; T4 = 12-month follow-up.
* $p < .05$. ** $p < .01$.

Table 5
Test of Moderated Mediation

Outcomes (Y) and mediators (M)	Path a moderated by treatment		Path b moderated by treatment			
	NRS	VVG and FSDS-R		NRS	VVG	FSDS-R
	B (SE)			*B (SE)*		
CPAQ Will						
Time → M	3.25 (.33)***	3.25 (.30)***	M → Y	−.13 (.04)***	−.08 (.03)**	−.37 (.12)***
Time × Treatment → M	−.27 (.47)	−.51 (.43)	M × treatment → Y	.12 (.04)**	.03 (.03)	.04 (.12)
CPAQ Act						
Time → M	1.88 (.34)***	1.99 (.31)***	M → Y	−.06 (.03)*	−.07 (.03)**	−.43 (.10)***
Time × Treatment → M	−.02 (.48)	−.31 (.43)	M × treatment → Y	.02 (.03)	.03 (.03)	.17 (.13)
SCS Self-compassion						
Time → M	.14 (.02)***	.12 (.02)***	M → Y	−1.02 (.46)*	−.47 (.34)	−4.93 (1.37)***
Time × Treatment → M	−.09 (.03)**	−.05 (.03)†	M × treatment → Y	.93 (.67)	−.06 (.51)	3.9 (2.0)†
SCS Self-criticism						
Time → M	.13 (.02)***	.12 (.02)***	M → Y	−1.42 (.41)**	−1.15 (.32)***	−5.68 (1.27)***
Time × Treatment → M	−.07 (.03)*	−.05 (.03)†	M × treatment → Y	1.27 (.75)†	.55 (.52)	2.50 (2.07)
FFMQ						
Time → M	3.33 (.49)***	3.01 (.45)***	M → Y	−.07 (.02)***	−.02 (.02)	−.14 (.05)*
Time × Treatment → M	−1.69 (.69)*	−1.36 (.65)*	M × treatment → Y	.07 (.03)*	−.02 (.02)	−.12 (.09)
EQ						
Time → M	1.70 (.25)***	1.69 (.23)***	M → Y	−.08 (.04)†	−.11 (.03)***	−.40 (.12)**
Time × Treatment → M	−.32 (.36)	−.32 (.33)	M × treatment → Y	.06 (.06)	.00 (.04)	.03 (.17)
PCS						
Time → M	−4.63 (.42)***	−4.60 (.40)***	M → Y	.12 (.02)***	.07 (.02)***	.44 (.06)***
Time × Treatment → M	.14 (.59)	.17 (.57)	M × treatment → Y	−.06 (.03)*	−.02 (.02)	.06 (.08)

Note. NRS = Numeric Rating Scale for vaginal pain intensity; VVG = vulvalgesiometer pain ratings; FSDS-R = Female Sexual Distress Scale—Revised; CPAQ = Chronic Pain Acceptance Questionnaire; Will = Pain Willingness Scale; Act = Activities Engagement Scale; SCS Self-compassion = self-compassion subscale of the Self Compassion Scale; SCS Self-criticism = self-criticism subscale of the Self Compassion Scale; FFMQ = Five Facet Mindfulness Questionnaire; EQ = Experiences Questionnaire; PCS = Pain Catastrophizing Scale.
† $.05 < p < .10$. * $p < .05$. ** $p < .01$. *** $p < .001$.

presence of moderated mediation. Thus, the moderated mediation is present when either path a or path b or both are moderated.

Bootstrap analysis of indirect effects computed separately for each treatment group confirmed presence of mediation and elucidated how the mediation effect differed in the two treatment groups. When testing path a of the mediation process on the subsample of participants with vaginal pain intensity scores, a significant interaction of time and type of treatment was found for improvements in self-compassion, self-criticism, and mindfulness, indicating that path a in the mediation process (treatment predicting changes in these mediators from baseline to 12-month follow-up) was conditional on type of treatment. When tested on the whole sample, the interactions were marginally significant for improvements in self-compassion and self-criticism (see Table 5).

Evidence of path b moderation (mediator predicting outcome) was found for the same three mediators. Type of treatment interacted with changes in self-compassion ($p = .05$) when predicting sexual distress and with changes in self-criticism ($p = .09$) and mindfulness when predicting vaginal pain intensity. The marginal significance is noted because the further bootstrap analyses, which are considered more powerful than one sample models (MacKinnon et al., 2002) confirmed the conditionality of mediation path b for those mediators. Finally, type of treatment interacted with willingness to accept pain and with pain catastrophizing when predicting changes in vaginal pain intensity. There was no indication of path b moderation for vulvalgesiometer ratings.

All the interactions were further probed using the bootstrap approach. In this study, we created 10,000 samples to perform the bootstrap testing and computed the indirect effect and confidence intervals separately for each treatment group (see Table 6). Improvements in willingness to accept pain, in self-criticism, and in mindfulness mediated decreases in vaginal pain intensity scores for the MBCT arm only. None of those mediation effects reached significance for the CBT group. Improvement in pain catastrophizing mediated decreases in vaginal pain intensity for both the CBT and MBCT arms, however, the effect for MBCT participants was twice as large as that for CBT group participants.

Bootstrap results showed that changes in self-criticism mediated changes in vulvalgesiometer ratings and in sexual distress but only for the MBCT group. Changes in self-compassion also mediated changes in sexual distress again only in the MBCT participants.

In summary, the moderating effect of type of treatment on mediation, when present, was due to the mediation taking place for participants in the MBCT arm, but not for those in the CBT condition or, in case of mediating effect of pain catastrophizing, the mediation effect was present in both groups but was twice as strong for those in the MBCT arm.

Overall, the proportion of total effect accounted for by significant indirect effects ranged from 10% (changes in willingness to accept pain mediating decrease in vulvalgesiometer rating for CBT participants) to 56% (changes in pain catastrophizing mediating decreases in vaginal pain intensity for MBCT participants). Mediating effects of changes in pain catastrophizing for all three outcomes accounted for highest proportions of total effects. Another substantial level of mediation was found for changes in willingness to accept pain mediating improvements in vaginal pain

Table 6
Bootstrap Results for Moderated Mediation Indirect Effect Conditional on CBT Versus MBCT Treatment

Mediators	Vaginal pain intensity		Vulvalgesiometer pain rating		Sexual distress	
	Indirect effect [95% CI]	% of total effect explained by indirect effect	Indirect effect [95% CI]	% of total effect explained by indirect effect	Indirect effect [95% CI]	% of total effect explained by indirect effect
CPAQ Will						
CBT	−.05 **[−.20, .08]**	7.6%	−.13 **[−.25, −.03]**	9.7%	−.92 **[−1.55, −.38]**	22%
MBCT	−.41 **[−.68, −.16]**	40.2%	−.26 **[−.47, −.06]**	12.7%	−1.18 **[−1.96, −.42]**	26.6%
CPAQ Act						
CBT	−.06 **[−.15, .06]**	7.8%	−.07 **[−.15, .01]**	5.1%	−.45 **[−.96, −.06]**	11%
MBCT	−.04 **[−.19, .05]**	5.3%	−.14 **[−.29, −.00]**	9.7%	−.84 **[−1.25, −.45]**	18.7%
SCS Self-compassion						
CBT	−.004 **[−.05, .04]**	.6%	−.04 **[−.11, .01]**	2.8%	−.09 **[−.35, .07]**	2.3%
MBCT	−.14 **[−.30, .01]**	16.3%	−.06 **[−.14, .02]**	4.2%	−.59 **[−1.04, −.21]**	12.6%
SCS Self-criticism						
CBT	−.01 **[−.08, .07]**	1.4%	−.04 **[−.12, .02]**	2.9%	−.24 **[−.67, .02]**	6.1%
MBCT	−.17 **[−.32, −.04]**	19.3%	−.14 **[−.26, −.05]**	9.6%	−.70 **[−1.27, −.24]**	15.1%
FFMQ						
CBT	−.01 **[−.04, .06]**	1.4%	−.06 **[−.14, −.00]**	4.2%	−.05 **[−.31, .14]**	1.2%
MBCT	−.18 **[−.35, −.03]**	20.5%	−.06 **[−.15, .03]**	4.2%	−.45 **[−1.05, .04]**	9.7%
EQ						
CBT	−.04 **[−.11, .03]**	5.3%	−.15 **[−.28, −.04]**	10.8%	−.53 **[−.95, −.17]**	12.3%
MBCT	−.12 **[−.29, .04]**	14.3%	−.19 **[−.34, −.06]**	15.3%	−.69 **[−1.26, −.21]**	15.4%
PCS						
CBT	−.27 **[−.47, −.09]**	39.7%	−.26 **[−.43, −.08]**	19%	−2.22 **[−2.84, −1.61]**	52%
MBCT	−.52 **[−.76, −.30]**	55.9%	−.34 **[−.53, −.17]**	23.5%	−2.01 **[−2.69, −1.38]**	49.5%
Total effect of all mediators entered in the model						
CBT	−.57 **[−.96, −.18]**	63.5%	−.44 **[−.74, −.17]**	33.5%	−2.25 **[−4.03, −.56]**	52.7%
MBCT	−.40 **[.86, .05]**	50.4%	−.25 **[−.74, .18]**	18.5%	−3.27 **[−5.08, −1.66]**	74.1%

Note. CIs not including zeros are in bold. CBT = cognitive–behavioral therapy; MBCT = mindfulness-based cognitive therapy; CI = confidence interval; FSDS-R = Female Sexual Distress Scale—Revised; CPAQ = Chronic Pain Acceptance Questionnaire; Will = Pain Willingness Scale; Act = Activities Engagement Scale; SCS Self-compassion = self-compassion subscale of the Self Compassion Scale; SCS Self-criticism = self-criticism subscale of the Self Compassion Scale; FFMQ = Five Facet Mindfulness Questionnaire; EQ = Experiences Questionnaire; PCS = Pain Catastrophizing Scale.

intensity for MBCT participants, accounting for 40% of total effect of treatment on that outcome. Moderated mediation effects are visually summarized in Figure 4.

Discussion

The goals of this study were twofold. First, we investigated the posttreatment long-term outcomes of pain with vaginal penetration, pain with a vulvalgesiometer, and sex-related distress at 12-month follow-up in women with PVD who received either group CBT or MBCT. Our second goal was to examine mediators of improvement in pain and sexual distress across four time points from baseline to posttreatment followed by 6- and 12-month assessments. To our knowledge, this is the first study to focus on mediators of change following CBT or MBCT in women with this diagnosis. Overall, findings indicated that gains were maintained or greater at the 12-month follow-up relative to posttreatment and to 6-month follow-up, with no loss of improvements in either arm and no significant group differences. Further, changes in pain catastrophizing, pain acceptance, and decentering mediated improvements in vulvalgesiometer pain, and sexual distress in both arms, suggesting similar mechanisms of action in these two psychological interventions for PVD, as has been found among other chronic pain populations (Turner et al., 2016). Changes in activities engagement, a subscale of the Chronic Pain Acceptance Scale, also mediated improvements in sexual distress in both arms. The remaining significant mediators exerted their effects only (or to a larger extent) in the MBCT arm and will be explained more fully below.

Follow-Up Data at 12 Months Posttreatment

For both MBCT and CBT, the 12-month follow-up results confirmed continued benefit to pain with vaginal penetration, that is, there was no change in pain during vaginal penetration between posttreatment and 12-month follow-up. In addition, there was a continued significant decrease for vulvalgesiometer ratings of pain (medium effect size) and sexual distress (small effect size) to the 12-month follow-up, with no group differences on any of the three endpoints. Taken together, these findings suggest that CBT and MBCT have long-term, continued benefits for afflicted women, both in terms of pain and sexuality. This corroborates results of a study focusing on individual CBT for women with vulvodynia (Masheb et al., 2009), as well as those of a randomized trial comparing MBCT and CBT in individuals with chronic pain (Cherkin et al., 2016).

Mediators of Change Common to Both MBCT and CBT

Although we predicted that there would not be any common mediators of improvement to both CBT and mindfulness, we found

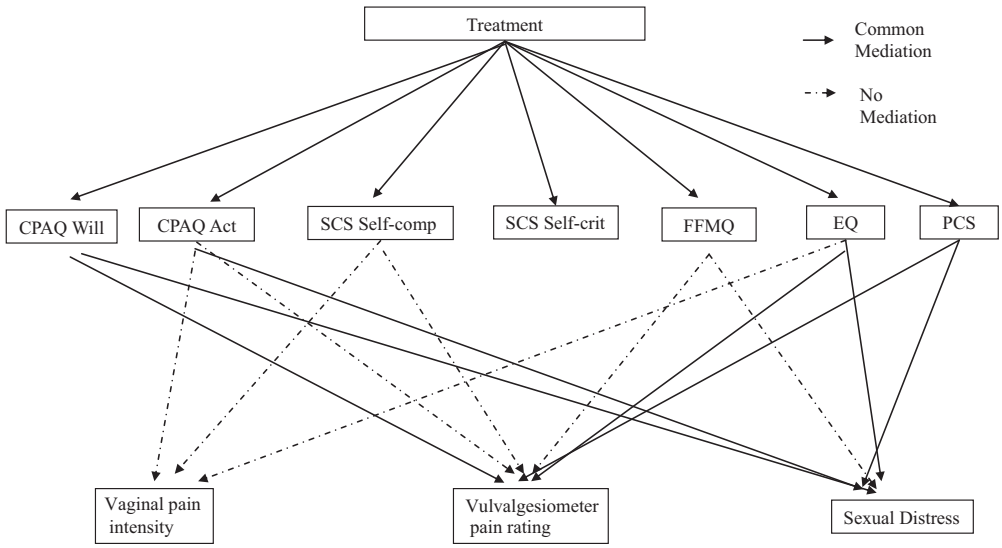

Figure 3. Mediation effects common across both mindfulness-based cognitive therapy (MBCT) and cognitive–behavioral therapy (CBT) treatments (solid arrow between mediator and outcome) and hypothesized mediation effects that were not found (dashed arrow between mediator and outcome). CPAQ = Chronic Pain Acceptance Questionnaire; Will = Pain Willingness Scale; Act = Activities Engagement Scale; SCS Self-comp = self-compassion subscale of the Self Compassion Scale; SCS Self-crit = self-criticism subscale of the Self Compassion Scale; FFMQ = Five Facet Mindfulness Questionnaire; EQ = Experiences Questionnaire; PCS = Pain Catastrophizing Scale.

that increases in willingness to accept pain (to confront it and not avoid it) mediated change with both treatments, but only for vulvalgesiometer-elicited pain and sex-related distress—not for pain with vaginal penetration. It is possible that both treatment arms contained elements of exposure treatment that facilitated these findings. Specifically, in the CBT arm, women were taught to identify and challenge avoidance behavior that prevented them from being sexually active. In the MBCT arm, though we did not specifically label any skills as exposure, it is possible that the practice of eliciting (vulvar) pain and mindfully noticing sensations functioned as an exposure activity. Thus, both treatments resulted in exposing participants to their feared stimuli (i.e., pain)

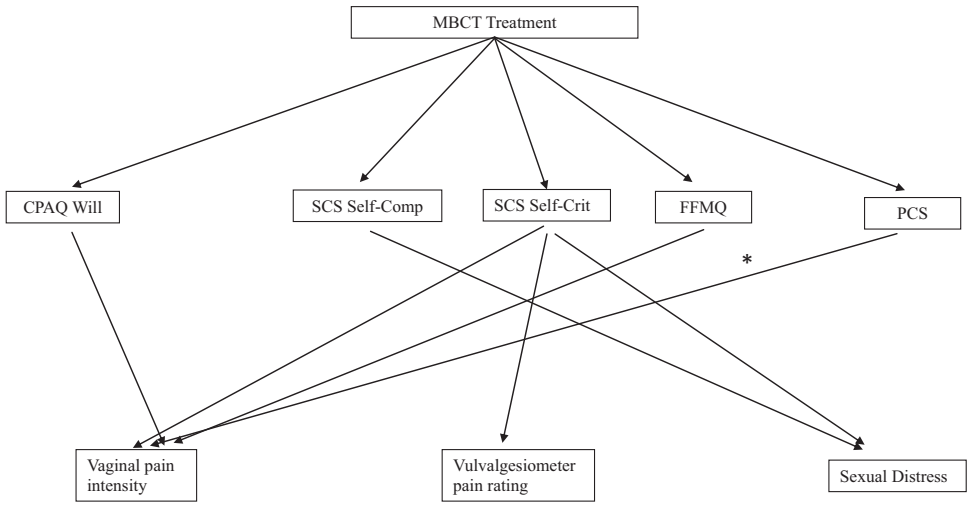

Figure 4. Moderated mediation effects—effects present only in mindfulness-based cognitive therapy (MBCT treatment). *Pain Catastrophizing Scale (PCS) mediation effect is also present for cognitive–behavioral therapy (CBT) treatment but smaller than in MBCT treatment. CPAQ = Chronic Pain Acceptance Questionnaire; Will = Pain Willingness Scale; SCS Self-comp = self-compassion subscale of the Self Compassion Scale; SCS Self-crit = self-criticism subscale of the Self Compassion Scale; FFMQ = Five Facet Mindfulness Questionnaire; PCS = Pain Catastrophizing Scale.

but using different sets of instructions. Being more accepting of one's pain may reduce feelings of perceived injustice about suffering from PVD—the latter of which is associated with higher sexual distress in women with PVD (Pâquet et al., 2016). The Chronic Pain Acceptance Scale that measures the pursuit of life activities regardless of pain also mediated improvements in sex-related distress in both arms. These findings are in line with those of a cross-sectional study showing significant associations between higher levels of pain acceptance and better sexual function and satisfaction in women with PVD (Boerner & Rosen, 2015).

Changes in decentering, or metacognitive awareness, also mediated improvements in vulvalgesiometer-elicited pain as well as the reduction in sexual distress in both treatment arms, partly supporting our original hypotheses. *Decentering*, which can be defined as separating oneself from one's thoughts, is a key element of mindfulness along with viewing thoughts as products of the mind (i.e., temporary and not intrinsic to oneself). That decentering also mediated improvements in both the MBCT (as hypothesized) and the CBT arm suggests that the prescribed exercises in challenging thoughts and targeting avoidance behavior may have also led to an increase in participants' ability to view thoughts as just thoughts, and this mediated improvements. Metacognitive awareness being a shared mediator for both MBCT and CBT has also been found for the improvements seen in depression with both treatments (van der Velden et al., 2015). In fact, Dobson (2013) argued that CBT may be approaching a shift in emphasis from cognitive processes to metacognitive processes, suggesting that examining and challenging thoughts may also lead one to have greater overall awareness of thoughts as just thoughts.

The reduction in pain catastrophizing was another mediator of improvements with both CBT and MBCT arms on all three outcomes, thus, our original hypothesis that pain catastrophizing would mediate changes in the CBT arm but not the MBCT arm was only partly supported. In fact, the mediating effects of changes in pain catastrophizing on improvements in vaginal pain intensity were moderated by treatment showing twice as large effect for the MBCT group than the CBT group. The original (Lethem, Slade, Troup, & Bentley, 1983) and the expanded (Vlaeyen et al., 2009) Fear-Avoidance Model posits that persons who catastrophize about the meaning of their pain are prone to escalation of the initial protective fear, which leads to avoidance of the unconditioned stimulus - here the stimulus being vaginal penetration. Catastrophic thoughts about their sexual future and their pain are common in women with PVD, especially thoughts of physical damage from intercourse (Klaassen & Ter Kuile, 2009). Both CBT and MBCT aim to increase the skill of identifying maladaptive catastrophic thoughts. The therapies differ only in whether there is further instruction to challenge and adjust the thought with a more balanced one (CBT), or to not accept them necessarily as truths, and instead view them as products of the mind without the need to engage further with them (MBCT). There is evidence that other non-CBT treatments can also reduce pain catastrophizing though mechanisms other than thought challenging. For example, physical therapy in those with chronic low back pain likely increased participants' levels of confidence, which then reduced pain catastrophizing, and the latter mediated their improvements in pain (Smeets, Vlaeyen, Kester, & Knottnerus, 2006). Though not tested, it is possible that MBCT in our study similarly improved women's self-confidence and, by extension, reduced their pain catastrophizing.

Mediators of Change in the MBCT Arm Only

None of the proposed variables mediated improvements in outcomes in the CBT arm only. On the other hand, there were some variables that mediated improvements in the MBCT arm but not the CBT arm. Specifically, willingness to accept pain mediated improvements in vaginal pain intensity in the MBCT arm only. This is in keeping with chronic pain acceptance and a willingness to accept pain in spite of pain being a primary target of MBCT but not CBT. The extent to which this construct lies on the same continuum, but opposite pole, of avoidance behavior is unknown. It is worth noting that avoidance is directly challenged in most CBT interventions but not directly in MBCT, even though accepting pain may be viewed as the opposite of avoidance behavior.

Self-compassion also mediated improvements with MBCT for sexual distress, but not CBT, as predicted. Radical self-acceptance was a core aspect of the MBCT intervention that was practiced in session and at home. Fear of negative evaluation by others and associated self-criticism rather than compassion toward herself is a common finding among women with PVD in their life generally (Ayling & Ussher, 2008; Brotto et al., 2003). Self-compassion has also been associated with lower levels of psychologic distress in chronic pain populations and is thought to be a protective factor in the face of the threatening experience that is chronic, intense pain (MacBeth & Gumley, 2012). As such, its mediating effects on improvements in sexual distress were not surprising. Interestingly, a cross-sectional study among women with PVD and their partners showed that higher levels of partners' self-compassion were associated with lower levels of sexual distress in both women and partners (Santerre-Baillargeon et al., 2018). The current findings that MBCT-associated changes in self-criticism mediated improvements in pain intensity with penetration as well as vulvalgesiometer-elicited pain and sexual distress (but none of these mediated changes after CBT) is novel and has notable clinical implications, discussed later.

Mindfulness was hypothesized as a mediator for the MBCT arm only and this was supported in our study where improvements in mindfulness mediated improvements in vaginal pain intensity in the MBCT arm only. This finding may be seen as consistent with theoretical formulations of mindfulness-based psychological interventions, which suggest that one of the ways in which this approach may be helpful for chronic pain and sexual difficulties is via its emphasis on nonjudgmental awareness of experience (Arora & Brotto, 2017; Stephenson, 2017). Indeed, a recent study showed that the two facets of mindfulness that were found to be the most highly correlated with lower chronic pain were nonjudging and acting with awareness (Poulin et al., 2016). In the context of PVD, observing one's sexual pain without judgment may be associated with lower anxiety and fear of pain, which in turn may lessen sexual distress.

Mediators of Change With CBT

As noted, none of our measured variables mediated improvements in the CBT arm only. It is possible that other mediators of treatment outcome, which were not measured in the current study, may have been at play in the CBT condition. For instance, pain self-efficacy has been identified as the most robust cognitive

predictor of pain, sexual function and sexual satisfaction over a 2-year period in a prospective study of women with PVD (Davis et al., 2015), as well as a significant predictor of CBT treatment outcome in a randomized clinical trial (Desrochers et al., 2010). Fear of pain and anxiety are two affective variables associated with daily and longitudinal pain outcomes in this population (Desrochers et al., 2010; Pâquet et al., 2018; Pâquet, Vaillancourt-Morel, Jodouin, Steben, & Bergeron, 2019). Behaviorally, as per the fear-avoidance model (Vlaeyen & Linton, 2000), a reduction in avoidance of sexual activity (more intercourse attempts) was found to mediate reductions in pain and increases in sexual satisfaction in women with PVD (Davis et al., 2015). Hence, future studies should examine changes in pain self-efficacy, fear of pain, anxiety, and avoidance as mediators of CBT for PVD.

Limitations and Strengths

As noted in Brotto et al. (2019), the original clinical trial on which these mediation analyses is based comprised of a sample who were assigned (2/3) as well as randomized (1/3) to treatment. Though no significant differences in efficacy were found between the assigned and randomized participants, future studies should seek to randomize all participants. Furthermore, data were available for only 88 of the original 130 women who provided baseline data, at the 12-month follow-up. Moreover, although our comparison of the participants who dropped out to those who stayed in the study did not show any significant differences on any of the measures we collected it is still possible that some unmeasured differences existed which would potentially limit the generalizability of our findings.

It is possible that significant correlations between mediators and the measures of pain might have been more frequent if measures of pain unpleasantness had been recorded. Some studies have shown mindfulness to lessen unpleasantness but not pain intensity (Brown & Jones, 2010; Grant, Courtemanche, & Rainville, 2011; Perlman, Salomons, Davidson, & Lutz, 2010; Zeidan et al., 2011, 2015). Further, measuring changes in mediators during the course of both therapies to allow for time-lagged analyses would have strengthened the design of the study, as opposed to measuring these putative mediators at the same four time points as outcomes.

The original efficacy study detailing the primary outcomes also reported that adherence to the treatment manuals by facilitators in both the CBT and MBCT groups was high. Specifically, on a 14-point measure of adherence, scores in the CBT group were 13.6 and scores in the MBCT group were 13.0 (Brotto et al., 2019). Nonetheless, despite these high ratings of facilitator adherence, we cannot rule out the possibility that facilitators may have experienced an unconscious bias toward one group or the other, because our design makes it impossible to keep facilitators blind to condition.

There was also some shared psychoeducational content in the MBCT and CBT arms, and the extent to which this shared content contributed to long-term improvements, and/or to similar mediating variables, is unknown and impossible to assess in this study. The fact that pain catastrophizing mediated results in both arms may be in keeping with shared material across the two treatment modalities. Future studies should aim to eliminate all shared material when comparing two different treatments.

Even though the analysis of secondary endpoints as potential mediators does not require correction of p values for multiple comparisons, our results should nevertheless be viewed with some caution and followed up with more rigorous and focused mediation tests in the future.

Despite these limitations, the present study contributed to the chronic pain literature in prominent ways. Methodologically, it boasted a long-term follow-up of therapy, a large sample size and manualized treatments delivered in a rigorous manner. Moreover, it filled an important gap in examining mediators of change following two psychological interventions for PVD, in an area where medical treatments show poor results, on the one hand (Brown, Bachmann, Wan, & Foster, & Gabapentin Study Group, 2018; Foster et al., 2010), yet mechanisms of action of CBT and MBCT remain largely understudied, on the other. Specifically, this was the first study to investigate mediators of therapeutic change in the treatment of PVD, and more broadly, in the treatment of women's sexual dysfunctions.

Clinical Implications

The current findings point toward theoretically relevant and empirically supported targets of intervention, suggesting that pain acceptance, decentering, and pain catastrophizing should figure among the central foci of cognitive approaches to the management of PVD, as they represent shared mechanisms of change. Moreover, the finding that both MBCT and CBT shared a number of common mediators accounting for improvements in pain and sexual distress suggests that patients can be reassured of some of the similar pathways of these two different treatment approaches to ultimately improve their symptoms. On the other hand, when a mindfulness-based approach is selected for treatment, the care provider might expect changes in self-criticism and self-compassion to be associated with improvements in outcomes. In particular, radical self-acceptance was included in the MBCT intervention as a means of improving self-compassion and may be an important skill to include in the treatment of PVD.

Conclusion

The current study contributes to increasing efforts to establish evidence-based psychological treatments for women with chronic genital pain, showing both mindfulness and CBT to be effective and to exert lasting improvements in symptoms of pain intensity and sexual distress when women were assessed 12 months later. Pain acceptance willingness, decentering, and pain catastrophizing mediated improvements in both MBCT as well as CBT, whereas self-compassion, self-criticism, and mindfulness mediated improvements only after MBCT. These findings may have implications for broader efforts within precision health that seek to determine what works best for the individual patient.

References

Aerts, L., Bergeron, S., Pukall, C. F., & Khalifé, S. (2016). Provoked vestibulodynia: Does pain intensity correlate with sexual dysfunction and dissatisfaction? *Journal of Sexual Medicine, 13,* 955–962. http://dx.doi.org/10.1016/j.jsxm.2016.03.368

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Washington, DC: Author.

Arora, N., & Brotto, L. A. (2017). How does paying attention improve sexual function in women? A review of mechanisms. *Sexual Medicine Reviews, 5,* 266–274. http://dx.doi.org/10.1016/j.sxmr.2017.01.005

Ayling, K., & Ussher, J. M. (2008). "If sex hurts, am I still a woman?" The subjective experience of vulvodynia in hetero-sexual women. *Archives of Sexual Behavior, 37,* 294–304. http://dx.doi.org/10.1007/s10508-007-9204-1

Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment, 13,* 27–45. http://dx.doi.org/10.1177/1073191105283504

Basson, R. (2012). The recurrent pain and sexual sequelae of provoked vestibulodynia: A perpetuating cycle. *Journal of Sexual Medicine, 9,* 2077–2092. http://dx.doi.org/10.1111/j.1743-6109.2012.02803.x

Basson, R., Brotto, L. A., Carlson, M., Driscoll, M., Grabovac, A., & Smith, K. B. (2012). *Moving on with our sexual lives despite painful penetration from provoked vestibulodynia and pelvic muscle tension: A mindfulness-based approach*. Unpublished treatment manual.

Benoit-Piau, J., Bergeron, S., Brassard, A., Dumoulin, C., Khalifé, S., Waddell, G., & Morin, M. (2018). Fear-avoidance and pelvic floor muscle function are associated with pain intensity in women with vulvodynia. *The Clinical Journal of Pain, 34,* 804–810. http://dx.doi.org/10.1097/AJP.0000000000000604

Bergeron, S., Binik, Y. M., Khalifé, S., Pagidas, K., Glazer, H. I., Meana, M., & Amsel, R. (2001). A randomized comparison of group cognitive–behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis. *Pain, 91,* 297–306. http://dx.doi.org/10.1016/S0304-3959(00)00449-8

Bergeron, S., Khalifé, S., Dupuis, M. J., & McDuff, P. (2016). A randomized clinical trial comparing group cognitive-behavioral therapy and a topical steroid for women with dyspareunia. *Journal of Consulting and Clinical Psychology, 84,* 259–268. http://dx.doi.org/10.1037/ccp0000072

Bergeron, S., Khalifé, S., Glazer, H. I., & Binik, Y. M. (2008). Surgical and behavioral treatments for vestibulodynia: Two-and-one-half year follow-up and predictors of outcome. *Obstetrics and Gynecology, 111,* 159–166. http://dx.doi.org/10.1097/01.AOG.0000295864.76032.a7

Bishop, S. R., Lau, M., Shapiro, S., Carlson, L., Anderson, N. D., Carmody, J., . . . Devins, G. (2004). Mindfulness: A proposed operational definition. *Clinical Psychology: Science and Practice, 11,* 230–241. http://dx.doi.org/10.1093/clipsy.bph077

Boerner, K. E., & Rosen, N. O. (2015). Acceptance of vulvovaginal pain in women with provoked vestibulodynia and their partners: Associations with pain, psychological, and sexual adjustment. *Journal of Sexual Medicine, 12,* 1450–1462. http://dx.doi.org/10.1111/jsm.12889

Brotto, L. A., Basson, R., Carlson, M., & Zhu, C. (2013). Impact of an integrated mindfulness and cognitive behavioural treatment for provoked vestibulodynia (IMPROVED): A qualitative study. *Sexual and Relationship Therapy, 28*(1–2), 3–19. http://dx.doi.org/10.1080/14681994.2012.686661

Brotto, L. A., Basson, R., & Gehring, D. (2003). Psychological profiles among women with vulvar vestibulitis syndrome: A chart review. *Journal of Psychosomatic Obstetrics & Gynecology, 24,* 195–203. http://dx.doi.org/10.3109/01674820309039673

Brotto, L. A., Basson, R., Smith, K. B., Driscoll, M., & Sadownik, L. (2015). Mindfulness-based group therapy for women with provoked vestibulodynia. *Mindfulness, 6,* 417–432. http://dx.doi.org/10.1007/s12671-013-0273-z

Brotto, L. A., Bergeron, S., Zdaniuk, B., Driscoll, M., Grabovac, A., Sadownik, L. A., . . . Basson, R. (2019). A comparison of mindfulness-based cognitive therapy vs. cognitive behavioral therapy for the treatment of provoked vestibulodynia in a hospital clinic setting. *Journal of Sexual Medicine, 16,* 909–923. http://dx.doi.org/10.1016/j.jsxm.2019.04.002

Brown, C. S., Bachmann, G. A., Wan, J., & Foster, D. C., & the Gabapentin Study Group. (2018). Gabapentin for the treatment of vulvodynia: A randomized controlled trial. *Obstetrics and Gynecology, 131,* 1000–1007. http://dx.doi.org/10.1097/AOG.0000000000002617

Brown, C. A., & Jones, A. K. P. (2010). Meditation experience predicts less negative appraisal of pain: Electrophysiological evidence for the involvement of anticipatory neural responses. *Pain, 150,* 428–438. http://dx.doi.org/10.1016/j.pain.2010.04.017

Cherkin, D. C., Sherman, K. J., Balderson, B. H., Cook, A. J., Anderson, M. L., Hawkes, R. J., . . . Turner, J. A. (2016). Effect of mindfulness-based stress reduction vs cognitive behavioral therapy or usual care on back pain and functional limitations in adults with chronic low back pain A randomized clinical trial. *Journal of the American Medical Association, 315,* 1240–1249. http://dx.doi.org/10.1001/jama.2016.2323

Coady, D., Futterman, S., Harris, D., & Coleman, S. H. (2015). Vulvodynia and concomitant femoro-acetabular impingement: Long-term follow-up after hip arthroscopy. *Journal of Lower Genital Tract Disease, 19,* 253–256. http://dx.doi.org/10.1097/LGT.0000000000000108

Corsini-Munt, S., Bergeron, S., Rosen, N. O., Mayrand, M. H., & Delisle, I. (2014). Feasibility and preliminary effectiveness of a novel cognitive-behavioral couple therapy for provoked vestibulodynia: A pilot study. *Journal of Sexual Medicine, 11,* 2515–2527. http://dx.doi.org/10.1111/jsm.12646

Costa, J., Marôco, J., Pinto-Gouveia, J., Ferreira, C., & Castilho, P. (2016). Validation of the psychometric properties of the Self-Compassion scale. testing the factorial validity and factorial invariance of the measure among borderline personality disorder, anxiety disorder, eating disorder and general populations. *Clinical Psychology & Psychotherapy, 23,* 460–468. http://dx.doi.org/10.1002/cpp.1974

D'Agostino, R. B., Sr. (2000). Controlling alpha in a clinical trial: The case for secondary endpoints. *Statistics in Medicine, 19,* 763–766. Retrieved from http://search.ebscohost.com.ezproxy.library.ubc.ca/login.aspx?direct=true&db=mnh&AN=1. http://dx.doi.org/10.1002/(SICI)1097-0258(20000330)19:6<763::AID-SIM517>3.0.CO;2-8

Davis, S. N. P., Bergeron, S., Binik, Y. M., & Lambert, B. (2013). Women with provoked vestibulodynia experience clinically significant reductions in pain regardless of treatment: Results from a 2-year follow-up study. *Journal of Sexual Medicine, 10,* 3080–3087. http://dx.doi.org/10.1111/jsm.12309

Davis, S. N. P., Bergeron, S., Bois, K., Sadikaj, G., Binik, Y. M., & Steben, M. (2015). A prospective 2-year examination of cognitive and behavioral correlates of provoked vestibulodynia outcomes. *The Clinical Journal of Pain, 31,* 333–341. http://dx.doi.org/10.1097/AJP.0000000000000128

DeRogatis, L., Clayton, A., Lewis-D'Agostino, D., Wunderlich, G., & Fu, Y. (2008). Validation of the female sexual distress scale-revised for assessing distress in women with hypoactive sexual desire disorder. *Journal of Sexual Medicine, 5,* 357–364. http://dx.doi.org/10.1111/j.1743-6109.2007.00672.x

de Rooij, A., de Boer, M. R., van der Leeden, M., Roorda, L. D., Steultjens, M. P., & Dekker, J. (2014). Cognitive mechanisms of change in multidisciplinary treatment of patients with chronic widespread pain: A prospective cohort study. *Journal of Rehabilitation Medicine, 46,* 173–180. http://dx.doi.org/10.2340/16501977-1252

Desrochers, G., Bergeron, S., Khalifé, S., Dupuis, M. J., & Jodoin, M. (2009). Fear avoidance and self-efficacy in relation to pain and sexual impairment in women with provoked vestibulodynia. *The Clinical Journal of Pain, 25,* 520–527. http://dx.doi.org/10.1097/AJP.0b013e31819976e3

Desrochers, G., Bergeron, S., Khalifé, S., Dupuis, M. J., & Jodoin, M. (2010). Provoked vestibulodynia: Psychological predictors of topical and cognitive-behavioral treatment outcome. *Behaviour Research and Therapy, 48,* 106–115. http://dx.doi.org/10.1016/j.brat.2009.09.014

Dobson, K. S. (2013). The science of CBT: Toward a metacognitive model of change? *Behavior Therapy, 44,* 224–227. http://dx.doi.org/10.1016/j.beth.2009.08.003

Dunkley, C. R., & Brotto, L. A. (2016). Psychological treatments for provoked vestibulodynia: Integration of mindfulness-based and cognitive behavioral therapies. *Journal of Clinical Psychology, 72,* 637–650. http://dx.doi.org/10.1002/jclp.22286

Farrar, J. T., Young, J. P., Jr., LaMoreaux, L., Werth, J. L., & Poole, R. M. (2001). Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain, 94,* 149–158. http://dx.doi.org/10.1016/S0304-3959(01)00349-9

Foster, D. C., Kotok, M. B., Huang, L. S., Watts, A., Oakes, D., Howard, F. M., . . . Dworkin, R. H. (2010). Oral desipramine and topical lidocaine for vulvodynia: A randomized controlled trial. *Obstetrics and Gynecology, 116,* 583–593. http://dx.doi.org/10.1097/AOG.0b013e3181e9e0ab

Fresco, D. M., Moore, M. T., van Dulmen, M. H. M., Segal, Z. V., Ma, S. H., Teasdale, J. D., & Williams, J. M. G. (2007). Initial psychometric properties of the experiences questionnaire: Validation of a self-report measure of decentering. *Behavior Therapy, 38,* 234–246. http://dx.doi.org/10.1016/j.beth.2006.08.003

Friedrich, E. G., Jr. (1987). Vulvar vestibulitis syndrome. *The Journal of Reproductive Medicine, 32,* 110–114.

Goldfinger, C., Pukall, C. F., Thibault-Gagnon, S., McLean, L., & Chamberlain, S. (2016). Effectiveness of cognitive-behavioral therapy and physical therapy for provoked vestibulodynia: A randomized pilot study. *Journal of Sexual Medicine, 13,* 88–94. http://dx.doi.org/10.1016/j.jsxm.2015.12.003

Goldstein, A. T., Pukall, C. F., Brown, C., Bergeron, S., Stein, A., & Kellogg-Spadt, S. (2016). Vulvodynia: Assessment and treatment. *Journal of Sexual Medicine, 13,* 572–590. http://dx.doi.org/10.1016/j.jsxm.2016.01.020

Grant, J. A., Courtemanche, J., & Rainville, P. (2011). A non-elaborative mental stance and decoupling of executive and pain-related cortices predicts low pain sensitivity in Zen meditators. *Pain, 152,* 150–156. http://dx.doi.org/10.1016/j.pain.2010.10.006

Harlow, B. L., Kunitz, C. G., Nguyen, R. H., Rydell, S. A., Turner, R. M., & MacLehose, R. F. (2014). Prevalence of symptoms consistent with a diagnosis of vulvodynia: Population-based estimates from 2 geographic regions. *American Journal of Obstetrics and Gynecology, 210,* 40.e1-40.e8. http://dx.doi.org/10.1016/j.ajog.2013.09.033

Hayes, A. F. (2013). *Introduction to mediation, moderation, and conditional process analysis: A regression-based approach*. New York, NY: Guilford Press.

Khandker, M., Brady, S. S., Vitonis, A. F., Maclehose, R. F., Stewart, E. G., & Harlow, B. L. (2011). The influence of depression and anxiety on risk of adult onset vulvodynia. *Journal of Women's Health, 20,* 1445–1451. http://dx.doi.org/10.1089/jwh.2010.2661

Klaassen, M., & Ter Kuile, M. M. (2009). Development and initial validation of the Vaginal Penetration Cognition Questionnaire (VPCQ) in a sample of women with vaginismus and dyspareunia. *Journal of Sexual Medicine, 6,* 1617–1627. http://dx.doi.org/10.1111/j.1743-6109.2009.01217.x

Leitenberg, H., & Henning, K. (1995). Sexual fantasy. *Psychological Bulletin, 117,* 469–496. http://dx.doi.org/10.1037/0033-2909.117.3.469

Lester, R. A., Brotto, L. A., & Sadownik, L. A. (2015). Provoked vestibulodynia and the health care implications of comorbid pain conditions. *Journal of Obstetrics and Gynaecology Canada, 37,* 995–1005. http://dx.doi.org/10.1016/S1701-2163(16)30049-4

Lethem, J., Slade, P. D., Troup, J. D. G., & Bentley, G. (1983). Outline of a fear-avoidance model of exaggerated pain perception—I. *Behaviour Research and Therapy, 21,* 401–408. http://dx.doi.org/10.1016/0005-7967(83)90009-8

MacBeth, A., & Gumley, A. (2012). Exploring compassion: A meta-analysis of the association between self-compassion and psychopathology. *Clinical Psychology Review, 32,* 545–552. http://dx.doi.org/10.1016/j.cpr.2012.06.003

MacKinnon, D. P., Lockwood, C. M., Hoffman, J. M., West, S. G., & Sheets, V. (2002). A comparison of methods to test mediation and other intervening variable effects. *Psychological Methods, 7,* 83–104. http://dx.doi.org/10.1037/1082-989X.7.1.83

Masheb, R. M., Kerns, R. D., Lozano, C., Minkin, M. J., & Richman, S. (2009). A randomized clinical trial for women with vulvodynia: Cognitive-behavioral therapy vs. supportive psychotherapy. *Pain, 141,* 31–40. http://dx.doi.org/10.1016/j.pain.2008.09.031

McCracken, L. M., Vowles, K. E., & Eccleston, C. (2004). Acceptance of chronic pain: Component analysis and a revised assessment method. *Pain, 107,* 159–166. http://dx.doi.org/10.1016/j.pain.2003.10.012

Neff, K. D. (2003a). The development and validation of a scale to measure self-compassion. *Self and Identity, 2,* 223–250. http://dx.doi.org/10.1080/15298860309027

Neff, K. D. (2003b). Self-compassion: An alternative conceptualization of a healthy attitude toward oneself. *Self and Identity, 2,* 85–102. http://dx.doi.org/10.1080/15298860309032

Neff, K. D. (2016). The self-compassion scale is a valid and theoretically coherent measure of self-compassion. *Mindfulness, 7,* 264–274. http://dx.doi.org/10.1007/s12671-015-0479-3

Norton, P. J., & Asmundson, G. J. G. (2003). Amending the fear-avoidance model of chronic pain: What is the role of physiological arousal? *Behavior Therapy, 34,* 17–30. http://dx.doi.org/10.1016/S0005-7894(03)80019-9

Pâquet, M., Bois, K., Rosen, N. O., Mayrand, M. H., Charbonneau-Lefebvre, V., & Bergeron, S. (2016). Why us? Perceived injustice is associated with more sexual and psychological distress in couples coping with genito-pelvic pain. *Journal of Sexual Medicine, 13,* 79–87. http://dx.doi.org/10.1016/j.jsxm.2015.11.007

Pâquet, M., Rosen, N. O., Steben, M., Mayrand, M. H., Santerre-Baillargeon, M., & Bergeron, S. (2018). Daily anxiety and depressive symptoms in couples coping with vulvodynia: Associations with women's pain, women's sexual function, and both partner's sexual distress. *The Journal of Pain, 19,* 552–561. http://dx.doi.org/10.1016/j.jpain.2017.12.264

Pâquet, M., Vaillancourt-Morel, M.-P., Jodouin, J.-F., Steben, M., & Bergeron, S. (2019). Pain trajectories and predictors: A 7-year longitudinal study of women with vulvodynia. *Journal of Sexual Medicine, 16,* 1606–1614. http://dx.doi.org/10.1016/j.jsxm.2019.07.018

PASS. (2019). *2019 power analysis and sample size software*. Kaysville, UT: NCSS. Retrieved from ncss.com/software/pass

Perlman, D. M., Salomons, T. V., Davidson, R. J., & Lutz, A. (2010). Differential effects on pain intensity and unpleasantness of two meditation practices. *Emotion, 10,* 65–71. http://dx.doi.org/10.1037/a0018440

Poulin, P. A., Romanow, H. C., Rahbari, N., Small, R., Smyth, C. E., Hatchard, T., . . . Wilson, K. G. (2016). The relationship between mindfulness, pain intensity, pain catastrophizing, depression, and quality of life among cancer survivors living with chronic neuropathic pain. *Supportive Care in Cancer, 24,* 4167–4175. http://dx.doi.org/10.1007/s00520-016-3243-x

Preacher, K. J., Rucker, D. D., & Hayes, A. F. (2007). Addressing moderated mediation hypotheses: Theory, methods, and prescriptions. *Multivariate Behavioral Research, 42,* 185–227. http://dx.doi.org/10.1080/00273170701341316

Pukall, C. F., Binik, Y. M., & Khalifé, S. (2004). A new instrument for pain assessment in vulvar vestibulitis syndrome. *Journal of Sex & Marital Therapy, 30,* 69–78. http://dx.doi.org/10.1080/00926230490275065

Pukall, C. F., & Cahill, C. M. (2014). New developments in the pathophysiology of genital pain: Role of central sensitization. *Current Sexual Health Reports, 6,* 11–19. http://dx.doi.org/10.1007/s11930-013-0007-1

Pukall, C. F., Goldstein, A. T., Bergeron, S., Foster, D., Stein, A., Kellogg-Spadt, S., & Bachmann, G. (2016). Vulvodynia: Definition, prevalence, impact, and pathophysiological factors. *Journal of Sexual Medicine, 13,* 291–304. http://dx.doi.org/10.1016/j.jsxm.2015.12.021

Pukall, C. F., Young, R. A., Roberts, M. J., Sutton, K. S., & Smith, K. B. (2007). The vulvalgesiometer as a device to measure genital pressure-pain threshold. *Physiological Measurement, 28,* 1543–1550. http://dx.doi.org/10.1088/0967-3334/28/12/008

Reed, B. D., Harlow, S. D., Sen, A., Legocki, L. J., Edwards, R. M., Arato, N., & Haefner, H. K. (2012). Prevalence and demographic characteristics of vulvodynia in a population-based sample. *American Journal of*

Obstetrics and Gynecology, 206, 170.e1–170.e9. http://dx.doi.org/10.1016/j.ajog.2011.08.012

Sadownik, L. A. (2014). Etiology, diagnosis, and clinical management of vulvodynia. *International Journal of Women's Health, 6,* 437–449. http://dx.doi.org/10.2147/IJWH.S37660

Samwel, H. J. A., Kraaimaat, F. W., Crul, B. J. P., van Dongen, R. D., & Evers, A. W. M. (2009). Multidisciplinary allocation of chronic pain treatment: Effects and cognitive-behavioural predictors of outcome. *British Journal of Health Psychology, 14,* 405–421. http://dx.doi.org/10.1348/135910708X337760

Santerre-Baillargeon, M., Rosen, N. O., Steben, M., Pâquet, M., Macabena Perez, R., & Bergeron, S. (2018). Does self-compassion benefit couples coping with vulvodynia? Associations with psychological, sexual, and relationship adjustment. *The Clinical Journal of Pain, 34,* 629–637.

Segal, Z. V., Teasdale, J. D., Williams, M. J., & Gemar, M. C. (2002). The mindfulness-based cognitive therapy adherence scale: Inter-rater reliability, adherence to protocol and treatment distinctiveness. *Clinical Psychology & Psychotherapy, 9,* 131–138. http://dx.doi.org/10.1002/cpp.320

Shallcross, R., Dickson, J. M., Nunns, D., Mackenzie, C., & Kiemle, G. (2018). Women's subjective experiences of living with vulvodynia: A systematic review and meta-ethnography. *Archives of Sexual Behavior, 47,* 577–595. http://dx.doi.org/10.1007/s10508-017-1026-1

Shapiro, S. L. (2009). The integration of mindfulness and psychology. *Journal of Clinical Psychology, 65,* 555–560. http://dx.doi.org/10.1002/jclp.20602

Shapiro, S. L., Astin, J. A., Bishop, S. R., & Cordova, M. (2005). Mindfulness-based stress reduction for health care professionals: Results from a randomized trial. *International Journal of Stress Management, 12,* 164–176. http://dx.doi.org/10.1037/1072-5245.12.2.164

Shapiro, S. L., Carlson, L. E., Astin, J. A., & Freedman, B. (2006). Mechanisms of mindfulness. *Journal of Clinical Psychology, 62,* 373–386. http://dx.doi.org/10.1002/jclp.20237

Simons, J. S., & Gaher, R. M. (2005). The Distress Tolerance Scale: Development and validation of a self-report measure. *Motivation and Emotion, 29,* 83–102. http://dx.doi.org/10.1007/s11031-005-7955-3

Smeets, R. J. E. M., Vlaeyen, J. W. S., Kester, A. D. M., & Knottnerus, J. A. (2006). Reduction of pain catastrophizing mediates the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *The Journal of Pain, 7,* 261–271. http://dx.doi.org/10.1016/j.jpain.2005.10.011

Stephenson, K. R. (2017). Mindfulness-based therapies for sexual dysfunction: A review of potential theory-based mechanisms of change. *Mindfulness, 3,* 527–543.

Sullivan, M. J. L., Bishop, S. R., & Pivik, J. (1995). The Pain Catastrophizing Scale: Development and validation. *Psychological Assessment, 7,* 524–532. http://dx.doi.org/10.1037/1040-3590.7.4.524

Teasdale, J. D., Moore, R. G., Hayhurst, H., Pope, M., Williams, S., & Segal, Z. V. (2002). Metacognitive awareness and prevention of relapse in depression: Empirical evidence. *Journal of Consulting and Clinical Psychology, 70,* 275–287. http://dx.doi.org/10.1037/0022-006X.70.2.275

ter Kuile, M. M., Melles, R., de Groot, H. E., Tuijnman-Raasveld, C. C., & van Lankveld, J. J. D. M. (2013). Therapist-aided exposure for women with lifelong vaginismus: A randomized waiting-list control trial of efficacy. *Journal of Consulting and Clinical Psychology, 81,* 1127–1136. http://dx.doi.org/10.1037/a0034292

ter Kuile, M. M., Melles, R. J., Tuijnman-Raasveld, C. C., de Groot, H. E., & van Lankveld, J. J. (2015). Therapist-aided exposure for women with lifelong vaginismus: Mediators of treatment outcome: A randomized waiting list control trial. *Journal of Sexual Medicine, 12,* 1807–1819. http://dx.doi.org/10.1111/jsm.12935

ter Kuile, M. M., van Lankveld, J. J., de Groot, E., Melles, R., Neffs, J., & Zandbergen, M. (2007). Cognitive-behavioral therapy for women with lifelong vaginismus: Process and prognostic factors. *Behaviour Research and Therapy, 45,* 359–373. http://dx.doi.org/10.1016/j.brat.2006.03.013

Turk, D. C., Dworkin, R. H., McDermott, M. P., Bellamy, N., Burke, L. B., Chandler, J. M., . . . Witter, J. (2008). Analyzing multiple endpoints in clinical trials of pain treatments: IMMPACT recommendations. *Pain, 139,* 485–493. http://dx.doi.org/10.1016/j.pain.2008.06.025

Turner, J. A., Anderson, M. L., Balderson, B. H., Cook, A. J., Sherman, K. J., & Cherkin, D. C. (2016). Mindfulness-based stress reduction and cognitive behavioral therapy for chronic low back pain: Similar effects on mindfulness, catastrophizing, self-efficacy, and acceptance in a randomized controlled trial. *Pain, 157,* 2434–2444. http://dx.doi.org/10.1097/j.pain.0000000000000635

Van Dam, N. T., Sheppard, S. C., Forsyth, J. P., & Earleywine, M. (2011). Self-compassion is a better predictor than mindfulness of symptom severity and quality of life in mixed anxiety and depression. *Journal of Anxiety Disorders, 25,* 123–130. http://dx.doi.org/10.1016/j.janxdis.2010.08.011

van der Velden, A. M., Kuyken, W., Wattar, U., Crane, C., Pallesen, K. J., Dahlgaard, J., . . . Piet, J. (2015). A systematic review of mechanisms of change in mindfulness-based cognitive therapy in the treatment of recurrent major depressive disorder. *Clinical Psychology Review, 37,* 26–39. http://dx.doi.org/10.1016/j.cpr.2015.02.001

Vlaeyen, J. W. S., Crombez, G., & Linton, S. J. (2009). The fear-avoidance model of pain. *Pain, 157,* 1588–1589. http://dx.doi.org/10.1097/j.pain.0000000000000574

Vlaeyen, J. W., & Linton, S. J. (2000). Fear-avoidance and its consequences in chronic musculoskeletal pain: A state of the art. *Pain, 85,* 317–332. http://dx.doi.org/10.1016/S0304-3959(99)00242-0

Wammen Rathenborg, F. L., Zdaniuk, B., & Brotto, L. A. (2019). What do different measures of pain tell us? A comparison in sexually active women with provoked vestibulodynia. *Journal of Sexual Medicine, 16,* 278–288. http://dx.doi.org/10.1016/j.jsxm.2018.12.001

Wang, L. P., & Maxwell, S. E. (2015). On disaggregating between-person and within-person effects with longitudinal data using multilevel models. *Psychological Methods, 20,* 63–83. http://dx.doi.org/10.1037/met0000030

Wetherell, J. L., Afari, N., Rutledge, T., Sorrell, J. T., Stoddard, J. A., Petkus, A. J., . . . Atkinson, J. H. (2011). A randomized, controlled trial of acceptance and commitment therapy and cognitive-behavioral therapy for chronic pain. *Pain, 152,* 2098–2107. http://dx.doi.org/10.1016/j.pain.2011.05.016

Zeidan, F., Emerson, N. M., Farris, S. R., Ray, J. N., Jung, Y., McHaffie, J. G., & Coghill, R. C. (2015). Mindfulness meditation-based pain relief employs different neural mechanisms than placebo and sham mindfulness meditation-induced analgesia. *The Journal of Neuroscience, 35,* 15307–15325. http://dx.doi.org/10.1523/JNEUROSCI.2542-15.2015

Zeidan, F., Martucci, K. T., Kraft, R. A., Gordon, N. S., McHaffie, J. G., & Coghill, R. C. (2011). Brain mechanisms supporting the modulation of pain by mindfulness meditation. *The Journal of Neuroscience, 31,* 5540–5548. http://dx.doi.org/10.1523/JNEUROSCI.5791-10.2011

Zhang, Z., Zyphur, M. J., & Preacher, K. J. (2009). Testing multilevel mediation using hierarchical linear models: Problems and solutions. *Organizational Research Methods, 12,* 695–719. http://dx.doi.org/10.1177/1094428108327450

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