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ORIGINAL PAPER

Mindfulness-based Group Therapy for Women with Provoked Vestibulodynia

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Abstract Provoked vestibulodynia (PVD) is the most common cause of painful intercourse in women of reproductive age and research supports psychological approaches in the management of chronic pain. We developed a four-session group treatment for women with PVD that relied mostly on mindfulness meditation skills along with education and some discussion of cognitive theory. A total of 85 women were assigned either to immediate treatment (n=62; mean age, 39 years) or to a 3-month wait-list condition followed by treatment (n=23; mean age, 40 years). Questionnaires and a genital pain assessment were administered at pre- and post-treatment, and at 6 months follow-up. Women assigned to the two groups did not significantly differ on any measure at baseline. During the pretreatment wait-list period, there were significant improvements in pain self-efficacy, and non-significant improvements in feelings of helplessness, and sex-related distress. Pain self-efficacy, pain catastrophizing, genital pain induced by a cotton swab exam, pain hypervigilance, and sex-related distress all improved with treatment. There was no change in pain with intercourse. Pretreatment genital pain was the best predictor of post-treatment genital pain. Genital pain at 6-month follow-up was predicted by pretreatment genital pain, change in pain self-efficacy, and number of comorbid chronic pain conditions. Taken together, these findings support the use of a brief mindfulness-based program as a promising treatment for distressing genital pain.

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Introduction

Provoked vestibulodynia (PVD), characterized by severe pain on touch to the vulvar vestibule (the part of the vulva that contains the opening to the vagina, the surrounding hymen, the opening to the urethra, and the inner edge of the inside surface of the labia minora), is the most common cause of chronic premenopausal sexual pain (i.e., dyspareunia), affecting 12–21 % of women (Danielsson, Sjoberg, Stenlund, and Wikman 2003; Reed et al. 2012a, 2012b). Vestibular pain, hyperalgesia (severe pain from a minor painful stimulus), and allodynia (pain from a touch stimulus) make vaginal penetration painful, which, in turn, leads to broader symptoms of sexual dysfunction, and negative effects on psychological and relationship adjustment (Desrochers, Bergeron, Landry, and Jodoin 2008). The associated cost to women in terms of ongoing distress as well as to healthcare is high: typically three or more physicians are consulted before an accurate diagnosis is made (Harlow and Stewart 2003). Furthermore, contact with healthcare professionals often continues postdiagnosis given the limited benefit from medical treatments (Bornstein, Tuma, Farajun, Azran, and Zarfati 2010; Foster et al. 2010; Gunter 2007; Landry, Bergeron, Dupuis, and Desrochers 2008; Nyirjesy et al. 2001). The strict criteria for vestibulectomy (surgical excision of a portion of the painful vestibule) (Tommola, Unkila-Kallio, and Paavonen 2010), the frequent co-morbidity of other pain syndromes (Reed et al. 2012a, b), and women's hesitancy to consider this option, limit the role of surgery.

Central sensitization (Foster, Dworkin, and Wood 2005; Giesecke et al. 2004; Sutton, Pukall, and Chamberlain 2009b), possible genetic vulnerability (Gerber, Bongiovanni, Ledger,

and Witkin 2003; van Lankveld et al. 2010), and high stress (i.e., allostatic load; Ehrstrom, Kornfeld, Rylander, and Bohm-Starke 2009) underlie current conceptualizations of the pathogenesis of PVD (Basson 2012). Evidence to support these concepts includes the observation that a history of anxiety and mood disorders is 11 and 4 times more common, respectively, in women with acquired PVD compared to controls (Khandker et al. 2011). Emotional, as opposed to environmental stressors (van der Vegt, van der Ende, Kirschbaum, Verhulst, and Tiemeier 2009), are more prevalent in women with PVD than controls, and include self-dislike, hypervigilance and somatic preoccupation, perfectionism, somatization, fear of negative evaluation (Brotto, Basson, and Gehring 2003), and harm avoidance (Ehrstrom et al. 2009; Jantos and White 1997; Payne et al. 2005). Furthermore, hyporesponsiveness of the hypothalamic pituitary adrenal axis (HPA) has been identified in women with PVD (van der Vegt, van der Ende, Kirschbaum, Verhulst, and Tiemeier 2009). The HPA axis is known to be negatively affected by stresses in early life: its subsequent dysregulation is linked to sensitivity to stress, pain, and fatigue in adult life and specifically to fibromyalgia and irritable bowel syndrome which are commonly comorbid with PVD (Arnold, Bachmann, Rosen, Kelly, and Rhoads 2006; Reed et al. 2012a, 2012b). Of importance to the understanding of PVD, stress and/or mood may not only maintain but trigger central sensitization (Davidson and McEwen 2012; Tracey and Bushnell 2009; Vachon-Presseau, Roy, Martel, and Caron 2013; Woolf 2011). Additionally, multiple neuroendocrine changes in the skin in response to stress may lead to the nocioceptor proliferation identified on biopsies of allodynic vestibular tissue. Mast cells and plasma cells are also seen on PVD biopsies alongside sensory nerve endings. These cells are found in lymphoid tissues which are innervated by the sympathetic nervous system. Their activation not only allows the expected chronic inflammation but also nerve hypersensitivity and pain through release of multiple substances (Theoharides et al. 2004). These include nerve growth factor to promote sprouting of nocioceptors (for review of the complexities of the effects of stress on skin physiology, see Black (2002) and Arck et al. (2006)).

Former models of PVD postulate nerve trauma (mechanical, hormonal, and inflammatory), as the primary event leading to increased afferent nocioceptive signaling. It is likely that there are subsets of PVD reflecting different etiologies. While mechanical trauma has never been confirmed and approximately 50 % of women report pain from their first attempts of vaginal penetration, a hormonal factor (i.e., estrogen deficit) may well be relevant for a peri- or postmenopausal onset. While an autoimmune reaction to *Candida* or other microbial or nonmicrobial antigen, previously thought to underlie PVD (Chadha et al. 1998) may not apply to the majority of women; nevertheless, a small subset of women with acquired PVD have a documented candidiasis at its onset. Interestingly, our clinical experience is that the personality traits reflecting internal stress are present in the women with perimenopausal and post-candida onset.

A recent model proposes that reduction in allostatic load by cognitive behavior therapy (CBT) and mindfulness practices can address the pain amplification and neuroendocrine skin pathophysiology of PVD (Basson 2012). Group CBT is effective for PVD (Bergeron et al. 2001; Bergeron, Khalifé, Glazer, and Binik 2008; Masheb, Kerns, Lozano, Minkin, and Richman 2009) and incorporates change-oriented education, cognitive, and behavioral interventions (e.g., challenging catastrophizing thoughts; reducing sexual avoidance). Important to sexual pain, changes in sexual behavior can enable reward and anticipation of pleasure from the overall sexual experience to lessen pain during sex (Soderman and Unterwald 2008).

In contrast with change-oriented CBT strategies, mindfulness is an acceptance-based approach (Bishop et al. 2004) with established effectiveness for lessening perceived stress (Carlson, Speca, Faris, and Patel 2007; Carmody, Baer, Lykins, and Olendzki 2009; Ludwig and Kabat-Zinn 2008; Matousek and Dobkin 2010) and a long history of use for chronic pain. Reducing stress is expected to influence top-down regulation of pain responsivity inherent to central sensitization and neuroendocrine skin pathophysiology of PVD (Basson 2012). Acceptance and nonjudgment of the present moment, including self-acceptance, are hallmarks of mindfulness practice; reduction of frequently noted self-criticism (Ehrstrom et al. 2009) may be a key mechanism by which mindfulness may improve symptoms of PVD. Mindfulness is associated with reductions in pain, accompanying distress and pain-related brain activity in healthy volunteers (Gaylord et al. 2011; McCracken, Gauntlett-Gilbert, and Vowles 2007; Perlman, Salomons, Davidson, and Lutz 2010; Ussher et al. 2012) and in patients with irritable bowel syndrome and fibromyalgia (Clauw and Crofford 2003; Fries, Hesse, Hellhammer, and Hellhammer 2005). Low mindfulness has been linked to pain catastrophizing—the latter correlating with intercourse pain intensity in PVD (Desrochers et al. 2008; Sutton, Pukall, and Chamberlain 2009a). Both mindfulness and CBT may improve co-morbid anxiety and depression, and foster sexual arousal (which is known to be analgesic; Komisaruk and Whipple 2000).

Despite strong evidence supporting the potential utility of mindfulness in ameliorating the symptoms of PVD, there is no literature that has empirically evaluated a mindfulness-based intervention for this population. Thus, the goal of the current study was to test the effectiveness of a mindfulness-based group treatment in women seeking management of their PVD. We chose to include some CBT skills in addition to our major focus on mindfulness as a result of discussions with our patients. Having been referred to our clinic after consulting a number of primary care practitioners and gynecologists,

most patients were expecting a medical approach and some had expressed reservations about mindfulness. Given the therapeutic effect of positive expectations (Koyama, McHaffie, Laurienti, Coghill, and Smith 2005), we chose to introduce some CBT skills to allow for individual preferences and needs.

Building on the work of others who have combined elements of CBT and mindfulness therapy for depression (Lau and McMain 2005; Ma and Teasdale 2004; Teasdale, Segal, and Williams 1995) and anxiety (Roemer and Orsillo 2002), our objective was to use the CBT model to illustrate the potential to deliberately change one's attitude to thoughts in various ways. We wished to focus on the concept that thoughts are mental events—not necessarily truths. To assist this reconceptualization of thoughts, we encouraged the identification of thought biases. We hypothesized that as women became observant of problematic thoughts (accomplished via thought records), while aware that they were dysfunctional thoughts that could be more accurately structured, they could choose to remind themselves that thoughts are just "what the brain does" and need not be followed or believed.

We deliberately emphasized mindfulness therapy over cognitive skills such as distraction given the potential for continued distraction during sexual encounters to inhibit sexual response. As well, experimental pain was recently shown to be reduced more effectively by focused attention and open monitoring than by either distraction or relaxation (McCracken and Eccleston 2005). A desired outcome of our treatment was to increase sexual pleasure, arousal, and satisfaction—parameters that have shown benefit from both mindfulness practice (Brotto et al. 2008a; Brotto et al. 2008b; Brotto et al. 2012) and CBT (Trudel et al. 2001). The practice of noticing distracting thoughts but not following them during a meditation is noted to be especially helpful for women's sexual experience as distractions are a common cause of problematic sexual arousal (Brotto et al. 2008a). Refocusing on erotic thoughts subsequent to harboring non-erotic thoughts (frequently about body image) has been shown to predict women's difficulties with arousal (Nelson and Purdon 2011). Cultivating mindfulness can lessen such self-judgment and enhance the ability to refocus. A mindfulness approach to pelvic floor physiotherapy for PVD has also been advocated (Rosenbaum 2013). The woman is encouraged to be nonjudgmental as she places vaginal inserts (a common component of pelvic floor physiotherapy), rather than to strive for a particular outcome.

We were aware that possibly a majority would not continue regular mindfulness practice in the longer term. Thus, the interesting findings resulting from brain plasticity in long-term mindfulness practitioners including deactivation of the orbitofrontal cortex (OFC), reflecting decreased appraisal/elaboration of pain sensations may not apply (Grant, Courtemanche, and Rainville 2011). However, other research has shown that after just 4 days of mindfulness practice for 20 min, participants have increased activity in the OFC along with pain reduction from a painful stimulus while meditating (Zeidan, Gordon, Merchant, and Goolkasian 2010). The researchers have hypothesized that in early stages of mindfulness practice, some cognitive reappraisal does occur and only with further practice is there freedom from appraisal/elaboration (Zeidan et al. 2012). Thus, some CBT skills may prove to be useful clinically in early mindfulness practice.

This exploratory study is the first to evaluate mindfulness-based therapy as a treatment for PVD. Our endpoints were grouped into three broad domains, and were chosen based on previous evidence that they respond positively to a psychological intervention and that they each contribute unique information. Endpoints were: (1) pain related (e.g., pain provoked in a clinic setting; pain self-efficacy, pain catastrophizing, and pain hypervigilance), (2) sex-related (e.g., sex-related distress, dyspareunia), and (3) mood (e.g., depression and anxiety symptoms). Predictors of clinic-assessed genital pain were also examined.

Method

Participants

At the time of designing this study, there were no available data on mindfulness-based treatment for PVD from which to establish an effect size. Thus, we used the findings of Bergeron et al. (2001) in which group CBT significantly reduced pain with intercourse with a moderate effect size (effect size=0.55) and improved psychological function (effect size=0.28) to suggest a more conservative estimate of effect size and determined that a total sample size of n=44 would be required to detect improvements with treatment. Eligible participants were women seeking treatment for PVD at a provincial Sexual Medicine treatment center or a hospital Vulvar Pain Clinic. Inclusion criteria were: diagnosis of PVD, English fluency, and willingness to attend four treatment sessions. Women with other medical comorbidities that may have accounted for the vulvar pain (e.g., lichen sclerosus) were excluded from the study. Women with comorbid sexual complaints, with mood or anxiety disorders (unless severity precluded useful group participation), or women who were consistently taking medications believed to influence sexual function were not excluded.

Procedures

Clinicians came to a diagnosis of PVD following a detailed biopsychosocial assessment (typically over two to three 1-h visits, alone and with the woman's partner if available) and a vulvovaginal examination (see below). After a diagnosis of

PVD was made, women were provided with information about the study by a clinician. If interested, they contacted a study coordinator who then explained the procedures in more detail, and mailed each woman a consent form. The return of this signed document in the mail was taken as the basis for informed consent. All procedures were approved by our university and hospital clinical research ethics boards. Partners were seen in the clinic as part of the initial assessment process prior to group sessions beginning. Issues including those related to relationship quality, partner responsiveness, and sexual communication were identified and addressed in office visits which occurred before, during, and after the 8-week group treatment completed. Confidentiality concerns, scheduling, and availability as well as partners' willingness to participate in groups precluded us from enrolling partners in the group treatment protocol.

Women assigned to the immediate treatment arm completed assessment measures on three occasions: at least a week prior to the first group session, 4–6 weeks after the last session (post-treatment), and 6 months after the last session (follow up). Whenever possible, and if there was at least a 3-month delay before the woman was scheduled to begin her sessions, women were assigned to the delayed treatment arm and completed a second pretreatment questionnaire package. This allowed us to examine the impact of anticipating treatment or a form of placebo response. Apart from the additional assessment point, all subsequent procedures were identical for women in the two arms.

The vulvovaginal examination included a cotton swab test, which is the standard method of diagnosing PVD and assessing pain intensity. The clinician used a cotton swab to lightly touch seven points around the vulvar vestibule in random order. The woman then reported how much pain was experienced (i.e., allodynia or pain from a touch stimulus) on a 0 (no pain) to 10 (worst pain ever) numeric rating scale. This cotton swab exam was repeated at each assessment, typically by the same clinician.

At the conclusion of the study, participants were provided a $60 honorarium for completion of the questionnaire packages and cotton swab examinations.

Dependent Measures

Pain-related Endpoints Changes in allodynia with treatment were captured with the cotton swab exam. The allodynia score was derived by taking the mean pain rating across each of the seven sites palpated on the vulvar vestibule and yielding a score between 0 (no pain) and 10 (worst pain ever).

Pain self-efficacy was measured by the Painful Intercourse Self-Efficacy Scale (PISES; adapted from the Arthritis Self-Efficacy Scale (Lorig, Chastain, Ung, Shoor, and Holman 1989)). The PISES is a 20-item self-report questionnaire used to measure a participant's perceived ability to participate in sexual activity or to reach certain goals in pain management. It measures self-efficacy for controlling pain during intercourse (penetrative sex), self-efficacy for sexual function, and self-efficacy for controlling other symptoms. Participants responded to items on a 10-point scale ranging from 10 (very uncertain), 50 (moderately uncertain) to 100 (very certain). The original version of the scale was found to have good internal consistency among a sample of patients with arthritis (Cronbach α ranging from 0.76 to 0.89) and acceptable test–retest reliability. The adapted version for women with vulvar pain had good internal consistency for the total score (Cronbach α=0.89) and subscales (Cronbach α ranging from 0.76 to 0.88; Desrochers, Bergeron, Khalifé, Dupuis, and Jodoin 2009). Factorial analyses also revealed a factorial structure identical to the original scale. Cronbach's α in the current sample was high at 0.915.

Pain catastrophizing was measured with the Pain Catastrophizing Scale (PCS; Sullivan, Bishop, and Pivik 1995). The PCS has three subscales: helplessness, magnification, and rumination. It asks participants to think about past PVD-related painful experiences or a specific experience of genital pain, and to indicate the degree to which they have any of the presented thoughts or feelings when they are experiencing pain. Thirteen-items are rated on a Likert scale from 0 (not at all) to 4 (all the time). The PCS has been shown to have high test–retest reliability over a 6-week period (r=0.75) and also over a 10-week period (r=0.70). Cronbach's α in the current sample was high at 0.915.

Pain hypervigilance was measured by the 16-item Pain Vigilance and Awareness Questionnaire (PVAQ; McCracken 1997), which is found to have good internal consistency (Cronbach's α=0.86). Over a 2-week period, test–retest reliability was found to be high with r=0.80. Roelofs, Peters, McCracken, and Vlaeyen (2003) found the reliability and validity of the PVAQ to be supported among three samples of fibromyalgia patients. Furthermore, strong convergent validity has been found between PVAQ scores and other pain-related self-report constructs. A higher total score is thought to reflect more vigilance to pain. Cronbach's α in the current sample was moderately high at 0.820.

Sex-related Endpoints Sex-related distress was measured by the Female Sexual Distress Scale (FSDS) (Derogatis, Rosen, Leiblum, Burnett, and Heiman 2002), a 12-item self-report questionnaire. Scores on the scale range from 0 to 48, where higher scores represent higher levels of distress. The FSDS has satisfactory internal consistency (ranging from 0.86 to 0.90) and test–retest reliability over 4 weeks [r=0.91], and demonstrates moderate correlations with measures of nonsexual distress.

Dyspareunia, as measured by the Pain subscale on the Female Sexual Function Index (FSFI) (Rosen et al. 2000) was

also assessed. The FSFI is a 19-item self-report questionnaire, and we included only the three-item Pain domain of the FSFI, which has been found to be sensitive to treatment outcome among women with PVD (Spoelstra, Dijkstra, van Driel, and Weijmar Schultz 2011). Women were advised to temporarily stop engaging in painful sexual intercourse for the duration of the group; however, we were aware that not all women chose to follow this recommendation and that in later sessions, this instruction changed such that women were encouraged to consider when and how to reincorporate penetrative activities. As such, we were not expecting significant changes in this endpoint.

Mood-related Endpoints The Beck Depression Inventory (BDI; Beck and Beamesderfer 1974) allowed us to measure the potential impact of treatment on mood. The BDI is a 21-item self-report questionnaire that is found to be sensitive to treatment effects on severity of depressive symptoms. Each item is rated along a 4-point scale from 0 to 3, with higher numbers reflecting increasing depressive severity, and total BDI scores can range from 0 to 63. A score ≥15 denotes probable depression. Cronbach's alpha in the current sample was 0.842.

The State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, Lushene, Vagg, and Jacobs 1983) was used to examine any effect of treatment on anxiety. The STAI has 20 items in each of two subscales (state and trait) with items rated on a 4-point Likert scale. Cronbach's alpha in the current sample was low at 0.554.

Exploratory Endpoint We included a measure of mindfulness, The Five Factor Mindfulness Questionnaire (FFMQ; Baer, Smith, Hopkins, Krietemeyer, and Toney 2006), to explore the extent to which improvements in allodynia could be predicted from changes in mindfulness. The FFMQ is a 39-item self-report questionnaire with responses on a 5-point Likert scale ranging from 1 (never or very rarely true) to 5 (very often or always true). The five facets are observing sensations, describing sensations, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience. The FFMQ has been found to have adequate to good internal consistency with alphas ranging from 0.72 to 0.92 (Baer et al. 2008).

Demographic Variables

Demographic information collected from participants also included information about their PVD pain history, relationship status and duration, and their perception of the level of closeness in their relationship. The number of chronic pain conditions (e.g., irritable bowel syndrome, chronic migraines, fibromyalgia, and temporomandibular jaw pain) were assessed.

Description of "IMPROVED" Treatment

The first two authors developed an integrated mindfulness-based group intervention comprising mindfulness meditation skills, CBT, and education following the well-established protocols developed for management of chronic pain, plus information on chronic pain and on sexual function. In keeping with a mindfulness approach, we avoided the temptation to have goals, and thus the front page of participant materials listed the name of the program as "Moving on with our sexual lives despite the pain from provoked vestibulodynia" to emphasize an acceptance-based approach. We called the program, IMPROVED, which stood for: "Integrated Mindfulness for Provoked Vestibulodynia".

Sessions took place once every 2 weeks. Session 1 covered the current state of the science regarding the pathophysiology and etiology of PVD, including a discussion of central sensitization and the role of stress in exacerbating symptoms. Mindfulness skills were introduced with an eating meditation and the cognitive behavioral model, which illustrates how thoughts, emotions, behaviors, and pain are associated, was illustrated and described. Homework involved daily mindfulness practice "in everyday life" as well as encouraging women to think about the timeline and sequelae of their PVD. Session 2 went into more detail regarding the impact of cognitions and chronic stress on pain, and introduced the use of Thought Records. Behavioral avoidance was discussed with specific skills in how to promote initially nonpenetrative, pain-free sexual activity through the use of in-session practice of Progressive Muscle Relaxation. Mindfulness applied to everyday life situations was then practiced and encouraged for homework. In session 3, participants practiced the Body Scan followed by more didactic information on the mechanisms of mindfulness in chronic pain. We also covered the circular sexual response cycle as it has been adapted to women with PVD (Basson 2012). Homework included daily body scans, practicing mindfulness in everyday life, completing the sexual response cycle specific to their own personal experience, and completing one thought record. Session 4 used thoughts as the focus during in-session mindfulness practice, and discussed how to work with thoughts in meditation. There was more discussion of the impact of thoughts on chronic pain using the CBT model as a guide for illustration. A mindfulness practice to begin in future weeks which allowed brief self-touch to the vestibule in a nonjudgmental way, focusing on the physical sensations was described. Women were encouraged to practice their skills daily and facilitators assigned each participant a homework compliance score at the end of each session (measured on a 0–2 Likert scale). It was emphasized throughout that the four session program was only the very beginning of an ongoing psychological readjustment to living with PVD: continued follow up with their clinicians to support continued

use of new skills was strongly advocated. Both a facilitator and a participant manual were developed.

Analyses

Effects of waiting for treatment were analyzed with a dependent-samples *t* test on women assigned to the delayed treatment arm. We next carried out a series of between-within repeated measures analyses of variance (ANOVA) with three levels (pretreatment, immediate post-treatment, and 6-month follow-up) and a between-group factor (immediate treatment, delayed treatment). Significant ANOVAs were followed up with pairwise comparisons between time points. Greenhouse Geisser adjustments were applied in cases of violations to homogeneity of variances. We applied a Bonferroni correction of $p<0.0125$ to the set of pain-related variables (0.05/4 variables), a correction of $p<0.025$ to sex-related variables (0.05/2), and a correction of $p<0.025$ to mood-related variables (0.05/2).

Results

Final Sample Size

Out of approximately 121 women who were informed of the study, 119 were eligible (two did not have PVD). Ninety-seven women provided written consent to participate in the study and completed all aspects of the baseline assessment. Of these 97 women, six withdrew before the start of session 1, and another six withdrew from the study after completing one or two of the four treatment sessions. One-way ANOVAs comparing these three groups indicated no significant differences in age, duration or severity of PVD, onset of PVD as primary versus secondary, rumination, depression, catastrophizing, state or trait anxiety, or sex-related distress. Demographic data and all analyses are therefore only presented on the $n=85$ women who completed at least three of the four IMPROVED sessions ($n=62$ immediate treatment; $n=23$ wait-list treatment; See CONSORT diagram Fig. 1).

Participant Characteristics

The mean age of women in the immediate treatment arm ($n=62$; mean age, 39.0 years; SD, 13.8) did not differ from the mean age of women in the delayed treatment arm ($n=23$; mean age, 40.4 years; SD 11.4; $t(83)=0.43$, $p>0.05$). There were no significant group differences in relationship status, the length of current relationship, ethnicity, education, or women's self-reported level of emotional closeness in the relationship (Table 1).

Regarding pain variables, there were equal proportions of women in the two groups with lifelong (primary) and acquired (secondary) pain. Whereas 42.9 % of women in the delayed treatment group had attempted intercourse in the past 4 weeks prior to treatment, significantly fewer women (23.0 %) in the immediate treatment group had done so ($X^2(4)=10.83$, $p=0.029$). Among the sexually active women, the mean level of vulvar pain with intercourse (dyspareunia) prior to treatment ranged from 5.18 to 6.11 and mean ratings of intercourse unpleasantness ranged from 4.88 to 6.33 out of 10 for women in the two arms. Most women who had recent intercourse continued to have vulvar pain following intercourse, and some had painful urination following intercourse, with no significant group differences (Table 1). Medical factors (current use of hormones, history of vaginal yeast infections, irritable bowel syndrome, migraine headaches, fibromyalgia, temporomandibular jaw pain, and bladder infections) were gathered by self-report, and their prevalence was not found to significantly differ between the groups (Table 1).

Regarding mood and anxiety, there were no significant group differences on baseline anxiety, as assessed by the state and trait domains of the STAI, or on depressive symptoms, as measured by the BDI, all ps>0.05. State and trait anxiety were significantly higher in our sample than normative data available for female college students though not as high as individuals with a diagnosed anxiety disorder (Spielberger et al. 1983). Scores on the BDI fell into the minimally depressed range.

Effects of Wait-List on Endpoints

Using a dependent samples *t* test and a Bonferroni correction, there was a statistically significant change in the positive direction during the wait-list period for the pain-related endpoint of pain self-efficacy ($t(22)=-3.38$, $p=0.003$; mean at pretreatment time 1, 5.87; SD, 1.39; mean at pretreatment time 2, 6.65; SD, 1.37). Pain catastrophizing: helplessness subscale, also improved; however, this did not reach significance with the Bonferroni correction ($t(23)=2.22$, $p=0.036$). There were no significant changes on the rumination and magnification subscales of the PCS, on pain hypervigilance, or on the mean allodynia rating during the wait-list period (ps>0.05).

On sex-related endpoints, sex-related distress decreased, though this was not statistically significant with the Bonferroni correction ($t(23)=2.25$, $p=0.034$). There was no significant change in dyspareunia ratings during the wait-list period.

Neither depressive symptoms nor state or trait anxiety significantly changed during the two pretreatment assessment points (ps>0.05).

Effects of IMPROVED on Pain-Related Endpoints

Given the significant improvement in pain self-efficacy during the pretreatment period, responses to treatment in the two

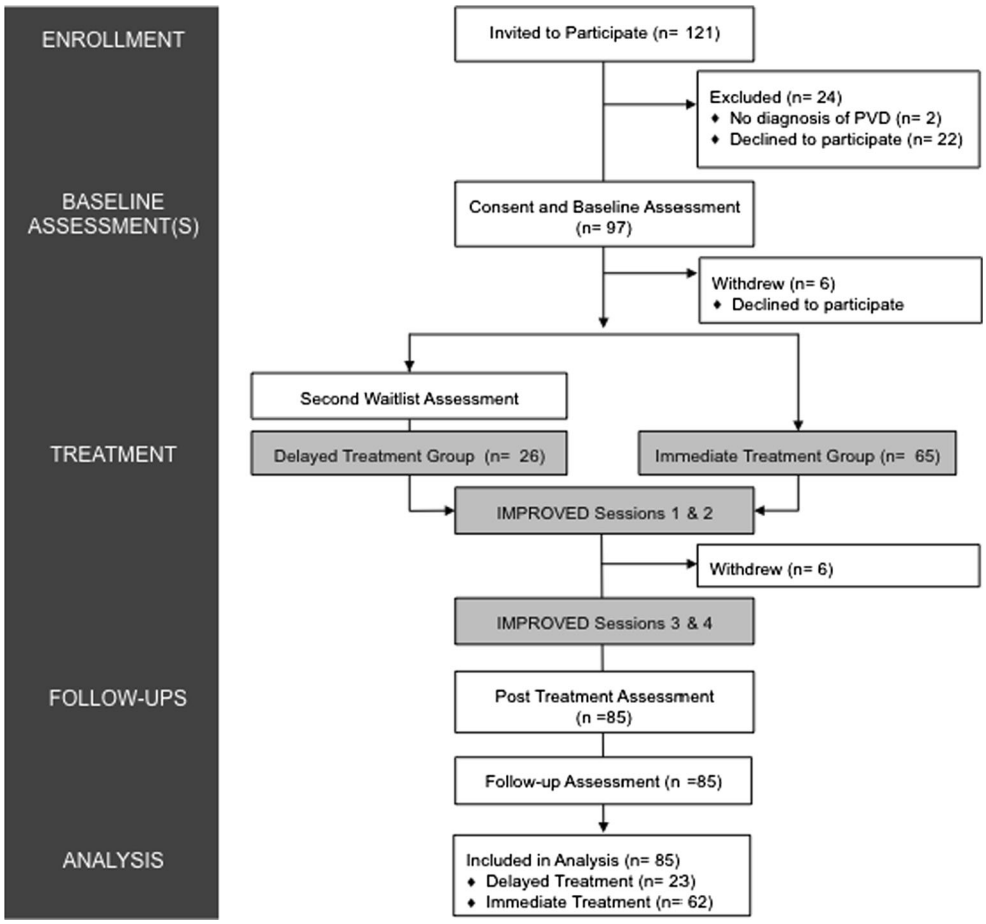

Fig. 1 CONSORT diagram of participant flow

arms were examined separately using a mixed between (two levels; immediate treatment group, delayed treatment group)-within (three levels; pretreatment, post-treatment, follow-up) repeated measures ANOVA followed by pairwise comparisons between pre- and post-treatment, and/or between post-treatment and follow-up. See Table 2 for the means and SDs of the pain-related, sex-related, and mood-related endpoints presented by group and timepoint.

Overall compliance with the homework activities was very good; however, women assigned to the delayed treatment condition had significantly higher compliance ratings (mean, 1.84; SD, 0.30) than women in the immediate treatment group (mean, 1.56; SD, 0.56; $t(71.8)=-3.02$, $p=0.003$).

On pain self-efficacy, there was a significant main effect of treatment ($F(2,126)=22.33$, $p<0.001$), such that scores increased over time, and a significant main effect of group ($F(1, 63)=6.24$, $p=0.015$), such that the delayed treatment group, on average, had higher scores than the immediate treatment group. There was no significant time × group interaction ($F(2, 126)=1.05$, $p>0.05$). Follow-up pairwise tests between time points indicated a significant improvement between pretreatment and post-treatment ($p<0.001$) and further significant improvements from post-treatment to follow-up ($p=0.021$).

On the rumination subscale of the PCS, there was a significant main effect of treatment ($F(2,126)=20.41$, $p<0.001$), such that scores decreased over time. Neither the main effect of group, $F(1, 63)=0.20$, nor the time × group interaction, $F(2, 126)=0.67$, were significant ($ps>0.05$). Follow-up pairwise tests indicated a significant decrease in rumination between pre-treatment and post-treatment ($p<0.001$) and another significant decrease from post-treatment to follow-up ($p<0.001$).

A similar pattern emerged for the helplessness subscale of the PCS such that scores significantly decreased over time ($F(2, 126)=16.11$, $p<0.001$), and there was neither a main effect of group ($F(1,63)=0.06$) nor a time × group interaction ($F(2, 126)=1.51$, $ps>0.05$). There was a significant decrease in helplessness between pre-treatment and post-treatment ($p<0.001$) and a further significant decrease from post-treatment to follow-up ($p<0.001$). Similarly, the magnification subscale on the PCS showed the same pattern. Scores significantly decreased with time ($F(2, 126)=5.85$, $p=0.004$) but there was neither a main effect of group ($F(1,63)=0.002$) nor a time × group interaction ($F(2, 126)=1.99$, $ps>0.05$). Follow-up pairwise tests between time points indicated a significant decrease in magnification between pre-treatment and post-treatment ($p<0.02$) and another significant decrease from post-treatment to follow-up ($p<0.02$).

Table 1 Baseline characteristics for women assigned to immediate treatment (n=62) and women assigned to the delayed treatment condition (n=23)

Variable	Immediate treatment		Delayed treatment	
	M	SD	*M*	SD
Age (years)	39.0	13.78	40.4	11.35
Relationship status (%)				
Single	20.0		17.4	
Partnered	80.0		82.6	
Duration of relationship (years)	9.7	9.11	12.6	11.43
Ethnicity (%)				
Euro-Canadian	71.0		87.0	
East Asian	19.4		4.3	
Other	9.7		8.7	
Education (%)				
High school only	8.2		4.3	
College educated	77.0		95.7	
Postgraduate education	14.8		0.0	
Level of closeness in relationship (%)				
Satisfied	55.6		52.6	
Dissatisfied	44.4		47.4	
Diagnosis				
Lifelong/primary (%)	48.4		43.5	
Acquired/secondary (%)	51.6		56.5	
% Attempting intercourse in the past 4 weeks*	23.0		42.9	
Dyspareunia (0–10)	5.18	2.74	6.11	2.32
Unpleasantness (0–10)	4.9	3.08	6.3	1.87
Vulvar pain following intercourse (%)	52.4		66.7	
Painful urination following intercourse (%)	20.0		44.4	
Currently using hormones (%)	19.4		27.3	
Concurrent medical conditions				
History vaginal yeast infections (%)	75.8		74.0	
Irritable bowel syndrome (%)	22.6		26.1	
Migraine headaches (%)	46.8		39.1	
Fibromyalgia (%)	6.5		4.3	
Temporomandibular jaw pain (%)	24.2		17.4	
Bladder infections (%)	50.0		39.1	

Data, other than those shown by percentages, represent means and SD

All data gathered by self-report

*p<.05

Pain hypervigilance significantly decreased with time (F(2, 124)=5.11, p=0.007), and there was no significant main effect of group (F(1, 62)=0.04) or time × group interaction (F(2, 124)=1.98, ps>0.05). Follow-up pairwise tests between time points indicated a significant decrease in pain hypervigilance between pretreatment and post-treatment (p=0.024) and another significant decrease from post-treatment to follow-up (p=0.035).

On the mean allodynia rating, scores significantly decreased with treatment (F(2, 120)=33.90, p<0.001) and there was neither a significant main effect of group (F(1, 60)=0.02) nor an interaction between time × group (F(2, 120)=1.45, ps>0.05). The decrease in allodynia from pretreatment to post-treatment (p<0.001) and from post-treatment to follow-up (p=0.024) were both significant.

Effects of IMPROVED on Sex-Related Endpoints

On the Pain subscale of the FSFI, data were only available for 15 women. There were no significant main effects of treatment or group, nor a significant time × group interaction. Table 3 lists the proportion of women at each time point who had engaged in sexual intercourse in the previous 4 weeks.

On sex-related distress, there was a significant decrease with treatment (F(2, 128)=14.52, p<0.001), but no significant main effect of group (F(1, 64)=1.42) or time × group interaction (F(2, 128)=2.33, ps>0.05). Analyses between time points showed a significant decrease in sex-related distress between pretreatment and post-treatment (p<0.001) and again from post-treatment to follow-up (p=0.023).

Mood-Related Endpoints

There was a statistically significant overall drop in depressive symptoms with treatment (F(2,118)=4.40, p=0.014), but no significant main effect of group (F(1,59)=0.07) or time × group interaction (F(2,118)=0.37, ps>0.05). Pairwise contrasts revealed a significant reduction in BDI scores between times 1 and 2 (p=0.001) but no significant change in scores from times 2 to 3 (p>0.05).

Only the State domain in the STAI was analyzed with respect to treatment effects. Neither the main effect of treatment (F(2,124)=0.03), the main effect of group (F(1,62)=0.004), nor the time × group interaction (F(2,124)=0.64) were statistically significant (all ps>0.05).

Effects of Treatment on Mindfulness Domains

There was no effect of wait-list on any of the subscales of the FFMQ, all ps>0.05. With treatment, however, there was a statistically significant improvement in observing sensations (F(2,128)=3.00, p=0.05). This improvement was seen from pre- to post-treatment (p=0.009) with no significant change from post-treatment to follow-up (p>0.05). There was also a time × group interaction for acting with awareness (F(2,128)=5.12, p=0.007) such that women in the immediate treatment arm did not have any increase but women in the delayed treatment arm had a significant increase in acting with awareness. Improvements in the domains of describing, nonjudgment, and nonreactivity were not statistically significant (ps>0.05; Table 4).

Table 2 Effect of treatment on pain-, sex-, and mood-related endpoints (at pretreatment, post-treatment, and follow-up) for women assigned to immediate treatment and women assigned to the delayed treatment arms

Variable	Immediate treatment			Delayed treatment		
	n	*M*	SD	*n*	*M*	SD
Allodynia*						
Pretreatment	48	6.06	2.60	14	5.49	2.64
Post-treatment***	48	3.74	2.42	14	3.53	2.57
Follow-up****	48	2.91	1.97	14	3.46	2.48
PISES*, **						
Pretreatment	48	5.24	1.78	17	6.70	1.48
Post-treatment***	48	6.36	1.97	17	7.40	1.57
Follow-up****	48	6.82	1.94	17	7.72	1.27
PCS—rumination*						
Pretreatment	48	9.10	4.43	17	8.88	4.96
Post-treatment***	48	7.29	3.98	17	8.06	5.07
Follow-up****	48	5.25	3.97	17	6.12	4.39
PCS—helplessness*						
Pretreatment	48	12.60	6.02	17	11.53	6.87
Post-treatment***	48	9.63	5.93	17	10.29	6.72
Follow-up****	48	7.04	5.91	17	8.53	6.83
PCS—magnification*						
Pretreatment	48	3.13	2.45	17	2.53	1.77
Post-treatment***	48	2.33	1.95	17	2.88	1.90
Follow-up****	48	1.90	1.61	17	1.88	1.69
PVAQ*						
Pretreatment	48	40.99	12.76	16	37.42	13.73
Post-treatment***	48	37.45	12.39	16	38.67	10.93
Follow-up****	48	35.08	12.80	16	35.39	9.45
FSDS*						
Pretreatment	49	29.22	10.57	17	24.47	13.13
Post-treatment***	49	24.67	12.10	17	19.59	12.68
Follow-up****	49	20.63	9.27	17	20.29	12.88
Pain subscale—FSFI						
Pretreatment	9	2.98	1.51	6	2.80	1.50
Post-treatment	9	3.33	1.48	6	3.93	1.61
Follow-up	9	3.47	0.94	6	3.00	1.15
BDI*						
Pretreatment	45	11.00	6.68	16	12.13	6.55
Post-treatment***	45	9.29	6.70	16	9.69	4.47
Follow-up	45	9.91	7.72	16	9.75	6.83
STAI state						
Pretreatment	47	40.72	9.89	17	39.24	9.91
Post-treatment	47	39.13	11.03	17	40.71	9.95
Follow-up	47	39.94	10.50	17	39.35	10.58

Allodynia was self-reported along a 0 (no pain) to 10 (worst pain ever) scale

PISES Painful Intercourse Self-Efficacy Scale, *PCS* Pain Catastrophizing Scale, *PVAQ* Pain Vigilance and Awareness Questionnaire, *FSDS* Female Sexual Distress Scale, *FSFI* Female Sexual Function Index, *BDI* Beck Depression Inventory, *STAI* State-Trait Anxiety Inventory

*$ps \leq 0.01$, significant main effect of treatment

** $p=0.015$, significant main effect of group

*** $ps<0.05$, significant improvement between pre-treatment and post-treatment

**** $ps<0.05$, significant improvement from post-treatment to follow-up

Effects of Pre-existing Chronic Pain Conditions on Efficacy

We next explored the influence of women's pre-existing chronic pain conditions (e.g., irritable bowel syndrome, chronic migraines, fibromyalgia, and temporomandibular jaw pain) on the primary endpoint of allodynia during the cotton swab test. Women could receive a score from 0 (no comorbid chronic pain condition) to 4 (reported all four) on this variable. A Pearson product moment correlation coefficient showed a significant positive relationship ($r(64)=0.288$, $p=0.021$) such that women with more comorbid pain conditions had higher allodynia at 6-month follow-up.

Table 3 Proportion of women who engaged in sexual intercourse in the previous 4 weeks following the end of treatment

Group	Pretreatment (%)	Post-treatment (%)	Follow-up
Delayed treatment group	42.9	50	47.1
Immediate treatment group	23.0	30.9	47.1

Multiple Regression Analysis

We next carried out a Stepwise Multiple Regression using the allodynia endpoint (mean score) at immediate post-treatment as the criterion variable and change in FFMQ observing sensations, change in FFMQ acting with awareness, pretreatment allodynia, change in pain catastrophizing (helplessness, rumination, and magnification), change in pain self-efficacy, and number of comorbid chronic pain conditions, as predictor variables. The model was significant ($F(8,49)=2.93$, $p=0.009$) and accounted for 21.3 % of the variance in allodynia ratings. Examining individual predictors (Table 5) indicates that only severity of pretreatment allodynia ($p<0.001$) predicted allodynia severity at immediate post-treatment.

The multiple regression was then re-run examining allodynia severity at 6-month follow-up as the criterion variable, and again, the model was significant ($F(9, 46)=4.90$, $p<0.001$) and accounted for 39.0 % of the variance in allodynia ratings. Examination of individual predictors shows that pretreatment allodynia severity ($p<0.001$), change in pain self-efficacy ($p=0.021$), and comorbid chronic pain conditions ($p=0.023$) were significant predictors. Specifically, a 1 standard deviation unit change in baseline allodynia level was associated with a 0.576 standard deviation change in allodynia; a 1 standard deviation unit change in self-efficacy was associated with a −0.285 standard deviation change in allodynia; and a 1 standard deviation unit change in number of comorbid pain conditions was associated with a 0.258 standard deviation change in allodynia at follow-up (Table 6).

We carried out additional exploratory analyses to examine whether degree of homework completion predicted outcomes; however, compliance was not found to be associated with any of the pain-related or sex-related endpoints (data not shown).

Table 4 Effect of treatment on mindfulness domains (at pretreatment, post-treatment, and follow-up) for women assigned to immediate treatment and women assigned to the delayed treatment arms

Variable	Immediate treatment			Delayed treatment		
	n	*M*	SD	*n*	*M*	SD
FFMQ—observing sensations*						
Pretreatment	49	25.73	5.73	17	23.00	6.97
Post-treatment***	49	26.49	5.37	17	25.00	5.07
Follow-up	49	25.94	4.98	17	24.94	4.96
FFMQ—describing sensations						
Pretreatment	49	27.63	6.03	17	29.06	7.35
Post-treatment	49	27.82	6.07	17	28.65	7.56
Follow-up	49	27.53	6.69	17	29.06	7.20
FFMQ-acting with awareness**						
Pretreatment	49	25.20	5.78	17	21.24	6.14
Post-treatment	49	24.69	5.49	17	22.12	6.26
Follow-up	49	24.57	5.61	17	24.71	5.00
FFMQ—nonjudging						
Pretreatment	49	27.04	6.53	17	28.59	7.15
Post-treatment	49	28.22	6.01	17	29.65	6.86
Follow-up	49	28.55	6.06	17	29.94	7.71
FFMQ—nonreactivity						
Pretreatment	49	19.43	5.06	17	22.24	4.88
Post-treatment	49	20.86	4.06	17	22.12	4.87
Follow-up	49	20.41	4.32	17	23.12	4.90

FFMQ Five Factor Mindfulness Questionnaire

*$p=0.05$, main effect of treatment

**$p=0.007$, time × group interaction in that women in the delayed treatment arm had a significant increase in acting with awareness

***$p=0.009$, significant improvement between pretreatment and post-treatment

Discussion

This brief mindfulness-focused group treatment to address PVD-related pain and sex-related distress was associated with statistically significant improvements in pain-related (pain self-efficacy, pain catastrophizing, pain vigilance, and allodynia), sex-related (sexual distress), and depressive symptom endpoints. As we will discuss, changes in dyspareunia were not detected, perhaps linked, in part, to the fact that few women engaged in penetrative sex within the time frame examined.

Table 5 Multiple regression predicting mean allodynia ratings at immediate post-treatment

Predictor variable	Beta	*p*
FFMQ—observing sensations change score	0.049	ns
FFMQ—acting with awareness change score	0.029	ns
Allodynia mean at pretreatment	0.515	<0.001
PCS—rumination change score	0.038	ns
PCS—magnification change score	−0.069	ns
PCS—helplessness change score	0.157	ns
PISES total change score	0.076	ns
Number of chronic pain conditions	0.046	ns

FFMQ Five Factor Mindfulness Questionnaire, *PCS* Pain Catastrophizing Scale, *PISES* Painful Intercourse Self-efficacy Scale, *ns* not significant

Table 6 Multiple regression predicting mean allodynia ratings at 6-month follow-up

Predictor variable	Beta	*p*
FFMQ—observing sensations change score	−0.014	ns
FFMQ—acting with awareness change score	−0.044	ns
Allodynia mean at pretreatment	0.576	<0.001
PCS—rumination change score	−0.052	ns
PCS—magnification change score	0.073	ns
PCS—helplessness change	−0.096	ns
PISES total change score	−0.285	0.021
Number of chronic pain conditions	0.258	0.023

FFMQ Five Factor Mindfulness Questionnaire, *PCS* Pain Catastrophizing Scale, *PISES* Painful Intercourse Self-Efficacy Scale, *ns* not significant

Self-efficacy

Self-efficacy is a core belief that one has the power to produce desired effects by one's actions. The opposite belief is characteristic of women with PVD who view their pain as global (present in all situations), stable (will not change), and external (out of their control; Jodoin et al. 2011). That self-efficacy improved with treatment is encouraging since self-efficacy has been shown to predict treatment outcome in nongenital pain conditions (Vlaeyen et al. 2001; Vlaeyen, de Jong, Onghena, Kerckhoffs-Hanssen, and Kole-Snijders 2002) and to be a major predictor of response to CBT in PVD (Desrochers, Bergeron, Khalifé, Dupuis, and Jodoin 2010). Cognitive skills likely contributed to increased self-efficacy by identifying pain attributions, challenging fixed beliefs, and allowing women to no longer follow thoughts about sexual avoidance. In keeping with the fear-avoidance model of pain (Norton and Asmundson 2003), which suggests that avoidance behaviors become maintaining factors even after the healing process, avoidance of all aspects of sexuality is a common firmly established sequelae of PVD.

Pain Catastrophizing

There is a strong association between the tendency to harbor exaggerated thoughts about pain and pain intensity in women with PVD (Desrochers et al. 2009). Such catastrophizing is associated with the extent of increased gray matter identified in the brains of women with PVD compared to controls (Schweinhardt, Kuchinad, Pukall, and Bushnell 2008). In addition to lessening catastrophizing by changing cognitions—as in traditional CBT—there is now empirical evidence that the more mindful a person is, the lower the tendency to catastrophize about pain (Schutze, Rees, Preece, and Schutze 2010). Our results are in keeping with research in nongenital pain management where a 10-week mindfulness program was associated with reduced catastrophization (Gardner-Nix, Backman, Barbati, and Grummitt 2008). Less catastrophizing may reduce the fear-avoidance cycle which underlies many chronic pains (Leeuw et al. 2007) and may at least partially explain the chronicity of PVD (Basson 2012).

Cotton Swab-Evoked Allodynia

We found a significant improvement in allodynia (i.e., genital pain provoked by cotton swab in the clinical setting). The women had been encouraged to practice attending to physical sensations, whether pleasant or unpleasant, attending to them in the moment rather than distracting from or being overwhelmed by them: "tuning into" pain rather than "tuning out". Functional brain imaging has shown that experienced mindfulness practitioners demonstrate increased activity in brain areas associated with encoding sensory aspects of painful stimuli and lower activity in areas involved in appraisal, memory, and emotion compared to controls (Grant et al. 2011).

Allodynia may not be a perfect predictor of pain during sexual activity, however, we chose this endpoint given established guidelines in the field (e.g., IMMPACT guidelines for study endpoints in clinical trials in pain; Dworkin et al. 2005; Dworkin et al. 2008). Others have found differences in treatment outcome depending on whether cotton swab-evoked allodynia or dyspareunia was examined (Bergeron et al. 2008). Clinical experience confirms ongoing, albeit reduced, allodynia in women reporting minimal or no residual dyspareunia. The small number of women engaging in penetrative sex precluded sufficient power to investigate improvement in dyspareunia, but also is in keeping with clinical experience: motivation for penetrative sexual activity is complex and does not simply depend upon pain severity. Our recommendation to temporarily exclude penetration in order to allow the sexual arousal necessary for vaginal accommodation and lubrication when penetration was (re)introduced plus increased pleasure from other sexual activity with ongoing mindfulness practice may have contributed to a delay in resuming intercourse beyond the timeline of this trial. For some women, a profound reduction in sexual desire and motivation (even for nonpenetrative sex), which commonly develops as PVD persists, may have continued. Partner difficulties in adapting to what has often become a nonsexual relationship, and then re-adapting to view the relationship as sexual, may also have contributed.

Sexual Distress

Sexual distress and decreased sexual satisfaction are commonly associated with PVD (Ayling and Ussher 2008; Jantos and Burns 2007), and disclosure of emotional suffering may be difficult even to close friends (Nguyen et al. 2012). Conscious pain avoidance, fear-related inattention to sexual cues, and cognitive changes associated with central sensitization may all

impair sexual response, thereby lowering self-acceptance (Basson 2012). Mindfulness fostering present moment awareness and acceptance encourages self-acceptance. Less striving to excel and to avoid negative evaluation by others (including a sexual partner), traits common among women with PVD (Brotto et al. 2003; Jantos and White 1997), as well as encouragement to view sex as more than just intercourse and to make time for nonpenetrative sexual activities, may have lessened sexual distress. Of course, it is also possible that avoidance of sex itself may have contributed to the reductions we saw in distress; although clinically, sex-related distress seems to occur independent of whether the woman is engaging in sex or not. Although not captured in our assessment battery, qualitative feedback from women suggested that a resumption of rewarding nonpenetrative sex following treatment also contributed to less sex-related distress (Brotto, Basson, Carlson, and Zhu 2013).

Feeling Better While Waiting for Treatment

While women waited for treatment to begin, they reported a significant improvement in pain-related self-efficacy and in sex-related distress. Their pre-treatment clinical assessment, which included validating and explaining PVD, as well as providing an outline of treatment, possibly contributed to these improvements by inducing "placebo analgesia" (Holzel et al. 2010). There were slightly but significantly higher homework compliance scores in the wait-listed women, perhaps reflecting more positive expectations prior to treatment, even though degree of homework compliance was not associated with treatment outcome. A robust placebo response is characteristic of treatment for sexual dysfunction and can produce effect sizes that suggest outperformance of placebo compared to active treatment (Bradford and Meston 2007; Bradford and Meston 2009; Bradford and Meston 2011). Specifically, expectancies about improvement with treatment translate into actual improvements. Expectancies may decrease anxiety, positively impact patient-partner communication, and positively impact a partner's behavior—all of which may have contributed to improved self-efficacy. Despite more self-efficacy and less sexual distress before treatment, it is notable that women in the two arms benefited from treatment to the same degree on all endpoints (i.e., there were no significant time × group interactions).

Pain Vigilance and Pain Awareness

There were significant reductions in pain vigilance/awareness with treatment. This may, at first, appear paradoxical since mindfulness is aimed at increasing awareness. However, items on the PVAQ appear to reflect both neutral as well as pathological levels of (hyper)vigilance and the scoring does not allow for the separation of these two. In the future, it would be interesting to test the hypothesis that mindfulness might contribute to improvements in neutral vigilance but lead to a decrease in negative awareness/hypervigilance.

Mechanisms of Change

The mechanisms by which cognitions lessen pain are not fully understood. Neuroimaging research suggests that mindfulness-associated analgesia may share a final common brain circuitry with other cognitive techniques in pain modulation (Zeidan et al. 2012). Changes reflecting neuroplasticity resulting from stress, such as increases in amygdala volume have been shown to change after just 8 weeks of training in mindfulness-based stress reduction. MRI scans pre- and post-treatment in 26 participants showed that reductions in perceived stress correlated with reductions in gray matter volume in the right basolateral amygdala (Holzel et al. 2010). Mindfulness has been shown to increase the vagal tone index, which is associated with less stress and less inflammatory medical conditions (Butler, Chapman, Forman, and Beck 2006). Lessening stress can reduce muscle tension; increased pelvic muscle tone is characteristic of PVD while its amelioration with pelvic floor physiotherapy is known to lessen the allodynia of PVD (Bergeron et al. 2001). The improvement in depressive symptoms may have also contributed to some of the improvements in pain-related and sexual distress-related endpoints; however, given the lack of effect on state anxiety, changes in women's levels of anxiety were likely not responsible for these improvements.

Maintenance of Change

Not only were the improvements resulting from treatment statistically significant, all effects were either further significantly improved or at least not deteriorated between post-treatment and 6-month follow-up. These findings are supported by the findings of Bergeron et al. who found retained (and, in some cases, further improved), gains 2.5 years following 10 sessions of group CBT (Bergeron et al. 2008). It is likely that continued improvements were due to ongoing application and mastery of the skills acquired during treatment, though this speculation was not directly tested.

Limitations

Our study is limited by the relatively small sample size. We did not carry out an intent-to-treat analysis and only analyzed data in women who completed at least 75 % of the sessions. Another limitation relates to the previously mentioned inability to detect a significant improvement in dyspareunia despite an improvement in allodynia. Future studies which follow women over a more prolonged period may be better able to detect improvements in dyspareunia with treatment. Finally,

although partners were seen in assessment and after the program in most instances, their data were not part of the study.

Conclusions

Overall, our findings suggest significant beneficial effects of a brief mindfulness-based group intervention for women with PVD on both cotton swab-induced vestibular pain and psychological measures of pain. Given previously documented benefits from CBT and the consideration that women with PVD may respond differentially to change-oriented versus acceptance-based approaches, future studies directly comparing these two interventions are needed and may guide whether one treatment or the other is recommended in a patient presenting for treatment with PVD.

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Conflict of Interest None of the authors have any conflicts of interest.

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