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TITLE:

Feasibility and preliminary effectiveness of a novel cognitive-behavioral couple therapy for provoked vestibulodynia: A pilot study

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Introduction. Provoked vestibulodynia (PVD), a recurrent, localized vulvo-vaginal pain problem, carries a significant psychosexual burden for afflicted women, who report impoverished sexual function, and decreased frequency of sexual activity and pleasure. Interpersonal factors such as partner responses to pain, partner distress, and attachment style are associated with pain outcomes for women, and sexuality outcomes for both women and partners. Despite these findings, no treatment for PVD has systematically included the partner.

Aims. This study pilot-tested the feasibility and potential efficacy of a novel cognitive-behavioral couple therapy (CBCT) for couples coping with PVD.

Methods. Couples (women and their partners) in which the woman was diagnosed with PVD (n=9) took part in a 12-session, manualized CBCT intervention and completed outcome measures pre- and post-treatment.

Main Outcome Measures. The primary outcome measure was women's pain intensity during intercourse using a numerical rating scale. Secondary outcomes included sexual functioning and satisfaction for both partners. Exploratory outcomes included pain-related cognitions, psychological outcomes, and treatment satisfaction, feasibility and reliability.

Results. One couple separated before the end of therapy. Paired t-test comparisons involving the remaining 8 couples demonstrated significant improvements in women's pain, and sexuality outcomes for both women and partners. Exploratory analyses indicated improvements in pain-related cognitions, as well as anxiety and depression symptoms for both members of the couple. Therapists' reported high treatment reliability, and participating couples' reported high participation rates and treatment satisfaction indicate adequate feasibility.

Conclusions. Treatment outcomes along with treatment satisfaction ratings confirm the preliminary success of CBCT in reducing pain and psychosexual burden for women with PVD and their partners.

Further large-scale randomized controlled trials are necessary to examine the efficacy of CBCT compared to, and in conjunction with first-line biomedical interventions for PVD.

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Key Words., Provoked vestibulodynia, vulvodynia, genito-pelvic pain penetration disorder, cognitive-behavioral therapy, couple therapy, sex therapy, couple, sexual satisfaction, sexual function, pain.

Vulvodynia, or idiopathic, recurrent vulvo-vaginal pain, has a prevalence of 4 to 28% [1-3]. Vulvo-vaginal pain, often misunderstood and potentially underreported [4], carries stigma for many women [5], and can have deleterious consequences for women's sexual functioning and quality of life [6]. Provoked vestibulodynia (PVD), the most frequent form of vulvodynia among pre-menopausal women, is characterized as a recurrent, sharp or burning pain triggered by contact to the vulvar vestibule, such as during vaginal sexual intercourse [7]. Extending beyond the mechanics of sexual function, women with PVD also report decreased sexual satisfaction [8], and less positive sexual self-schema [9]. Epidemiological research indicates that anxiety and depression symptoms are significantly more frequent as antecedent conditions and as consequences to vulvodynia, in comparison to healthy controls [10]. Both women with vulvodynia and their partners report increased rates of depressive symptoms relative to a control sample [11]. While these women do not report significant differences in relationship satisfaction when compared to control women [12], qualitative studies suggest that women with vulvodynia report that the pain can have a damaging effect on the couple's relationship, and fear losing their partner because of the pain [13]. Recent research also highlights the significant positive correlation between intimacy and sexual function and satisfaction for women with PVD [14], and the influence of attachment styles on pain and sexuality outcomes for both women and partners [15]. Despite the growing evidence for the bidirectional associations between PVD and romantic relationship factors, current treatments typically focus solely on the woman, and no empirically-tested treatment has systematically included the partner.

Fueled by a biopsychosocial, multidimensional understanding of pain, there is a recent increase in the number of studies that have examined cognitive, affective, and behavioral factors related to PVD, and their associations with sexuality outcomes in afflicted women and their partners. With regard to cognitive factors, increased woman-reported PVD pain, and negative pain attributions made by the partner, have been associated with increased partner psychological distress [16]. Pain attributions refer

to one's personal theory or explanation for the pain. In this scenario, partners may be less likely to utilize healthy forms of coping and may feel more helpless in the face of their female partners' pain. For example, higher use of partner internal and global attributions, or beliefs that the pain is a result of the woman's responsibility and that it affects other areas of the partner's life, were associated with lower couple satisfaction. Moreover, partners' attributions that the pain was global and stable predicted lower partner sexual satisfaction [16]. Thus the meaning that partners give to the woman's pain problem may impact partners' adaptation to the pain.

Among women with PVD, higher levels of pain-related catastrophizing and lower pain self-efficacy are significantly correlated with higher ratings of pain during sexual intercourse, while greater pain self-efficacy is associated with women's improved sexual functioning [17]. Recent consideration of the impact of partner cognitive variables in the context of PVD has revealed that higher partner pain catastrophizing significantly contributes to the variance in women's reported higher pain intensity [18]. For example, partner pain catastrophizing may be manifested by a partner's belief that the woman's PVD pain will never end, or that it may get worse. According to the Communal Coping Model, pain catastrophizing represents a coping strategy through which the individual uses communication about the pain to solicit support and attention from others [19], whereas pain self-efficacy refers to one's belief in their ability to cope with and control the pain. These two cognitive factors may be associated with pain intensity and functioning by promoting or interfering with adaptive coping mechanisms.

Consistent with data from the chronic pain literature, a cross-sectional association between partner responses to the woman's PVD-related pain and pain intensity during intercourse has been reported [20]. Moreover, cognitive pain-related variables, such as pain catastrophizing, have been shown to significantly mediate the relation between solicitous (attention and concern) partner pain responding and increased pain intensity for women [21]. Findings from a dyadic daily diary study showed that sexual functioning improved for women with PVD when they perceived higher facilitative (encourages adaptive coping), and lower solicitous (attention and concern) and negative (frustration

and anger) responses to pain from their male partners, and partners' sexual functioning decreased when they responded to pain in a more solicitous and negative manner [22]. Further research into behavioral factors relevant to the couple's navigation of the pain experience has demonstrated that higher sexual assertiveness in partners is associated with higher sexual functioning among women with PVD, while higher sexual assertiveness among women is related to increased sexual satisfaction in partners [15]. These results, taken together, highlight how romantic relationship factors may influence the pain and sexual outcomes of couples coping with PVD.

Recent examination of the affective aspect of interpersonal factors related to PVD indicates that women's ratings of higher relationship intimacy (self- and partner-perceived disclosure and responsiveness) is associated with better sexual functioning, and that higher sexual intimacy (self-disclosure, perceived partner-disclosure and partner responsiveness relating to sexual activity) are associated with increased sexual satisfaction, sexual functioning, and pain self-efficacy [14]. In keeping with emotional disclosure being an important aspect of intimacy, couples with PVD demonstrating lower ambivalence over emotional expression report higher sexual satisfaction and sexual functioning, higher dyadic adjustment, and fewer depressive symptoms [23]. Couples unburdened by ambivalence when it comes to emotional expression may report increased functioning because of more optimal communication resources to address sexual negotiation, conflict resolution or problem-solving, and adjustments to their sexual repertoire.

The couple's interactions on cognitive, behavioral, and affective levels and their associations with the vulvo-vaginal pain, as well as their shared sexual experience, highlight several avenues for intervention. Despite this, no study has examined the efficacy of a treatment for PVD that systematically includes the partner. Inclusion of the partner may help target the related cognitive, affective and sexuality dimensions, in addition to pain intensity.

Of the women with PVD who seek medical help, the first stop for answers and relief is often a primary care physician, and thus many treatments target the pain symptoms. Despite the wide variety

of treatment options, which range from localized interventions such as topical ointments, physical therapy, and surgery to systemic interventions such as tricyclic antidepressants [24], there is a dearth of prospective studies assessing their efficacy. Given the multifaceted nature of PVD's etiology and impact, a treatment model that can target pain, as well as its associated psychological, sexual and relationship consequences may represent an advantageous addition to current treatment options for PVD.

Cognitive behavioral therapy (CBT) consists of a useful framework through which one can understand the interplay of interpersonal factors, sexual functioning, and sexual dissatisfaction in women with PVD. A long-term follow-up of women with PVD who had participated in a randomized controlled trial comparing vestibulectomy, biofeedback, and group CBT revealed treatment gains that were maintained at 2.5 years for improvements in pain and sexual functioning [25]. When considering self-reported pain during intercourse, vestibulectomy did not outperform CBT at long-term follow-up, highlighting the efficacy of CBT, a less invasive intervention that aims to target pain symptoms as well as the psychological, sexual, and relational sequelae of PVD. Further, a randomized trial examining the efficacy of individual CBT for vulvodynia compared to a supportive psychotherapy demonstrated that CBT resulted in significantly greater improvement in pain severity and sexual function from pre- to post-treatment, with gains being maintained at one-year follow-up [26]. These results demonstrate the efficacy and tolerability of psychosocial interventions for PVD while also indicating the potential benefit for improved treatment outcome and patient satisfaction associated with a more directed psychological treatment approach. Traditionally, the woman diagnosed with PVD is treated on her own, representing a missed opportunity to target partner variables that can influence pain and sexuality outcomes for the woman, as well as partner outcomes. Repeated recommendations that a psychological intervention for PVD include the partner [27], along with a dearth of manualized interventions that can be tested and disseminated to clinicians, prompted the development of a cognitive-behavioral couple therapy (CBCT) for couples experiencing PVD.

The goal of this study was to pilot test a novel, manualized, cognitive-behavioral couple therapy (CBCT) for women with PVD and their partners for initial effectiveness and feasibility. It was hypothesized that following CBCT, women would report significant pre- to post-treatment improvements in pain intensity experienced during intercourse, and that couples would report significant pre- to post-treatment increases in sexual functioning and satisfaction for both partners. In addition to these hypotheses, another goal of this pilot study was to conduct an exploratory examination of changes for women and partners' pain self-efficacy, pain catastrophizing, relationship satisfaction, anxiety and depression. It was also hypothesized that couples would report strong treatment satisfaction, and that CBCT would demonstrate adequate feasibility and reliability measured by couples' participation in interventions and homework exercises and therapists' ability to administer planned interventions.

Methods*Participants*

Women diagnosed with PVD and their partners were recruited in two large metropolitan areas. Women (and their partners) were contacted using a databank of participants from other non-treatment studies from the authors' laboratories, and couples who contacted these laboratories or who contacted collaborating health care professionals for information about ongoing research projects were also informed about this pilot study. Inclusion criteria for women with PVD were: (1) pain during intercourse which was reported as subjectively distressing and occurred at least during 80% of intercourse attempts, and had been present for at least one year; (2) pain limited to intercourse and other activities involving pressure to the vulvar vestibule; (3) significant pain in one or more locations of the vestibule during the gynecological examination, operationalized as a minimum average patient pain rating of 4 on a scale of 0 to 10; 4) a diagnosis of PVD following the gynecological examination; 5) sexually active as a couple in the last three months (intercourse, manual, or oral stimulation); 6) in a

committed monogamous relationship with a partner for at least six months. Pain was assessed using the cotton-swab test, in which a cotton-swab is placed along the exterior or edge of the vestibule using point palpation. The authors' research laboratories and collaborating physicians are familiar with this test, which has been standardized for research purposes. This procedure has been used successfully in previous research in the field, and demonstrates good inter-rater reliability between physicians [28]. PVD participants were excluded if: (1) vulvar pain was not clearly linked to intercourse or pressure applied to the vulvar vestibule; (2) one of the following was present: (a) major medical and/or psychiatric illness, (b) active infection, (c) deep dyspareunia, (d) vaginismus (as defined by Diagnostic and Statistical Manual of Mental Disorders-IV), (e) dermatologic lesion, (f) pregnancy or planning a pregnancy; (3) age less than 18 or greater than 45; (4) involved in ongoing couple therapy, and (5) currently being treated for PVD and unable/unwilling to cease treatment. Couples were also deemed ineligible if they did not live in the same city, and could not attend 12 weekly sessions, and if partners had: (1) a major medical and/or psychiatric illness, and (2) were less than 18 years of age. These eligibility criteria were chosen to ensure selection of a relatively homogeneous sample of sexually active couples in which the woman was suffering exclusively from PVD.

Procedure

The women and their partners were informed via telephone about the nature of the study, its anticipated schedule in terms of treatment and assessment, and the potential risks and benefits of participation. Across both research sites, a total of 39 women were approached and spoke directly with the research coordinator to receive information about the study. Of these, 10 were ineligible to participate for the following reasons: not currently partnered, no longer experiencing pain, currently pregnant, received an alternate diagnosis, currently living in separate cities, currently receiving treatment for PVD and unable/unwilling to cease this treatment, or currently undergoing psychotherapy, individually or as a couple. Of the remaining 29 eligible couples, 20 refused to participate. Reasons for refusal included: unable to make the time commitment, not currently interested

but may be in the future, not interested in treatment, not interested in couple therapy, and no longer interested in taking part in a research study. Couples who did not wish to participate were referred to other treatment resources if interested. Nine couples consented to participate, were scheduled for pre-treatment assessment, and began treatment immediately following pre-treatment assessment (31.0% acceptance).

Intervention: Cognitive-behavioral couple therapy (CBCT)

The CBCT intervention was delivered as 12 one-hour sessions. The treatment manual was adapted to reflect a similar content as that of Bergeron and colleagues' empirically-tested cognitive-behavioral group therapy [29], with pertinent interventions added to reflect recent research regarding dyadic factors and PVD, and the incorporation of materials that emphasize the interpersonal dynamics of PVD. Overarching goals of the CBCT intervention were to enable couples to: (1) re-conceptualize PVD as a multidimensional pain problem influenced by a variety of factors including thoughts, emotions, behaviors, and couple interactions; (2) understand PVD as a couple problem in which both members affect and are affected by the pain; (3) identify and problem-solve about factors associated with pain during sexual activity with a view to increasing adaptive coping, for example, by increasing self-efficacy and decreasing catastrophizing in each partner, with a goal to decrease pain intensity; (4) improve the quality of the couple's sexual functioning using communication skills training, working on sexual approach and avoidance goals, and modifying the sexual script; (5) consolidate skills developed during the treatment. Examples of the specific CBCT interventions include psychoeducation about pain, communication skills training, discussion and expansion on the couple's sexual narratives, mindfulness and cognitive defusion exercises, and pain journaling. Interventions were rooted in third generation cognitive-behavioral approaches, including an Acceptance and Commitment Therapy (ACT) approach, with an emphasis on engaging both partners, reducing experiential and behavioral avoidance, and identifying relevant relational patterns of the couple. A selection of the interventions across the 12 sessions is presented in Table 1.

Two therapists, one per site, were trained to use the CBCT manual. Each therapist underwent a training to familiarize themselves with the interventions, and worked with the manual's authors to develop a detailed understanding of the interventions comprised in CBCT, as well as the rationale for each intervention. To help increase treatment-reliability, the CBCT manual's interventions were structured and detailed, and included the empirical rationale behind the interventions. Therapists completed intervention checklists following each session to provide an indication of treatment reliability. Both therapists received weekly supervision from the CBCT manual's senior authors (XX and XX). Sessions were DVD-recorded. This study was reviewed and approved by the XX Institutional Review Boards. All participants provided written informed consent.

Outcome Measures

Couples completed standardized self-report measures and took part in brief semi-structured interviews conducted by a research assistant pre- and post-treatment. The pre-treatment brief interview served to assess demographic information and pain history. The post-treatment interview was delivered to assess perceived progress, satisfaction with treatment, and invite couples to provide their feedback about the treatment.

Main Outcome Measure - Pain

Pain Intensity. Pain intensity during sexual intercourse was assessed using a numerical rating scale (NRS), ranging from 0 to 10, where 0 is no pain at all, and 10 is the worst pain ever, as recommended by the IMMPACT guidelines for chronic pain clinical trials [30]. This method for measuring pain has been shown to detect significant treatment effects in women with PVD and demonstrates a significant positive correlation with other pain intensity measures [31].

Quality of Pain. Vulvo-vaginal pain was also measured using the McGill Pain Questionnaire (MPQ; [32], a measure of the multidimensional aspects of the pain experience, including its sensory, affective and evaluative components. The MPQ is a widely used adjective checklist, which assesses both

qualitative and quantitative aspects of pain. The Pain Rating Index Total (PRI) scale was used, and demonstrated good internal consistency for the present sample (pre-treatment: $\alpha = 0.81$; post-treatment: $\alpha = 0.88$).

Secondary Outcome Measures – Sexuality Outcomes for Women and Partners

Sexual function. Sexual function was measured using the Derogatis Interview for Sexual Functioning - Self-Report (DISF-SR), a 25-item self-report version of a semi-structured interview designed to assess sexual function in both men and women [33]. It measures five dimensions of sexuality: sexual cognition/fantasy, sexual arousal, sexual behavior/experience, orgasm, and sexual drive/relationship. Scores can be calculated for each dimension and for global sexual functioning. The DISF-SR boasts good internal consistency and reliability, specifically with women experiencing sexual dysfunction . It was chosen because it can be administered to both women and men. In the present study, the coefficient alpha for women with PVD was 0.86 pre-treatment, and 0.91 post-treatment, and 0.87 and 0.92 for partners.

Sexual satisfaction. Sexual satisfaction was assessed using the Global Measure of Sexual Satisfaction Scale (GMSEX), which consists of 5 items assessing global sexual satisfaction. The GMSEX has high internal consistency and test-retest reliability [34]. The coefficient alpha for the present sample of women with PVD was 0.81 and 0.82, at pre-treatment and post-treatment respectively, and 0.56 and 0.94 for partners. The irregular alpha coefficient for partners at pre-treatment may be a product of the small sample size in the present study.

Exploratory Outcome Measures

Pain catastrophizing. The Pain Catastrophizing Scale (PCS) is a 13-item scale that measures exaggerated negative perceptions and emotions regarding pain. Higher scores point to higher catastrophizing (range: 0-52). The PCS [35] has been tested for reliability and validity [36]. The partner version is also validated [37]. The PCS demonstrated good internal consistency in the present study

(pre-treatment for women and partners respectively: $\alpha = 0.72$ and 0.86 ; post-treatment: $\alpha =$

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0.91 and 0.88).

Pain self-efficacy. Pain self-efficacy, or the pain patient's belief in her capacity to cope and deal with the pain across different situations, was measured using the Painful Intercourse Self-Efficacy Scale (PISES). The PISES [38] is 20-item scale adapted from the Arthritis Self-Efficacy Scale [39]. The adapted version demonstrates identical factor structure to the original scale [38], for which reliability and validity have been established [39]. The partner version assesses the partner's perception of the pain patient's self-efficacy. The coefficient alpha for women in the present study was 0.64 pre-treatment, and 0.71 post-treatment for women with PVD, and 0.83 and 0.92 for partners for pre- and post-treatment respectively.

Relationship satisfaction. The 32-item version of the Couple Satisfaction Index (CSI) [40] was used to measure relationship satisfaction. Compared to other well-known relationship satisfaction measures (e.g., Dyadic Adjustment Scale [41]; and the Marital Adjustment Test [42]) it demonstrates strong convergent validity, and a higher precision and power for detecting distinctions in satisfaction levels. Moreover, unlike similar relationship satisfaction scales, the CSI has been tested with a sample of participants spanning the relationship spectrum (e.g., dating, engaged, married). The CSI demonstrated good internal consistency in the present study (pre-treatment for women and partners: $\alpha = 0.97$; post-treatment: $\alpha = 0.97$).

Anxiety. Anxiety was assessed using the Spielberger State-Trait Anxiety Inventory (STAI). The STAI [43] is a widely used 40-item measure of state and trait anxiety. The 20 items assessing trait anxiety was used for this study. Cronbach alpha scores for women in the present study were 0.86 and 0.86 at pre- and post-treatment, and 0.96 and 0.94 for partners.

Depression. The Beck Depression Inventory-II (BDI-II) was used to measure symptoms of depression. The BDI-II is comprised of 21 items, with scores for most items ranging from 0 (low intensity) to 3 (high intensity) [44, 45]. This measure of depression has been validated for use in chronic pain populations [46]. In the present study, the small sample size resulted in irregular Cronbach alpha values for this measure, which otherwise demonstrates good internal consistency (pre-treatment for women and partners respectively: $\alpha = 0.52$ and 0.96 ; post-treatment: $\alpha = 0.70$ and 0.44).

Participant ratings of global improvement. In order to measure the clinical significance of the findings and as recommended by IMMPACT guidelines [30], women with PVD and partners each rated perceived global improvements in pain and sexuality at post-treatment by selecting one of the following five options: Great improvement, moderate improvement, small improvement, no improvement, or deterioration.

Treatment Satisfaction, Feasibility and Reliability

At post-treatment, couples were asked to rate their satisfaction with the treatment on a NRS of 0 to 10, with 0 being completely dissatisfied, and 10 being completely satisfied. Both members of the couple were also asked to each identify which components of the treatment they found most helpful, and least helpful. At each session, couples reported on completion of at-home interventions (i.e., homework), and therapists completed an intervention checklist for each session to indicate whether planned in-session exercises were completed or not. If not, therapists indicated if time-overage occurred, and if the exercise could be conducted in the following session to help the authors improve the use of the treatment manual; time overages or interventions moved to following sessions were coded as not completed. Homework completion rates were determined based on homework completed during the week it was assigned; homework completed at a later time was not coded as completed. A treatment manual-reliability score was computed based on the number of planned interventions that were completed divided by the total number of interventions assigned for that particular session.

Treatment outcomes for primary and secondary outcomes – pain and sexuality measures – were determined by pre- and post-treatment differences calculated using two-tailed, paired-samples t-tests for all outcome variables. All tests used a significance level of $\alpha = 0.05$. Only parametric test results are presented given that Wilcoxon signed-rank tests were conducted to control for non-normality, and yielded similar conclusions to paired-sample t-tests. General linear model (GLM) contrasts were conducted between sites for primary and secondary outcome variables. Original standard deviations were used to compute Cohen's *d*, or effect size values, given the likelihood that pooled standard deviations are corrected for correlation between measures, and therefore yield overestimated values for effect size [47]. Effect sizes of 0.20, 0.50, and 0.80 or larger are respectively classified as small, medium, and large [48]. Exploratory analyses were conducted using percent change analyses of sample means for pain self-efficacy, pain catastrophizing, relationship satisfaction, anxiety, and depression. Treatment satisfaction, and treatment-manual reliability and homework completion scores were averaged across participants.

Results

Sample Characteristics

Participants' characteristics are displayed in Table 2. All recruited couples were heterosexual. The mean (*M*) age of women with PVD was 26.11 years ($R = 19-35$), and the average age of male partners was 28.44 years ($R = 21-45$). Couples had been in their relationship for an average of 4.4 years ($SD = 2.8$), with the pain often pre-dating the relationship for an average pain history of 6.72 years ($SD = 4.16$). The majority of the couples had post-secondary education ($M = 16.17$ years; $SD = 2.46$) and the sample was homogeneous in terms of ethnicity. While participants were asked not to use other treatments during their participation in this study, one participant saw a physical therapist twice during the course of the 12 sessions. Of the nine couples recruited, eight attended all 12 sessions of CBCT. One couple separated before completing all 12 sessions. This couple was not included in analyses.

Means and standard deviations for pain and sexuality outcomes are found in Table 3.

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Percent change values for exploratory variables are found in Table 4.

Primary outcome (n=8)

Pain. There was a significant decrease in pain during intercourse from pre- to post-treatment, $t(7) = 3.89$, $P = 0.006$, $d = 2.05$. No significant difference was found between sites ($F_{1,6} = 1.433$, $P = 0.276$). Using the MPQ PRI Total score, there was also a significant decrease in women's reported multidimensional aspects of pain, $t(7) = 2.64$, $P = 0.034$, $d = 0.45$, with no significant difference between sites ($F_{1,6} = 0.68$, $P = 0.803$).

Secondary outcomes (n=8)

Sexuality outcomes. From pre- to post-treatment, women with PVD reported significant improvements in sexual functioning, $t(7) = -3.47$, $P = 0.010$, $d = 0.72$, and sexual satisfaction, $t(7) = -3.06$, $P = 0.018$, $d = 1.28$. There were no significant differences between sites (sexual function: $F_{1,6} = 0.323$, $P = 0.968$; sexual satisfaction: $F_{1,6} = 1.263$, $P = 0.304$). Male partners also reported significant increases in sexual satisfaction, $t(7) = -3.78$, $P = 0.007$, $d = 1.90$, but increases in sexual functioning were not statistically significant, $t(7) = -1.41$, $P = 0.202$, $d = 0.21$. There was no significant difference in sexuality outcomes for partners between sites (sexual function: $F_{1,6} = 1.473$, $P = 0.270$; sexual satisfaction: $F_{1,6} = 0.165$, $P = 0.699$).

Exploratory outcomes (n=8)

Pain-related cognitions. In terms of pain-related factors, both women and partners demonstrated pre- to post-treatment decreases in pain catastrophizing (Women, 54.97% decrease, $d = 2.03$; Partners, 58.33% decrease, $d = 1.86$), and both women and partner perceptions of women's pain self-efficacy showed increases from pre- to post-treatment (Women, 23.64% increase, $d = 1.69$; Partners, 36.29% increase, $d = 1.88$).

Relationship satisfaction. Women and partners both reported small increases in relationship satisfaction following treatment (Women, 6.31% increase, $d = 0.33$; Partners, 6.46% increase, $d = 0.32$).

Psychological outcomes. Women reported decreased trait anxiety, 12.02% decrease, $d = 0.69$, and a large decrease in self-reported depression symptoms following treatment, 45.28% decrease, $d = 1.41$. Male partners also reported a decrease in anxiety, 9.96% decrease, $d = 0.32$, and in depression symptoms, 50.77% decrease, $d = 0.56$.

Participant ratings of global improvement. Across couples, 75% reported “moderate progress” to “complete resolution” of the woman’s pain following treatment. And for both women and partners, 100% reported “moderate” to “a lot” of progress in their sexual life after taking part in treatment.

Treatment Satisfaction, Feasibility and Reliability. In terms of treatment satisfaction, the mean rating from women was 9.0 out of 10 ($SD = 1.20$), and the mean partner rating was 9.13 ($SD=1.13$). Given that one couple did not complete treatment, the attrition rate was 11%. The average therapist-reported treatment manual reliability across all sessions was 89.8% (range 87.0 % to 99.0%). Women with PVD who completed all 12 sessions of treatment reported a mean of 64.8% for completion of at-home interventions (range 50.0% to 77.8%), and the average for male partners who completed all 12 sessions of treatment was 59.3% (range 28.6% to 76.9%). No adverse events occurred during the study.

Interventions identified as most helpful or most liked included emotional disclosure and building (sexual) communication as part of communication skills training, the progressive approach of all interventions, sensate focus or shared sensual and non-sensual massage, and cognitive defusion exercises. Certain couples also reported that it was beneficial and appreciated that each session focused on both the woman and the partner. The interventions that were reported as least helpful or liked were pain journaling, mindfulness body scan, and PVD psychoeducation. Some couples reported that the time required to complete at-home interventions was challenging.

Discussion

This study aimed to pilot test the effectiveness of CBCT in improving pain and sexuality, as well as to explore its potential usefulness in addressing psychological outcomes associated with PVD in women and their partners. Results of the present preliminary study suggest that CBCT is a promising treatment option for couples experiencing PVD. All participants who completed the 12 sessions of CBCT reported improvement across the targeted outcomes, and indicated high treatment satisfaction.

As hypothesized, there was a significant decrease in women's pain intensity during sexual intercourse as measured using the NRS and the McGill Pain Questionnaire's PRI. Specifically, women reported a 51% decrease in pain from pre- to post-treatment. The IMMPACT guidelines for clinical trials in chronic pain indicate that changes in self-reported pain of more than 30% from baseline on a NRS represent moderately important clinical differences [30], suggesting that the changes in the present sample are clinically significant. Further, all couples reported moderate improvement to complete resolution of the pain in the post-treatment interview. These results are consistent with or superior to those of previous treatment studies examining CBT interventions for PVD [26, 28]. Given the multidimensional aspect of pain, it is possible that CBCT contributed to reduce pain during intercourse by helping couples better understand its multifactorial aspects, develop a shared awareness of the thoughts, emotions and couple interactions that trigger and maintain it, and gradually become more efficient at managing this challenging experience together. For example, the pain-journaling coupled with newly acquired communication skills may have enabled couples to better navigate pain triggers, and problem-solve before or during a painful experience to reduce pain.

Women reported significant improvement in sexual functioning, and both members of the couple reported significant increases in sexual satisfaction. This significant increase in sexual functioning for women following treatment corroborates findings from previous treatment studies for PVD, which show that a CBT intervention contributes to improving sexual function [26, 28]. The increase in sexual functioning reported by partners was not significant, likely because partners did not

report difficulties with sexual functioning at pre-treatment. This is not surprising in light of the fact that the mean age of these men was 28 years. There was, however, a significant increase in sexual satisfaction for both women and partners at post-treatment, which highlights the subjective improvement in the couple's shared sexuality following treatment. There are many factors that contribute to one's subjective evaluation of his or her sexual experiences. A capacity to attend more to the eroticism and pleasure associated with their sexual activity may constitute one of the benefits of treating the couple together. Additionally, the focus CBCT places on mindfulness, sexual communication, expansion of the couple's sexual narrative and building of their sexual repertoire may have helped participants develop more positive sexual experiences. This may have worked by decreasing distress related to previously unspoken needs, and increasing focus on the pleasure associated with sexual activity, rather than the pressure and premium often associated with the mechanics of sexual intercourse. This interpretation is consistent with McCarthy and Wald's [49] premise that mindfulness and the encouragement of Good Enough Sex (e.g., lessened focus on erection maintenance and orgasm achievement as indicators of sexual success) help foster sexual desire and satisfaction, two key components of healthy sexuality for the couple [50].

The exploration of pre- to post-treatment changes in pain-related cognitions, relationship satisfaction, and psychological outcomes may contribute to elucidate other potential treatment gains of CBCT. Both members of the couple reported a large decrease in pain catastrophizing, which is the composite of rumination, magnification, and feelings of helplessness about the pain [35]. This improvement may derive from CBCT's emphasis on facilitating validation and empathic understanding of each other's experience of the pain that is fostered during therapy and for the couple. Targeting thoughts via cognitive defusion may be another mechanism by which couples' view of the pain may begin to change. The Communal Coping Model of Pain posits that catastrophizing represents a form of coping by communicating one's pain to another with the intention of increasing proximity and soliciting support and empathy [51]. Therefore, women and partners' decrease in catastrophizing could

reflect the acquisition of new coping strategies developed during therapy, and a shift toward more adaptive ways of communicating support needs in relation to the pain. Similarly, women's pain self-efficacy increased following treatment, as well as partners' perceptions of women's pain self-efficacy. As with the decrease in catastrophizing, an increase in pain self-efficacy may be indicative of the woman's exposure to and development of proactive, approach strategies for coping with her pain, which could lead to a better sense of her capacity to manage the pain. Moreover, CBCT incorporates components of third generation cognitive-behavioral therapy such as ACT, a form of treatment that has been empirically demonstrated to help reduce pain and pain-related cognitive-affective factors for patients with chronic pain [52].

Although slight, relationship satisfaction for both women and partners showed improvement following treatment. This change is likely small because the couples in the current sample, on average, did not report clinically significant relationship distress at pre-treatment. While decreased relationship satisfaction has been associated with higher pain ratings for women with PVD [53], previous research has indicated that women with PVD generally do not report significantly different relationship satisfaction than controls [12].

Moreover, women and partners reported an increase in psychological well-being as indicated by reductions in depression and anxiety. Viewing depression in its relation to helplessness [54], one can infer that CBCT offered support and hope to women with PVD. CBCT may have enabled women and partners to feel less alone through validation and normalization, helped enrich their understanding of the pain and its impact, as well as encouraged the development of more empathy towards themselves. This may have occurred, in part, by reducing negative feelings known to be associated with perceived pain intensity [55]. Therefore, CBCT may have modified negative attributions women and partners may have previously held about their pain, which have been previously associated with negative psychological and psychosexual outcomes for women with PVD [56]. Similarly, the decrease in depression and anxiety symptoms may stem from CBCT offering the couple tools to experience

closeness despite the pain, diminishing distress by fostering partner empathy for the spouse with pain [57], and to tackle the pain together, rather than viewing it as a burden for the woman to carry on her own. Through a third generation CBT framework, CBCT aimed to encourage acceptance of the pain problem, which can lead to positive pain and psychological outcomes for chronic pain patients [52]. Further examination of other distress indicators, such as sexual distress, and controlled investigation with larger samples are recommended to replicate this finding.

CBCT capitalizes on empirically established knowledge regarding the relationship factors that play important roles for couples experiencing PVD. Both members of the couple reported high treatment satisfaction ratings, as well as perceived improvement based on their experience in CBCT. It could be surmised that CBCT demonstrated a benefit for both partners because of the inherent nature of PVD's negative impact on the couple's shared sexuality. Previous work including the partner when targeting sexual and intimacy outcomes has yielded effective results for sexual desire problems among women and their partners [58, 59], for improving functioning among breast cancer patients and their partners [60], and for intimacy building among prostate cancer patients and their partners [61]. Acceptable homework completion rates and good therapist-reported treatment manual reliability suggest that CBCT can be considered an acceptable, well-received and feasible intervention for couples in which the woman is suffering from PVD. Comparison between sites showed no significant difference for primary and secondary outcomes, which implies a reliability of outcomes across sites. Despite several indicators of feasibility, recruitment for this treatment study yielded high participant refusal rates. While these rates may reflect a low preference for this couple-based therapy, high participant refusal rates may also be related to the recruitment of participants from previous research studies, rather than the use of advertising or clinical referrals meant to target treatment-seeking women and couples with PVD. More research is needed to shed light on this important issue. Nevertheless, given that CBCT demonstrates effectiveness in decreasing pain intensity, as well as improving sexual and psychosocial outcomes, it may represent a worthwhile concurrent or adjuvant treatment to current

medical and physical therapies for PVD, or a potential alternative treatment option for women and partners searching for a less invasive intervention with no physical side effects.

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Pilot studies represent a first step, and as such, there are limitations to the conclusions that can be drawn from the present findings [62, 63]. First, the sample size was small, which limited the power and complexity of the statistical analyses used to detect treatment-related changes. Additionally, given the small sample size, internal consistency was irregular for certain measures, despite these measures' previous validation and demonstration of excellent internal consistency among larger samples of the same population. Clinical implications of this pilot study may be limited because the present sample was comprised of couples that were sexually active throughout the duration of the treatment, which may not be representative of couples having ceased sexual activity due to the pain. The low acceptance rate of participation may represent a further limitation in regards to treatment uptake. This study did not include a control group, so it is not possible to know whether the observed changes in outcomes would have occurred with the passage of time, in the absence of active intervention. Moreover, only heterosexual couples were included in this study's sample. Because participants were not randomized to CBCT, there is a possibility of a self-selection bias for couples in search of a therapeutic intervention for PVD. Lastly, , the reported treatment manual reliability may be biased by therapist self-reports. These limitations point to the importance of further testing of CBCT in a randomized clinical trial.

Conclusions

The present study represents a timely integration of the growing body of research highlighting the importance of dyadic factors related to PVD. These preliminary findings show successful treatment outcomes following 12 sessions of CBCT, not only for affected women, but also for their partners. This suggests that the inclusion of the partner in the treatment of PVD appears beneficial. Taken together with high treatment satisfaction ratings, the lack of adverse events, good treatment reliability ratings provided by therapists, and the high attendance rate, CBCT may represent a potential intervention to

reduce pain intensity during intercourse, as well as improve the sexual and psychosocial well-being of women with PVD and their partners.

1. Bachmann, G.A., et al., *Chronic vulvar and gynecologic pain: Prevalence and characteristics in a self-reported survey*. The Journal of Reproductive Medicine, 2006. **51**(1): p. 3-9.
2. Harlow, B.L., et al., *Prevalence of symptoms consistent with a diagnosis of vulvodynia: Population-based estimates from 2 geographic regions*. American Journal of Obstetrics & Gynecology, 2013. **210**(1): p. 40.e1-8.
3. Reed, B.D., et al., *Pain at the vulvar vestibule: A web-based survey*. Journal of Lower Genital Tract Disease, 2004. **8**(1): p. 48-57.
4. Harlow, B.L. and E.G. Stewart, *A population-based survey of chronic unexplained vulvar pain: Have we underestimated the prevalence of vulvodynia?* Journal of the American Medical Women's Association, 2003. **58**(2): p. 82-88.
5. Nguyen, R.H.N., et al., *Perceived stereotyping and seeking care for chronic vulvar pain*. Pain Medicine, 2013. **14**(10): p. 1461-1467.
6. Arnold, L.D., et al., *Vulvodynia: Characteristics and associations with comorbidities and quality of life*. Obstetrics & Gynecology, 2006. **107**(3): p. 617-624.
7. Moyal-Barracco, M. and P.J. Lynch, *2003 ISSVD terminology and classification of vulvodynia: A historical perspective*. Journal of Reproductive Medicine, 2004. **49**: p. 772-777.
8. Smith, K.B., C.F. Pukall, and S.M. Chamberlain, *Sexual and relationship satisfaction and vestibular pain sensitivity among women with provoked vestibulodynia*. Journal of Sexual Medicine, 2013. **10**(8): p. 2009-2023.
9. Pazmany, E., et al., *Body image and genital self-image in pre-menopausal women with dyspareunia*. Archives of Sexual Behavior, 2013.

10. Khandker, M., et al., *The influence of depression and anxiety on risk of adult onset vulvodynia*. Journal of Women's Health, 2011. **20**(10): p. 1445-1451.
11. Nylanderlundqvist, E. and J. Bergdahl, *Vulvar vestibulities: Evidence of depression and state anxiety in patients and partners*. Acta Dermato-Venereologica, 2003. **83**: p. 369-373.
12. Reissing, E.D., et al., *Etiological correlates of vaginismus: Sexual and physical abuse, sexual knowledge, sexual self-schema, and relationship adjustment*. Journal of Sex and Marital Therapy, 2003. **29**: p. 47-59.
13. Sheppard, C., R. Hallam-Jones, and K. Wylie, *Why have you both come? Emotional, relationship, sexual and social issues raised by heterosexual couples seeking sexual therapy (in women referred to a sexual difficulties clinic with a history of vulval pain)*. Sexual and Relationship Therapy, 2008. **23**(3): p. 217-226.
14. Bois, K., et al., *Sexual and relationship intimacy among women with provoked vestibulodynia and their partners: Associations with sexual satisfaction, sexual function, and pain self-efficacy*. Journal of Sexual Medicine, 2013. **10**: p. 2024-2035.
15. Leclerc, B., et al., *Attachment, sexual assertiveness and sexual outcomes in women with provoked vestibulodynia and their partners: A mediation model*. Archives of Sexual Behavior, in revision.
16. Jodoin, M., et al., *Male partners of women with provoked vestibulodynia: Attributions for pain and their implications for dyadic adjustment, sexual satisfaction, and psychological distress*. Journal of Sexual Medicine, 2008. **5**: p. 2862-2870.
17. Desrochers, G., et al., *Provoked vestibulodynia: Psychological predictors of topical and cognitive-behavioral treatment outcome*. Behavior Research and Therapy, 2010. **48**: p. 106-115.

18. Lemieux, A.J., et al., *Do romantic partners' responses to entry dyspareunia affect women's experience of pain? The roles of catastrophizing and self-efficacy.* Journal of Sexual Medicine, 2013. **10**: p. 2274-2284.
19. Sullivan, M.J.L., et al., *The relation between catastrophizing and the communication of pain experience.* Pain, 2006. **122**: p. 282-288.
20. Desrosiers, M., et al., *Psychosexual characteristics of vestibulodynia couples: partner solicitousness and hostility are associated with pain.* Journal of Sexual Medicine, 2008. **5**: p. 418-427.
21. Rosen, N.O., et al., *Provoked vestibulodynia: Mediators of the associations between partner responses, pain and sexual satisfaction.* Archives of Sexual Behavior, 2013. **42**: p. 129-141.
22. Rosen, N.O., et al., *Impact of partner responses on sexual function in women with vulvodynia and their partners: A dyadic daily experience study.* Health Psychology, in press.
23. Awada, N., et al., *To say or not to say: Dyadic ambivalence over emotional expression and its associations with pain, sexual function, distress, and dyadic adjustment of women with provoked vestibulodynia and their partners.* Journal of Sexual Medicine, in press.
24. Landry, T., et al., *The treatment of provoked vestibulodynia - A Critical Review.* Clinical Journal of Pain, 2008. **24**(2): p. 155-171.
25. Bergeron, S., et al., *Surgical and behavioral treatments for vestibulodynia.* Obstetrics & Gynecology, 2008. **111**(1): p. 159-166.
26. Masheb, R.M., et al., *A randomized clinical trial for women with vulvodynia: Cognitive-behavioral therapy vs. supportive psychotherapy.* Pain, 2009. **141**: p. 31-40.
27. Barsky Reese, J., *Results from an RCT testing a psychosocial treatment for vulvodynia: Methodological strengths and future directions.* Pain, 2009. **141**: p. 8-9.

28. Bergeron, S., et al., *A randomized comparison of group cognitive-behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dysparenia resulting from vulvar vestibulities*. *Pain*, 2001. **91**: p. 297-306.
29. Bergeron, S., Y.M. Binik, and J. Larouche, *Cognitive-Behavioral Pain and Sex Therapy (CBPST) - Treatment Manual*. 2001: Montreal.
30. Dworkin, R.H., et al., *Core outcome measures for chronic pain clinical trials: IMMPACT recommendations*. *Pain*, 2005. **113**: p. 9-19.
31. Jensen, M.P. and P. Karoly, *Self-report scale and procedures for assessing pain in adults*, in *Handbook of pain assessment*, D.C. Turk and R. Melzack, Editors. 2001, The Guilford Press: New York. p. 15-34.
32. Melzack, R., *McGill Pain Questionnaire: Major properties and scoring methods*. *Pain*, 1975. **1**: p. 277-299.
33. Derogatis, L.R., *The Derogatis Interview for Sexual Functioning (DISF/DISF-SR): An introductory report*. *Journal of Sex and Marital Therapy*, 1997. **23**(4): p. 291-304.
34. Lawrance, K. and E.S. Byers, *Sexual satisfaction in long-term heterosexual relationships: The interpersonal exchange model of sexual satisfaction*. *Personal Relationships*, 1995. **2**: p. 267-285.
35. Sullivan, M.J.L., S. Bishop, and J. Pivik *The pain catastrophizing scale: Development and validation*. *Psychological Assessment*, 1995. **7**: p. 524-532.
36. Osman, A., et al., *The pain catastrophizing scale: Further psychometric evaluation with adult samples*. *Journal of Behavioral Medicine*, 2000. **23**(4): p. 351-365.
37. Cano, A., M.T. Leonard, and A. Franz, *The significant other version of the Pain Catastrophizing Scale (PCS-S): Preliminary validation*. *Pain*, 2005. **119**: p. 26-37.

38. Desrochers, G., et al., *Fear avoidance and self-efficacy in relation to pain and sexual impairment in women with provoked vestibulodynia*. *The Clinical Journal of Pain*, 2009. **25**(6): p. 520-527.
39. Lorig, K., et al., *Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis*. *Arthritis & Rheumatism*, 1989. **32**: p. 37-44.
40. Funk, J.L. and R.D. Rogge, *Testing the ruler with Item Response Theory: Increasing precision of measurement for relationship satisfaction with the Couples Satisfaction Index*. *Journal of Family Psychology*, 2007. **21**(4): p. 572-583.
41. Spanier, G.B., *Measuring dyadic adjustment: New scales for assessing the quality of marriage and similar dyads*. *Journal of Marriage and the Family*, 1976. **38**: p. 15-28.
42. Locke, H.J. and K.M. Wallace, *Short marital adjustment and prediction tests: Their reliability and validity*. *Marriage and Family Living*, 1959. **21**: p. 251-255.
43. Spielberger, C.D., R. Gorsuch, and R. Lushene, *The State-Trait Anxiety Inventory (STAI) Manual*. 1970, Palo Alto, CA: Consulting Psychologists Press.
44. Beck, A.T., R.A. Steer, and M.A. Garvin, *Psychometric properties of the Beck Depression Inventory: 25 years of evaluation*. *Clinical Psychology Review*, 1988. **8**: p. 77-100.
45. Beck, A.T., R.A. Steer, and G.K. Brown, *BDI-II, Beck Depression Inventory: Manual*. 2nd ed. 1996, Boston, MA: Harcourt, Brace, and Company.
46. Turner, J.A. and J.M. Romano, *Self-reported screening measures for depression in chronic pain patients*. *Journal of Clinical Psychology*, 1984. **40**: p. 909-913.
47. Dunlop, W.P., et al., *Meta-analysis of experiments with matched groups or repeated measures designs*. *Psychological Methods*, 1996. **1**: p. 170-177.

48. Cohen, J., *Statistical power analysis for the behavioral sciences*. 2nd ed. 1988, Hillsdale, NJ.: Lawrence Earlbaum Associates.
49. McCarthy, B. and L.M. Wald, *Mindfulness and good enough sex*. *Sexual and Relationship Therapy*, 2013. **28**(1-2): p. 39-47.
50. McCarthy, B. and L.M. Wald, *Sexual desire and satisfaction: The balance between individual and couple factors*. *Sexual and Relationship Therapy*, 2012. **4**(27): p. 310-312.
51. Sullivan, M.J.L., et al., *Theoretical perspectives on the relation between catastrophizing and pain*. *The Clinical Journal of Pain*, 2001. **17**(1): p. 52-64.
52. Vowles, K.E., L.M. McCracken, and J. Zhao O'Brien, *Acceptance and values-based action in chronic pain: A three-year follow-up analysis of treatment effectiveness and process*. *Behavior Research and Therapy*, 2011. **49**: p. 748-755.
53. Meana, M., et al., *Affect and marital adjustment in women's rating of dyspareunic pain*. *Canadian Journal of Psychiatry*, 1998. **43**: p. 381-385.
54. Seligman, M.E., *Depression and learned helplessness*, in *The psychology of depression: Contemporary theory and research*, R.J. Friedman and M.M. Katz, Editors. 1974, John Wiley & Sons: Oxford, England.
55. Rainville, P., Q.V. Huynh Bao, and P. Chrétien, *Pain-related emotions modulate experimental pain perception and autonomic responses*. *Pain*, 2005. **118**: p. 306-318.
56. Jodoin, M., et al., *Attributions about pain as predictors of psychological symptomatology, sexual function, and dyadic adjustment in women with vestibulodynia*. *Archives of Sexual Behavior*, 2011. **40**(1): p. 87-97.
57. Goubert, L., et al., *Facing others in pain: The effects of empathy*. *Pain*, 2005. **118**: p. 285-288.

58. Hurlburt, D.F., et al., *Orgasm consistency training in the treatment of women reporting hypoactive sexual desire: An outcome comparison of women only groups and couples-only groups*. Journal of Behavior Therapy and Experimental Psychiatry, 1993. **24**(1): p. 3-13.
59. Trudel, G., et al., *The effect of a cognitive-behavioral group treatment program on hypoactive sexual desire in women*. Sexual and Relationship Therapy, 2001. **16**(2): p. 145-164.
60. Baucom, D.H., et al., *A couple-based intervention for female breast cancer*. Psycho-Oncology, 2009. **18**: p. 276-283.
61. Manne, S.L., et al., *Intimacy-enhancing psychological intervention for men diagnosed with prostate cancer and their partners: A pilot study*. Journal of Sexual Medicine, 2011. **8**: p. 1197-1209.
62. Lancaster, G.A., S. Dodd, and P.R. Williamson, *Design and analysis of pilot studies: Recommendations for good practice*. Journal of Evaluation in Clinical Practice, 2004. **10**(2): p. 307-312.
63. Leon, A.C., L.L. Davis, and H.C. Kraemer, *The role and interpretation of pilot studies in clinical research*. Journal of Psychiatric Research, 2011. **45**(5): p. 626-629.