Cognitive-behavioral couple therapy versus lidocaine for provoked vestibulodynia: A randomized clinical trial

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Abstract

Objective: This randomized clinical trial compared a novel cognitive-behavioral couple therapy (CBCT) and topical lidocaine for provoked vestibulodynia. ***Method***: Participants were 108 women ($M_{age} = 27.06$) and their partners randomized to one of two treatments and assessed at pre- and post-treatment and 6-month follow-up via questionnaires pertaining to the primary outcomes of women's pain (numerical rating scales of pain intensity and unpleasantness), and secondary outcomes of pain anxiety (Pain Anxiety Symptoms Scale), both partners' sexual function (Female Sexual Function Index; International Index of Erectile Function), sexual distress (Female Sexual Distress Scale Revised), pain-related psychological distress (Pain Catastrophizing Scale), treatment satisfaction, and global ratings of improvements in pain and sexuality. ***Results***: Intent-to-treat multilevel analyses showed that for women, CBCT yielded significantly more improvements than lidocaine in pain unpleasantness at 6-month follow-up, pain anxiety and pain catastrophizing at post-treatment and 6-month follow-up, and sexual distress at post-treatment, and resulted in better treatment satisfaction and global sexuality improvements at both time points. Partners significantly improved in their sexual function, sexual distress, and pain catastrophizing from pre- to post-treatment and pre-treatment to 6-month follow-up, with no significant group differences. Partners in the CBCT condition reported significantly greater treatment satisfaction at both time points, and greater sexuality improvements at post-treatment. ***Conclusions***: CBCT yielded better outcomes on more dimensions of provoked vestibulodynia than lidocaine.

Keywords*:* Genito-pelvic pain; Provoked vestibulodynia; Cognitive-behavioral couple therapy

Public health significance: This study shows that CBCT is an efficacious treatment for women

with a subset of genito-pelvic pain and that involving partners may be beneficial.

Genito-pelvic pain/penetration disorder (GPPPD), a sexual dysfunction in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) (American Psychiatric Association, 2013), has a population prevalence of 8% to 10% in women of all ages (Bergeron et al., 2020). Provoked vestibulodynia (PVD)—an acute recurrent vulvar pain experienced primarily during vaginal intercourse—is the most frequent cause of GPPPD. Controlled studies have shown that PVD is associated with women and their partners' lower sexual function and satisfaction, and greater sexual distress (Arnold et al., 2006). Yet there is a scarcity of randomized clinical trials (RCTs) assessing treatments for women's pain and both partners' sexual difficulties. Recent guidelines for the management of GPPPD recommend CBT as a first-line treatment (Goldstein et al., 2016). However, most women will initially receive a medical treatment after first consulting a physician (Updike & Wiesenfeld, 2005).

Whereas women with GPPPD list an understanding partner as the most helpful factor when coping with their pain (Gordon et al., 2003), no RCT to date has examined the efficacy of couple CBT—an often-recommended but non-validated treatment option. Most studies have focused on group or individual CBT (Bergeron et al., 2020), de facto ignoring a growing body of evidence showing robust associations between relationship factors and women's pain, and both partners' psychological and sexuality outcomes (Rosen & Bergeron, 2019). The present RCT builds on these latter findings, as well as on past RCTs showing the efficacy of group CBT.

Cognitive-behavioral interventions aim to reduce pain and restore sexual function by targeting the thoughts, emotions, and behaviors associated with the experience of GPPPD (Bergeron et al., 2016). A RCT comparing vestibulectomy, a minor day surgery, group CBT and electromyographic (EMG) biofeedback in the treatment of PVD showed that at the 2.5-year

follow-up, vestibulectomy and CBT demonstrated equivalent treatment gains related to pain during intercourse (Bergeron et al., 2008). In another RCT, women with PVD who took part in group CBT reported significantly lower levels of pain and catastrophizing, and better treatment satisfaction in addition to global improvements in pain and sexual function relative to women in a topical corticosteroid condition (Bergeron et al., 2016). In a RCT involving 50 women with GPPPD, individual CBT resulted in significantly greater reductions in pain and improvements in sexual function than supportive psychotherapy (Masheb et al., 2009). A partly randomized study comparing mindfulness-based group CBT to standard group CBT in 130 women with PVD, found that both were equivalent in improving pain during intercourse, pain catastrophizing, sexual function and sexual distress (Brotto et al., 2020). Taken together, findings suggest that CBT is an empirically validated treatment for PVD. However, none of these treatments included women's partners, who are also affected by GPPPD (Smith & Pukall, 2014).

The *Interpersonal Emotion Regulation Model* of women's genito-pelvic pain proposes that interpersonal factors acting at the distal (i.e., predisposing aspects of the relationship) and proximal (i.e., what occurs during painful sexual activities) levels modulate couples' emotion regulation concerning the pain and associated sexual difficulties, and in turn, women's pain and couples' sexual and psychological adjustment (Rosen & Bergeron, 2019). Both distal and proximal factors can be targeted in cognitive-behavioral couple therapy (CBCT). In an open trial, Corsini-Munt et al. (2014) examined the feasibility and effectiveness of a 12-week CBCT for PVD (n = 10 couples). This novel intervention resulted in significant pre- to post-treatment improvements in pain and sexual function for women, and sexual satisfaction for both partners.

Given that the majority of women with PVD first consult a physician for their pain, and will be prescribed a topical treatment, determining whether psychological interventions are as

efficacious as medical options has important implications for quality of care. Lidocaine is among the most commonly used medical treatments (Updike & Wiesenfeld, 2005) and is thought to act peripherally by reducing nociceptor sensitization (Foster et al., 2010). Published treatment algorithms recommend topical lidocaine as an effective first-line intervention for PVD (ACOG, 2006; Mandal et al., 2010), and two surveys indicated that a local anesthetic and/or local measures including lidocaine, are the most commonly used intervention (89% and 83.8% respectively) (Reed et al., 2008; Updike & Wiesenfeld, 2005). In a first prospective study, nightly applications of 5% lidocaine resulted in a significant pre- to post-treatment decrease in self-reported pain during intercourse (Zolnoun et al., 2003). A RCT comparing topical lidocaine and EMG biofeedback showed that both treatments yielded a significant decrease in vestibular pain pressure thresholds and improved sexual function (Danielsson et al., 2006). Although promising, the lack of placebo control arms in these studies precludes a conclusion that lidocaine is efficacious. To examine the efficacy of lidocaine and the antidepressant desipramine, Foster and colleagues (2010) conducted a randomized, double-blinded, placebo-controlled trial. Using the tampon-test (i.e., pain during the insertion/removal of a tampon), they found that all of the active treatments resulted in similar pain reductions compared to placebo. However, the study was not powered adequately, and the tampon-test may not reproduce the experience of pain during vaginal intercourse. Considering the multifaceted nature of PVD, a treatment targeting pain and psychological, sexual, and relationship consequences, would have a presumed advantage over one targeting only its biomedical aspects.

The purpose of the present RCT was to compare the efficacy of a novel CBCT and overnight topical lidocaine on the primary endpoint of pain during intercourse (intensity and unpleasantness), as well as secondary sexuality and psychological endpoints at post-treatment

and six-month follow-up in couples coping with PVD. Based on findings of previous RCTs and because CBCT targets the relationship dimensions of pain and sexuality, we hypothesized that CBCT would yield better improvements in women's pain and both partners' sexual and psychological outcomes, in addition to greater participant self-reported improvements in pain and sexuality and treatment satisfaction.

Method

Participants

Participants were 108 women diagnosed with PVD and their partners. Couples were recruited in two sites (May 2014 to March 2018) in order to facilitate and accelerate (1) the recruitment process and (2) treatment delivery, as well as to minimize length of time between randomization and treatment delivery, which reduces the risk of participant drop-out. Forty-five (42%) were recruited through newspaper advertisements, websites, universities, hospitals and medical clinics, 37 (34%) through participation in prior studies by the authors, 25 (23%) were referred by a physician and one (1%) by a friend. Research Site A recruited 47 couples and Research Site B recruited 61.

Inclusion criteria were: 1) at least 18 years of age; 2) women experiencing pain on at least 80% of vaginal penetration attempts in the last six months; 3) women's pain limited to vaginal intercourse or other activities involving pressure to the vulvar vestibule (e.g., tampon insertion); 4) women having a confirmed diagnosis of PVD; 5) penetration or attempted penetration at least once a month during the last three months (main outcome=pain during intercourse); 6) being in a couple relationship for at least six months, and 7) cohabiting and/or having at least four in-person contacts per week with partner in the last six months. Exclusion criteria were: 1) women with pain being over 45 years of age and/or having started menopause; 2) actively receiving treatment

for PVD; 3) women with pain having an active infection (e.g., candida) or dermatological condition; 4) severe untreated self-reported medical or psychiatric condition in either partner; 5) being pregnant or planning to be during the duration of the clinical trial; 6) currently being in couple therapy; 7) clinical levels of relationship distress, based on the cut-off score of the Couple Satisfaction Index (Funk & Rogge, 2007); and 8) self-reported intimate partner violence. The recruitment and flow of participants throughout the study appears in Figure 1.

Procedure

All de-identified data, syntax for the analyses, and materials used in this study can be found at https://osf.io/dg98t/?view_only=21537debd6414525bc4f21e753fae5cb. Data were collected at pre-treatment, post-treatment and six-month follow-up assessments. A brief telephone screening was conducted by a research assistant with the woman experiencing pain. Potentially eligible couples were then invited to a laboratory-based appointment with a research assistant, during which free and informed consent was obtained. A structured interview was conducted with both partners (together), and then they completed online self-report questionnaires independently, using Qualtrics online software. Eligibility was then determined by reviewing couples' interview and questionnaire responses. All women eligible after the pre-treatment evaluation took part in a gynecological examination including a standardized cotton-swab test to confirm their PVD diagnosis. This test utilized a dry cotton swab to palpate the 3-, 6-, and 9-o'clock positions of the vulvar vestibule, while the woman rated her pain intensity.

Eligible couples were randomized to either CBCT or lidocaine, according to the independent stratified randomization method provided by Dacima. Only each site's research coordinator, the research assistant dedicated solely to the lidocaine condition and the CBCT therapists were aware of treatment randomization. All other research personnel and investigators were blind for

the entire duration of the study. A post-treatment assessment, including a structured interview and self-report questionnaires, followed the twelve weeks of treatment, with a final assessment six months after the post-treatment assessment. Couples were compensated $30 per assessment.

Treatment Conditions

Topical lidocaine. Participants randomized to this condition applied applications of a 5% lidocaine ointment on the vulvar vestibule nightly, at the entry of the vagina (50mg/g, Xylocaïne®, AstraZeneca, tube of 35g) for 12 weeks. The ointment was applied to a cotton ball kept on the vestibule via the participant's underwear overnight to ensure a continued seven to eight-hour contact. A research assistant was trained by one of the Co-I physicians in the use of a protocol to explain its application to participants in a standardized manner. Participants were given a pamphlet with figures detailing how to apply the ointment and instructions to apply the size of a marble. A research assistant performed standardized weekly phone calls to monitor potential adverse events, and participants tracked their own adherence in a booklet.

Cognitive-behavioral couple therapy (CBCT). CBCT consisted of 12 weekly face-to face sessions of 75 minutes. A detailed treatment manual was followed by all the therapists. This manual can be obtained by writing to the first or last author. Adherence to the treatment manual was assessed by two independent clinical associates who viewed and coded a random sample of videotapes representing a quarter of all entire therapy sessions, with an inter-rater reliability of .70 (mean weighted kappa), which indicates substantial agreement. Based on this coding of videotapes, therapists adhered to the treatment manual 93.8% of the time. Therapists were clinical psychology PhD students (n = 10) or junior clinicians (PsyD or PhD, n = 2; MA in clinical sexology, n = 1) who received training on delivering the CBCT manual interventions, literature on PVD and sex and couple therapy. All therapists had weekly supervision with a

registered clinical psychologist specialized in sex and couple therapy. Participant treatment adherence was assessed via frequency ratings of weekly home practice of exercises, based on homework completed during the week it was assigned. The goals of CBCT were to enable participants to: (1) re-conceptualize PVD as a multidimensional pain problem influenced by thoughts, emotions, behaviors and, importantly, couple interactions in which both partners affect and are affected by the pain; (2) modify factors associated with pain during intercourse, with a view to increasing adaptive coping and decreasing pain intensity; (3) improve sexual function, satisfaction and distress; and (4) consolidate skills. The treatment included: information about CBCT; education about PVD, how it impacts sexuality, and a multifactorial view of pain; mindfulness exercises; vaginal dilation exercises; cognitive defusion; expansion of the sexual repertoire; and, as per the *Interpersonal Emotion Regulation Model* of women's genito-pelvic pain, exercises to improve pain and sexuality-relevant couple interactions focusing on couple communication, partner responses to pain, sexual motivation, and relationship intimacy.

Study Measures

Socio-demographics as well as relationship and vulvo-vaginal pain history were collected during the pre-treatment interview. The measures' Cronbach's alphas can be found in Table 2.

Treatment credibility. This was assessed after randomization and prior to starting treatment via one question rated on a scale of 0 = *not at all* to 10 = *totally confident*: How confident are you that the present treatment will improve your/your partner's pain condition?

Primary Outcome Measures

Women's pain. Pain measures included a numerical rating scale (NRS) for pain intensity during intercourse (NRS-I) and a NRS for pain unpleasantness during intercourse (NRS-U). Women with PVD provided ratings on a scale from 0 = *no pain/not unpleasant* to 10 = *worst*

pain ever/most unpleasant ever in reference to the pain they had experienced during intercourse in the past three to six months, depending on the assessment point.

Secondary Outcome Measures

Women's pain anxiety. The Pain Anxiety Symptoms Scale (PASS-20; McCracken & Dhingra, 2002) is a 20-item self-report questionnaire designed for individuals with chronic pain. Items are measured on a 6-point Likert scale from 0 = *never* to 5 = *always* with a total score varying between 0 and 100. It was previously adapted for use in a sexual context for women with PVD, demonstrating a stable factorial structure (Desrochers et al., 2009).

Sexual function. Women's sexual function in the previous four weeks was measured with the validated 19-item Female Sexual Function Index (FSFI; Rosen et al., 2000), which assesses sexual desire, arousal, lubrication, orgasm, satisfaction, and pain. To avoid overlap with the pain outcomes, the three items on pain were removed from the total FSFI score for women diagnosed with PVD, thus their total score included 16 items. Scores obtained in these sexual domains were summed and multiplied by a respective factor that homogenizes the influence of each dimension to form a total score ranging from 2 to 30, with a higher score indicating better sexual function. Male partners' sexual function in the past four weeks was measured with the International Index of Erectile Function (IIEF; Rosen et al., 1997), a 15-item scale that assesses desire, erectile function, orgasmic function, intercourse satisfaction, and sexual satisfaction. Items were summed to provide a total score ranging from 5 to 75, with a higher score indicating better sexual function. For the three female partners, the validated 19-item FSFI was used and transformed to the same scale as the IIEF via this formula: $[(\chi - 2) \times (75/34)]$. For the FSFI and IIEF, participants who had no sexual activity in the last four weeks received a code of 'missing' for that question, to avoid biasing the score towards dysfunction (Meyer-Bahlburg & Dolezal, 2007).

Sexual distress. Sex-related distress was measured with the Female Sexual Distress Scale-Revised (FSDS-R), also validated for men (Derogatis et al., 2008; Santos-Iglesias et al., 2018). Participants rated 13 items that assess how often a sexual problem has caused distress in the past 30 days on a five-point frequency scale (0 = *never*, 4 = *always*). Items were summed to obtain a total score ranging from 0 to 52 with higher scores indicating more sexual distress.

Pain Catastrophizing. The Pain Catastrophizing Scale (PCS; Sullivan et al., 1995) was used to assess catastrophizing thoughts and feelings related to the woman's pain. This scale includes 13 items ranging from 0 = *not at all* to 4 = *all the time* with a total score from 0 to 52.

Global ratings of improvement and satisfaction. These involved two questions about subjective improvement—one for pain during sexual intercourse on a scale of 1 = *deterioration* to 6 = *complete recovery, no more pain* and one for sexuality on a scale of 1 = *deterioration* to 6 = *complete improvement, my sex life has never been better*. One additional question asked about treatment satisfaction on a scale of 0 = *completely dissatisfied* to 10 = *completely satisfied*. These questions were part of the post-treatment and six-month follow-up structured interviews.

Data Analytic Strategy

An a priori power analysis determined that we needed 124 couples to detect small effects (i.e., $d = 0.32$, $f = 0.16$) with 95% power, based on our pilot study and previous clinical trials (Bergeron et al., 2016; Corsini-Munt et al., 2014), with a design including two treatment arms, three time points, and a moderate correlation between repeated measures. As recruitment was slower than expected, we stopped at 108 couples. Given that our original power analysis focused on 95% rather than 80% power (usually the norm), we were confident that our sample had adequate power to test our main hypotheses.

Preliminary analyses were conducted using SPSS 26.0. Treatment condition differences on completion and follow-up rates, pre-treatment participant sociodemographic and clinical characteristics, and pre-treatment outcome measures were examined with *t* tests and chi-square analyses. Bivariate correlations were also conducted between sociodemographic and clinical characteristics and pre-treatment outcome measures to examine the need to control for covariates. To examine the effects of treatment and the differences between treatment condition, data were analyzed using multilevel models (hierarchical linear modeling) with maximum-likelihood (ML) estimation of parameters implemented in M*plus* 8.2 (Muthén & Muthén, 1998-2017). Analyses were conducted using the intention-to-treat principle whereby all randomized participants were included in the analyses. In these models, we examined the main effect of time (pre-treatment, post-treatment, six-month follow-up) with pre-treatment as the reference as a within-subjects variable, the main effect of intervention condition (CBCT, Lidocaine) as a between-subjects variable, and the interaction of the within- and between-subjects factors (i.e., interaction between time by treatment condition) as a cross-level interaction. Treatment condition was effect coded with CBCT = 0.5 and topical lidocaine = -0.5. To facilitate main effect interpretation, continuous covariates were grand-mean centered and dichotomous covariates were effect coded (e.g., treatment site, 0.5 = Site A and -0.5 = Site B). Six models were estimated – one model for each outcome measure. For outcomes measured in both women and their partners, models were estimated using the actor-partner interdependence model (APIM; Kenny et al., 2006), in which both partners' scores were modeled as multivariate outcomes and residual terms were allowed to be correlated between partners. Effect sizes (Cohen *d*) were calculated using the model estimated mean differences at post-treatment and six-month follow-up divided by the pre-treatment standard deviation of the raw scores (Feingold, 2009).

Results

Sample Size and Characteristics

One-hundred and eight couples were randomized: 53 to CBCT and 55 to lidocaine. Overall, 88.0% (n = 95) of couples completed treatment with no significant differences by treatment condition. Post-treatment and follow-up assessment completion rates were 90.7% (n = 98), with no significant differences by treatment condition. Sociodemographic and clinical characteristics for the sample and by treatment condition (no significant differences) are presented in Table 1.

Treatment Credibility and Adherence

At pre-treatment, there were no significant differences in how women (M = 6.44, SD = 1.92) and partners (M = 6.45, SD = 1.95) randomized to lidocaine rated their confidence in treatment compared to women (M = 6.11, SD = 2.56) and partners (M = 6.43, SD = 1.99) randomized to CBCT, women: $t(106) = 0.02$, $p = .957$; partners: $t(106) = 0.32$, $p = .461$. Couples in CBCT attended 10.6 out of 12 (SD = 3.53; 88.7%) sessions and women completed 67.7% of homework exercises, whereas partners completed 58.6% of homework exercises. Women in the lidocaine arm applied the cream 79.4% of the nights during the treatment period.

Treatment Outcomes

The means and standard deviations of primary and secondary outcome measures by treatment condition and time of assessment are presented in Table 2. Sociodemographic and clinical characteristics significantly associated with pre-treatment measures were added as covariates in their respective models (Table 3 and Table 4). Research site (0 = Site B; 1 = Site A) was significantly associated with lower pain intensity (NRS-I; r = -.30, p = .001), higher partners' sexual function (r = .26, p = .008), lower women's sexual distress (r = -.23, p = .018), and lower women's catastrophizing (r = -.22, p = .026). Women's education was significantly

associated with higher pain intensity (NRS-I; $r = .21$, $p = .031$) and higher pain unpleasantness (NRS-U; $r = .20$, $p = .037$). Relationship length was significantly associated with lower women's sexual function ($r = -.20$, $p = .043$), higher partners' sexual distress ($r = .34$, $p < .001$), lower women's catastrophizing ($r = -.22$, $p = .023$), and higher partners' catastrophizing ($r = .22$, $p = .022$). Women and partners' age were also associated with higher partners' sexual distress, but not added in the model as these were correlated with relationship length – already a covariate.

Primary Outcomes

Women with PVD's pain. As seen in Table 3, pain intensity during intercourse (NRS-I) and pain unpleasantness (NRS-U) decreased significantly from pre- to post-treatment and pre-treatment to six-month follow-up. There was no main effect for Treatment condition and no significant interaction between Time and Treatment condition for pain intensity (NRS-I). There was a significant interaction between Time and Treatment condition for pain unpleasantness (NRS-U). Simple slope tests (Table 3) showed that the CBCT group had a greater reduction in pain unpleasantness from pre-treatment to six-month follow-up compared to the lidocaine group.

Secondary Outcomes

Women with PVD's pain anxiety. As presented in Table 4, women's pain anxiety decreased significantly from pre- to post-treatment and pre-treatment to six-month follow-up. There was no main effect for treatment condition. There was a significant interaction between Time and Treatment condition. Simple slope tests reported in Table 4 showed that women in CBCT reported significantly greater reduction in their pain anxiety from pre- to post-treatment and from pre-treatment to six-month follow-up, compared to women in the lidocaine condition

Sexual function. As presented in Table 4, sexual function increased significantly between pre- and post-treatment in both women and their partners as well as between pre-treatment and

six-month follow-up in women. There was no main effect for treatment condition and no significant interaction between Time and Treatment condition.

Sexual distress. As seen in Table 4, sexual distress decreased significantly from pre- to post-treatment and pre-treatment to six-month follow-up in women and partners. There were no main effects for treatment condition for women and partners and no significant interaction between Time and Treatment condition for partners. There was a significant interaction between Time and Treatment condition for women, with those in CBCT reporting a significantly greater reduction in sexual distress from pre- to post-treatment compared to those in topical lidocaine.

Pain catastrophizing. As seen in Table 4, pain catastrophizing decreased significantly from pre- to post-treatment and pre-treatment to six-month follow-up in women and partners. There were no main effects for treatment condition for women and partners and no significant interaction between Time and Treatment condition for partners. There was a significant interaction between Time and Treatment condition for women. Simple slope tests (Table 4) showed that CBCT yielded a significantly greater reduction in pain catastrophizing from pre- to post-treatment and pre-treatment to six-month follow-up, compared to lidocaine.

Global Participant Ratings of Improvement and Satisfaction

As reported in Table 5, at post-treatment and six-month follow-up, women and partners in CBCT were significantly more satisfied with their treatment than those randomized to lidocaine. At post-treatment, women and partners in CBCT reported significantly greater improvements in their sexuality than those in the lidocaine condition. At six-month follow-up, women in CBCT reported significantly greater improvements in their sexuality than women in the lidocaine condition. There were no significant group differences for self-reported improvements in pain.

Discussion

This two-center RCT compared the differential efficacy of cognitive-behavioral couple therapy (CBCT) and overnight topical lidocaine in improving the primary endpoints of pain intensity and unpleasantness, as well as secondary sexual and psychological endpoints, in a sample of 108 couples coping with PVD. Findings showed that CBCT and overnight topical lidocaine yielded significant improvements in women's pain, sexuality and psychological outcomes at post-treatment and six-month follow-up. For women with PVD, CBCT resulted in greater improvements than lidocaine across multiple domains of well-being, including decreased pain unpleasantness at six-month follow-up, pain anxiety and catastrophizing at post-treatment and six-month follow-up, and sexual distress at post-treatment, as well as better treatment satisfaction and global sexuality improvements at both time points. Partners significantly improved in terms of their sexual function, sexual distress, and pain catastrophizing from pre- to post-treatment and pre-treatment to six-month follow-up, with no group differences. However, partners in CBCT reported significantly greater treatment satisfaction at both time points, and greater global sexuality improvements at post-treatment.

Both treatments were associated with statistically significant improvements in pain intensity and pain unpleasantness—dimensions considered as key outcomes in vulvodynia/GPPPD clinical trials and the primary outcome of this RCT (Pukall et al., 2017). The scope of the pre- to post-treatment and pre-treatment to six-month follow-up changes was also clinically significant, whereby a change in perceived pain intensity from baseline of approximately two points on a 0 to 10 NRS is considered meaningful (Pukall et al., 2017). These levels of pain reduction mirror those reported in previous RCTs of CBT for GPPPD (Bergeron et al., 2016; Masheb et al., 2009). However, CBCT yielded greater reductions in pain unpleasantness, which refers to the affective component of pain. This is consistent with the therapeutic targets of CBT.

Importantly, secondary pain-related psychological findings showed that women who took part in CBCT reported greater reductions in pain anxiety and pain catastrophizing, with gains maintained at the six-month follow-up. Anxiety is a robust predictor of the development, chronicity and exacerbation of PVD (Bergeron et al., 2020). Specific components of pain anxiety, such as avoidance and fear of pain, were also associated with greater pain intensity in a cross-sectional study of women with PVD (Desrochers et al., 2009), in addition to being significant predictors of worse pain treatment outcomes in a RCT comparing group CBT to topical management (Desrochers et al., 2010). Pain catastrophizing is a well documented psychological correlate of pain and disability, and a significant predictor (Desrochers et al., 2010) and mediator (Brotto et al., 2020) of PVD treatment outcome. Findings thus suggest that CBCT interventions, such as focusing on pain acceptance and emotional disclosure, are more effective than topical lidocaine in relieving pain-related distress.

Findings concerning women with PVD's sexuality were two-fold. First, both interventions yielded significant pre- to post-treatment and pre-treatment to six-month follow-up improvements in sexual function, although mean levels of post-treatment and six-month follow-up scores for women in both groups were still within the clinical range (Wiegel et al., 2005). These results are surprising in light of the fact that improving sexual wellbeing is a specific target of CBCT and not of lidocaine. They could indicate that improvements in sexual function stem in part from the reduction of pain, such that women may be more aroused during sex as pain decreases, independent of treatment. Second, although both treatments yielded significant improvements in sexual distress, women randomized to CBCT fared better at post-treatment than those in the lidocaine arm. Focusing on sexuality, intimacy, and communication in couple

therapy may facilitate perspective taking between both partners and thereby reduce sexual distress (Bois et al., 2016).

As for partners of women with PVD, whether they were randomized to CBCT or lidocaine, they demonstrated significant pre- to post-treatment and pre-treatment to six-month follow-up positive changes on most outcomes, i.e., sexual function, sexual distress, and pain catastrophizing. This result is consistent with findings from a pilot study showing that partners significantly improved on pain catastrophizing following CBCT (Corsini-Munt et al., 2014). In light of research showing that partner pain catastrophizing contributes to women's pain in PVD samples (Lemieux et al., 2013) and that partners also suffer from sexual difficulties (Smith & Pukall, 2014), these results are promising. The fact that partners also benefited from a medical treatment is novel and clinically relevant.

Beyond objective changes on validated measures, the clinical significance of the present results was captured via participant ratings of treatment satisfaction and self-reported improvements in pain and sexuality. Both women and partners randomized to CBCT were significantly more satisfied with their treatment than participants in the lidocaine condition at post-treatment and six-month follow-up, in addition to perceiving significantly more improvements in their sexuality, at both time points for women and at post-treatment for partners. These high levels of satisfaction for women are consistent with results of other treatment studies of CBT for PVD (Bergeron et al., 2016; Masheb et al., 2009). Mirroring the findings from the pain intensity measure (NRS-I), there were no group differences in self-reported improvements in pain. The more novel finding is that partners were also highly satisfied and felt that their sexuality had improved, suggesting an additional strength of couple CBT.

This RCT presents some limitations. Focusing solely on PVD increased internal validity, but findings may not apply to all types of GPPPD. Further, although this comparison group reflected standard medical care, it did not control for attention from a health professional, which could account for some of the findings. Despite having an a priori primary outcome of pain during intercourse (intensity and unpleasantness), other outcomes were examined in an exploratory manner and no adjustments for multiple testing were applied. Although CBCT was superior to lidocaine for some specific outcomes, it remains unknown how either treatment is different from placebo or treatment-as-usual. Lastly, we did not control for continued use of lidocaine or CBCT homework exercises during the follow-up period, although participants received a small, pre-calculated amount of lidocaine for 12 weeks only, and homework alone is not a predictor of CBT treatment success (Bergeron et al., 2001). Nevertheless, the present study boasts several strengths, including the use of a randomized trial design and intent to treat analyses, a rigorous selection process combining medical and psychological in-person assessments of the couples, and careful monitoring of treatment delivery. In addition, this study tested a novel couple intervention grounded in a body of evidence concerning the role of relationship factors in PVD (Rosen & Bergeron, 2019) and conducted assessments using a wide range of outcomes reflecting the multiple dimensions of PVD, as per vulvodynia trials guidelines (Pukall et al., 2017).

In conclusion, findings indicate that CBCT is significantly more beneficial than topical lidocaine for reducing women's pain unpleasantness, anxiety, and catastrophizing, as well as sexual distress, in addition to both women and their partners being more satisfied with this treatment and reporting significantly more subjective improvements in their sexuality. Results contribute to a growing body of literature on empirically validated CBTs for GPPPD and support recommending CBCT as a first-line treatment for PVD.

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Data Transparency Statement

This is the first submitted paper involving the full RCT data with three time points. We published three cross-sectional papers using part of this sample's pre-treatment data. None focused on treatment and none involved post-treatment or six-month follow-up data. Investigators remained blind to randomization until the end of the six-month follow-up. Further, once the present paper is accepted for publication, we plan to submit other papers using the RCT data, i.e., one on dyadic moderators of treatment outcome for both partners, one on moderators of treatment outcome for women with GPPPD only, one on in- treatment, CBCT mediators of treatment outcome and another on mediators of treatment outcome measured at pre-treatment, post-treatment and six-month follow-up. None of these planned manuscripts are submitted.