

A Randomized Clinical Trial Comparing Group Cognitive–Behavioral Therapy and a Topical Steroid for Women With Dyspareunia

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Objective: This 13-week randomized clinical trial aimed to compare group cognitive–behavioral therapy (GCBT) and a topical steroid in the treatment of provoked vestibulodynia, the most common form of dyspareunia. **Method:** Participants were 97 women randomly assigned to 1 of 2 treatment conditions and assessed at pretreatment, posttreatment and 6-month follow-up via structured interviews and standard questionnaires pertaining to pain (McGill Pain Questionnaire, 11-point numerical rating scale of pain during intercourse), sexual function (Female Sexual Function Index, intercourse frequency), psychological adjustment (Pain Catastrophizing Scale, Painful Intercourse Self-Efficacy Scale), treatment satisfaction, and participant global ratings of improvements in pain and sexuality. **Results:** Intent-to-treat multilevel and covariance analyses showed that both groups reported statistically significant reductions in pain from baseline to posttreatment and 6-month follow-up, although the GCBT group showed significantly more pain reduction at 6-month follow-up on the McGill Pain Questionnaire. The 2 groups significantly improved on measures of psychological adjustment, and the GCBT group had significantly greater reductions in pain catastrophizing at posttreatment. Both groups' sexual function significantly improved from baseline to posttreatment and 6-month follow-up, and the GCBT group was doing significantly better at the 6-month follow-up. Treatment satisfaction was significantly higher in the GCBT group, as were self-reported improvements in pain and sexuality. **Conclusions:** Findings suggest that GCBT may yield a positive impact on more dimensions of dyspareunia than a topical steroid, and support its recommendation as a first-line treatment for provoked vestibulodynia.

What is the public health significance of this article?

This study shows that group cognitive–behavioral therapy is an effective treatment for women with dyspareunia due to provoked vestibulodynia.

Keywords: dyspareunia, provoked vestibulodynia, pain, cognitive–behavioral therapy, vulvodynia

Dyspareunia, or painful intercourse, has a population prevalence of 6.5–45% in older women and 14–34% in younger women (van

Lankveld et al., 2010). Furthermore, 20% of sexually active adolescent girls report vulvovaginal pain during intercourse lasting more than 6 months (Landry & Bergeron, 2011). The new *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition classification has collapsed dyspareunia and vaginismus into a single diagnostic entity called *genito pelvic pain/penetration disorder*, due to considerable overlap between the two conditions (American Psychiatric Association, 2013). Provoked vestibulodynia (PVD)—an acute recurrent pain localized within the vulvar vestibule and experienced primarily during intercourse—is suspected to be the most frequent cause of dyspareunia in premenopausal women (Friedrich, 1987). Its prevalence is 12% in community samples and its incidence is increasing (Danielsson, Sjöberg, Stenlund, & Wikman, 2003; Harlow, Wise, & Stewart, 2001). In addition to disrupting all aspects of sexual function, controlled studies have shown that PVD can adversely affect women and their partners' general psychological well-being and overall quality of life (Arnold, Bachmann, Rosen, Kelly, & Rhoads, 2006;

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Desrochers, Bergeron, Landry, & Jodoin, 2008). Epidemiological results indicate that only 60% of women who report chronic vulvovaginal pain seek treatment, and 40% of these never obtain a formal diagnosis (Harlow et al., 2001). The quality of health care received by this population is thus less than optimal. Despite this, there are only a handful of published randomized clinical trials assessing PVD treatments.

The last decade of research suggests that psychological factors may contribute to the maintenance and exacerbation of dyspareunia. Controlled studies have found that women with dyspareunia report more anxiety than controls (Granot & Lavee, 2005; Landry & Bergeron, 2011; Payne, Binik, Amsel, & Khalife, 2005). A recent epidemiologic study showed that anxiety and depression were both antecedent and consequent to dyspareunia. Khandker et al. (2011) found that odds of vulvovaginal pain were four times more likely among women with antecedent mood or anxiety compared to women without, and that suffering from vulvovaginal pain was associated with new or recurrent onset of mood or anxiety disorder. Psychological factors may also exacerbate dyspareunia and associated sexual impairment. Cross-sectional studies suggest that pain catastrophizing, fear of pain, hypervigilance to pain, lower self-efficacy, negative attributions about the pain, avoidance, anxiety and depression are all associated with greater pain intensity or sexual dysfunction (Desrochers, Bergeron, Khalife, Dupuis, & Jodoin, 2009; Desrochers et al., 2008). According to the fear-avoidance model, an initial pain experience may be interpreted as threatening (catastrophizing), leading to fear of pain and to avoidant behaviors, which in turn may lead to hypervigilance followed by disability (sexual dysfunction) and disuse (reduction of the frequency of intercourse; Bergeron, Rosen, & Morin, 2011; ter Kuile, Both, & van Lankveld, 2010; Vlaeyen & Linton, 2000).

Current treatment algorithms for dyspareunia are largely based on data from uncontrolled studies (Haefner et al., 2005). Presently, these suggest that cognitive-behavioral therapy (CBT) and topical applications are appropriate first line interventions, although there is little empirical evidence to support this recommendation. In practice, most women will be prescribed a topical application as a first line option, rather than CBT (Updike & Wiesenfeld, 2005). Typical cognitive-behavioral interventions aim at reducing pain, restoring sexual function and improving the romantic relationship by targeting the thoughts, emotions, behaviors and couple interactions associated with the experience of dyspareunia (Bergeron, Rosen, & Pukall, 2014). In terms of treatment outcome, a randomized trial of PVD comparing vestibulectomy, a minor day surgery, group CBT (GCBT) and electromyographic biofeedback showed that at the 2.5-year follow-up, vestibulectomy was superior to the other conditions in its impact on pain during the gynaecological examination, but was equal to CBT for pain during intercourse. This suggests that CBT may be beneficial in the long run for the most relevant functional outcome, pain during sexual activity (Bergeron, Khalifé, Glazer, & Binik, 2008). In a randomized clinical trial involving a mixed group of 50 women with vulvodynia, Masheb, Kerns, Lozano, Minkin, and Richman (2009) also found that CBT resulted in significantly greater reductions in pain and improvements in sexual function than supportive psychotherapy. Although findings from these two trials indicate that CBT is a promising intervention for dyspareunia, their designs were limited by relatively small sample sizes and in one of the studies, by a heterogeneous sample composition (Masheb et al., 2009). Fur-

ther, these trials did not involve a nonsurgical medical intervention, which is the most frequently recommended treatment offered by physicians (Updike & Wiesenfeld, 2005), in addition to figuring prominently in best practice guidelines (Haefner et al., 2005). It is thus not yet possible to determine whether CBT might present any advantage over standard first line care—topical applications. Given that the majority of women with PVD will first consult a physician for their pain, and will be prescribed a topical treatment, answering this question is crucial.

Although a survey showed that 34% of clinicians specialized in vulvo-vaginal pain use topical steroids to treat PVD, only one study has focused on this modality (Brown, Wan, Bachmann, & Rosen, 2009). In their randomized trial involving a sample of 53 women with different subtypes of vulvodynia, including PVD, and aged 18 to 72, Brown et al. (2009) found that the 14 participants who received the 0.1% topical triamcinolone combined with low-dose amitriptyline did not show significant reductions in pain. The small and heterogeneous sample precludes the possibility of drawing firm conclusions from these findings.

The purpose of the present randomized clinical trial was to prospectively evaluate and compare the differential efficacy of GCBT and a topical steroid in relieving pain as well as improving sexual function and psychological adjustment in a sample of women diagnosed with PVD. Based on findings of previous studies and because GCBT targets multiple dimensions of PVD, including the cognitive, affective, behavioral and interpersonal aspects of pain and sexuality, we hypothesized that it would yield better outcomes than a topical steroid.

Method

Participants

Participants were 97 women diagnosed with PVD. They were selected from a pool of 116 women recruited through professional referral and local media announcements pertaining to painful sexual intercourse. They were initially screened during a short preliminary telephone contact to determine their eligibility based on selection criteria. Inclusion criteria were the following: (a) pain during intercourse that is (i) subjectively distressing, (ii) occurs (or occurred) on most (75%) intercourse attempts, and (iii) has lasted for at least 6 months (women who stopped attempting intercourse as a result of the pain were included if the pain could be confirmed during the gynecological examination); (b) pain limited to intercourse and other activities involving vestibular pressure (e.g., bicycling); (c) moderate to severe pain in one or more locations of the vestibule during the cotton-swab test (cf. Procedure), and this was operationalized as a minimum average patient pain rating of 4 on a scale of 0 to 10. Exclusion criteria were the following: (a) unprovoked pelvic or vulvar pain; (b) deep dyspareunia; (c) presence of one of the following: (i) major medical and/or psychiatric illness, (ii) active infection, (iii) dermatologic lesion, and (iv) vaginismus, as per *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition criteria; (c) ongoing treatment for dyspareunia; (d) pregnancy; (e) age less than 18 or greater than 45. Eligible women were invited to take part in an assessment at a participating gynecologist's office, where the study procedures were first reexplained and informed consent was obtained. Figure 1 depicts the flow of participants throughout the study. Of the

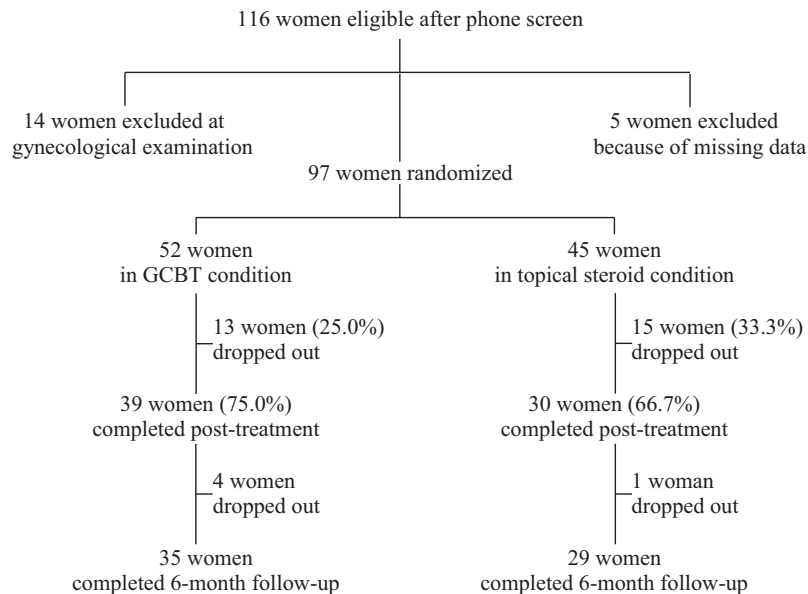


Figure 1. Recruitment and flow of participants throughout the study.

initial pool of potential participants, 14 women were excluded at the screening phase or during the gynecological examination because of the presence of an infection or another dermatologic condition (e.g., lichen sclerosus). No further data were collected from these women. Another five women completed the questionnaires but were excluded because of missing data. *T* tests and chi-square analyses did not detect differences between nonparticipants and participants on any of the sociodemographic or dependent variables. The study was approved by the participating institutions' Institutional Review Boards.

Procedure

Recruitment ran from January 2003 to June 2007 in a large metropolitan area. On the first visit, each potential participant underwent a gynecological examination carried out by one of the two gynecologist coinvestigators accompanied by a research assistant who recorded the gynecologist's observations on a standardized form. The following standardized protocol was used: (a) a brief interview about obstetrical/gynecological history, including painful intercourse, was conducted by the gynecologist; (b) vaginal cultures were taken for *Candida*, *Gardnerella*, and *Trichomonas*, as well as a Pap smear if the patient had not been tested in the past year; (c) a randomized cotton-swab palpation of three vestibular sites (3:00, 6:00, and 9:00) was performed—this is commonly referred to as the cotton-swab test and constitutes the main diagnostic tool for PVD. Participants rated the pain at each site on a scale of 0 (*no pain*) to 10 (*worst pain ever*) and these ratings were noted by the research assistant; (d) a standard gynecological examination was carried out. In addition, any other physical findings were noted, as were the gynecologists' final diagnoses. A structured interview and standardized questionnaires followed the gynecological examinations. This procedure has shown substantial interrater reliability ($k = 0.68$) for the diagnosis of PVD and

moderate test-retest reliability ($k = 0.54$; Bergeron, Binik, Khalifé, Pagidas, & Glazer, 2001).

Participants who did not meet our selection criteria ($N = 14$) were referred appropriately. Those meeting our criteria were given detailed explanations about the two treatments by an experienced research coordinator (RC). The 97 participants having provided written consent were randomized by the RC to one of the two treatments using a stratified randomization method, based on the language of treatment (English or French). Assignments were conducted using a randomization software after confirmation that all eligibility criteria had been satisfied. In each stratum, allocation was computer-generated randomly by blocks. The principal investigators were unaware of randomization status, as were all members of personnel conducting the assessments. Specifically, the RC was instructed to keep all randomization information strictly confidential, and was the only person on the team to have the password allowing her to use the randomization software. As the two treatments were delivered outside the university, the therapists and physicians delivering treatments never communicated with the assessors—only with the RC. Participants were instructed not to reveal their treatment to research personnel during assessments, both in writing in the consent form, and in person by the assessor, prior to beginning each assessment. They were also required to forego receiving other interventions for the entire duration of the study. All treatments were provided free of charge.

Treatments

The topical corticosteroid condition aimed to reduce presumed inflammation in PVD (Brown, Wan, Bachmann, & Rosen, 2009). It involved three components: (a) a twice daily application of 1% hydrocortisone cream (Cortate 1%) for 13 weeks; (b) written education materials about PVD and its day to day management, such as using cotton underwear and mild soap; and (c) the instruc-

tion to use a water-based lubricant for intercourse. Participants discontinued use of the cream after 8 weeks if they found no improvement. Participants were randomly assigned to one of the two participating gynecologists. They met with their gynecologist at the beginning of treatment to receive information regarding application. They then received weekly phone calls by the project coordinator to monitor compliance and adverse events.

GCBT was delivered in a university hospital by one of three doctoral-level female clinical psychologists, in 2-hr group sessions with seven to eight women per group. The psychologists were specialized in sex and couple therapy. Participants received 10 sessions over a 13-week period. They were randomly assigned to either therapist taking into account the language of the group. Therapists were trained and supervised via a treatment manual designed specifically for this purpose (Bergeron, Binik, & Larouche, 2001). This manual can be obtained by writing to the first 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 interrater reliability of .83. Based on this coding of videotapes, therapists adhered to the treatment manual 79.2% of the time. The treatment package included the following: education and information about PVD and how dyspareunia impacts on desire and arousal, education concerning a multifactorial view of pain, education about sexual anatomy, progressive muscle relaxation, abdominal breathing, Kegel exercises, vaginal dilation, distraction techniques focusing on sexual imagery, rehearsal of coping self-statements, communication skills training, and cognitive restructuring. Such interventions aimed at reducing fear of pain and other maladaptive affective and cognitive responses, decreasing avoidance, increasing sexual activity level and broadening the sexual repertoire, and reducing pain. Treatment adherence for GCBT was measured via frequency ratings of weekly home practice of exercises, which included breathing, Kegels, dilation, and cognitive restructuring.

Measures

The following outcome measures were administered by an independent clinical associate, in the context of a structured interview at the first visit of the participant selection process (pretreatment), at posttreatment, and at 6-month follow-up. Sociodemographic information as well as relationship, gynecological and vulvo-vaginal pain history were collected during this interview.

Pain. Pain dependent measures included (a) a Numerical Rating Scale (NRS) measure of the intensity of painful intercourse on a scale of 0 to 10, administered during the structured interview; (b) the Present Pain Intensity scale of the McGill Pain Questionnaire (MPQ; Melzack, 1975). For the last two measures, participants were asked to provide global ratings of the pain they had experienced in the past 3–6 months, depending on the assessment point.

Sexual function. This was assessed using (a) the Female Sexual Function Index (FSFI; R. Rosen et al., 2000), a self-report questionnaire that has demonstrated excellent psychometric properties (Daker-White, 2002) and consists of 19 items assessing five dimensions of global sexual functioning including (i) desire and arousal, (ii) lubrication, (iii) orgasm, (iv) satisfaction, and (v) pain/discomfort; women who had not been sexually active in the

last 4 weeks at posttreatment and 6-month follow-up were excluded from analyses involving the FSFI ($N = 5$); (b) a self-report measure of frequency of intercourse per month, taken during the structured interview.

Psychological adjustment. Participants completed (a) the Pain Catastrophizing Scale (Sullivan, Bishop, & Pivik, 1995), which consists of 13 items divided into three subscales: rumination, magnification, and helplessness; (b) the Painful Intercourse Self-Efficacy Scale (Desrochers et al., 2009), designed to assess three dimensions of self-efficacy associated with pain during intercourse: (i) self-efficacy for sexual function, (ii) self-efficacy for controlling other symptoms, and (iii) self-efficacy for controlling pain during intercourse. This questionnaire was adapted from the Arthritis Self-Efficacy Scale (Lorig, Chastain, Ung, Shoor, & Holman, 1989), developed to assess perceived self-efficacy in arthritis patients. Participants indicated their perceived ability to carry out sexual activity or to achieve specific outcomes in pain management. Responses were recorded on a 10-point scale ranging from 10 (*very uncertain*) to 100 (*very certain*). Factorial analyses yielded a factorial structure identical to that of the original scale.

Participant global ratings of improvement and satisfaction. These involved two questions about subjective improvement—one for pain (scale of 1 [*complete cure*] to 6 [*deterioration*]) and another one for sexuality (scale of 1 [*great improvement*] to 5 [*deterioration*])—in addition to one question about treatment satisfaction (scale of 0 [*completely dissatisfied*] to 10 [*completely satisfied*]). These were part of the posttreatment and 6-month follow-up structured interviews.

Treatment credibility. This was assessed at the first treatment session or during the appointment with the gynecologist for the topical arm, via a question rated on a scale of 0 (*not at all*) to 10 (*completely*): “How confident are you that the present treatment will improve your pain condition?”

Data Analytic Strategy

Data from a prior randomized trial involving CBT for PVD were used to inform our power analysis. Specifically, we focused on the effect size for the measure of pain during intercourse (NRS), $d(t_1-t_2) = .61$ and $d(t_2-t_3) = .67$ (Bergeron et al., 2001b). To detect a significant difference between two independent groups with an effect size of 0.60, power of at least 0.80 and an alpha of 0.05, we estimated that an N of 38 participants per group was required. Adjusting for a predicted 20% dropout rate, we aimed for a total N of 91 participants.

Univariate analysis of variance for continuous variables and chi-square analyses for categorical variables were used to compare groups on sociodemographic, clinical and pretreatment outcome measures.

Randomized participants ($N = 97$) completed measures at pre- and posttreatment and 6-month follow-up (t_1 , t_2 , and t_3). Within and between group comparisons were analyzed using a random coefficient analysis (multilevel analysis) with time as the within-subjects variable and treatment group as the between-subjects variable on SPSS 21.0 (Curran, Obeidat, & Losardo, 2010). Main effects for time (pre- to posttreatment and pretreatment to 6-month follow-up) were examined to assess changes within treatment group and interaction effects for time by treatment group were examined to compare differences between GCBT and the topical

corticosteroid at posttreatment and 6-month follow-up. Six models were calculated, one per outcome measure. Effect sizes and confidence intervals were also calculated. We also conducted analysis of covariance (ANCOVA) analyses, controlling for baseline (t_1) scores, on the six outcomes to examine differences between the two treatment groups at posttreatment (t_2) and 6-month follow-up (t_3). Analyses for the sexual function measure were conducted on the 92 women who had been sexually active in the 4 weeks prior to completing these measures. An intent-to-treat strategy was chosen because it is a more conservative approach and preserves the comparability of groups allowed by randomization (Newell, 1992). In the multilevel modeling analyses, missing data were handled using the full-information maximum likelihood method (Enders & Bandalos, 2001). In the ANCOVAs however, the last observation was carried forward (Shao & Zhong, 2003). Global ratings of participant improvement and satisfaction were also analyzed using random coefficient analysis. Treatment success was defined a priori as self-reported good to great improvement or complete relief of pain on the subjective improvement measure of the participant ratings of global improvement for (a) pain and (b) sexuality. Chi-square tests were conducted to examine whether there were group differences in the number of treatment successes.

Results

Final Sample Size

Figure 1 shows the flow of participants throughout the study. Ninety-seven women were randomized: 52 to GCBT and 45 to the topical corticosteroid. In the GCBT condition, there were 13 dropouts at the posttreatment assessment as well as four more at

the 6-month follow-up. In the topical corticosteroid condition, there were 15 dropouts at the posttreatment assessment and one more at the 6-month follow-up assessment. Detailed sociodemographic and clinical characteristics of the sample are shown in Table 1. None of the sociodemographic variables were significantly correlated with the pretreatment dependent measures.

Results for Pain, Sexuality, and Psychological Adjustment Outcomes

The means and standard deviations for the pain, sexual function, and psychological adjustment measures by treatment and time of assessment are shown in Table 2. Models for the random coefficient analyses can be found in Table 3. Pain during intercourse as measured by a NRS and pain as measured by the MPQ both decreased significantly between pre- and posttreatment and between pretreatment and 6-month follow-up. There was a Time (t_1 to t_3 period) \times Group interaction, showing that GCBT participants reported significantly more pain reduction than those in the topical steroid group. ANCOVA analyses did not show additional group differences.

Sexual function as measured by the FSFI improved significantly from pre- to posttreatment and from pretreatment to 6-month follow-up. Intercourse frequency significantly improved from pretreatment to 6-month follow-up. No significant Time \times Group interaction effects emerged for the sexuality outcomes. However, ANCOVA analyses showed that women in the GCBT arm had improved significantly more at the 6-month follow-up than women in the topical steroid arm, $F(1, 93) = 7.42, p < .01$.

Pain catastrophizing and pain self-efficacy significantly improved from pre- to posttreatment and from pretreatment to

Table 1
Sociodemographic Characteristics of the Sample

Variable	GCBT	Topical steroid	Total
Age, <i>M</i> (<i>SD</i>)	27.79 (6.48)	26.07 (5.54)	26.99 (6.09)
Pain duration, <i>M</i> (<i>SD</i>)	6.42 (5.27)	4.60 (4.19)	5.58 (4.86)
Education, <i>M</i> (<i>SD</i>)	15.98 (2.54)	15.59 (2.11)	15.80 (2.35)
Age of first intercourse, <i>M</i> (<i>SD</i>)	17.19 (2.96)	17.73 (2.42)	17.44 (2.72)
Religion, <i>N</i> (%)			
Catholic	36 (69.2)	32 (71.1)	68 (70.1)
Protestant	1 (1.9)	1 (2.2)	2 (2.1)
Jewish	1 (1.9)	1 (2.2)	2 (2.1)
Other	3 (5.8)	2 (4.4)	5 (5.2)
None	11 (21.2)	9 (20.0)	20 (20.6)
Place of birth, <i>N</i> (%)			
North America	43 (82.7)	40 (88.9)	83 (85.6)
Europe	5 (9.6)	2 (4.4)	7 (7.2)
Latin/South America	0 (0)	3 (6.7)	3 (3.1)
Other	4 (7.7)	0 (0)	4 (4.1)
Marital status, <i>N</i> (%)			
No partner	8 (15.4)	8 (17.8)	16 (16.5)
Dating	17 (32.7)	16 (35.6)	33 (34.0)
Living with partner	22 (42.3)	16 (35.6)	38 (39.2)
Married	5 (9.6)	5 (11.1)	10 (10.3)
Annual income, <i>N</i> (%)			
\$0–\$19,999	17 (32.7)	17 (37.8)	34 (35.1)
\$20,000–\$39,999	11 (21.2)	13 (28.9)	24 (24.7)
\$40,000–\$59,999	15 (28.8)	6 (13.3)	21 (21.6)
>\$60,000	9 (17.3)	9 (20.0)	18 (18.6)

Note. GCBT = group cognitive-behavioral therapy.

Table 2
Dependent Measures by Time of Assessment and Treatment Condition

Measure and group	Pretreatment <i>M (SD)</i>	Posttreatment <i>M (SD)</i>	Follow-up <i>M (SD)</i>
Pain			
Pain during intercourse (NRS)			
GCBT	7.29 (2.52)	5.46 (2.75)	5.21 (2.87)
Topical steroid	7.67 (2.13)	5.67 (3.32)	5.87 (3.07)
MPQ-PPI			
GCBT	3.55 (1.13)	3.02 (1.28)	2.65 (1.36)
Topical steroid	3.50 (1.13)	2.82 (1.30)	3.07 (1.29)
Sexual function			
FSFI			
GCBT	20.04 (5.03)	23.03 (7.59)	22.33 (7.75)
Topical steroid	20.46 (5.18)	22.53 (7.63)	23.30 (7.20)
Intercourse frequency			
GCBT	4.85 (5.69)	5.12 (5.67)	6.70 (7.45)
Topical steroid	2.59 (2.90)	3.93 (5.15)	4.47 (4.97)
Psychological Adjustment			
PCS			
GCBT	27.90 (10.18)	19.29 (11.41)	19.62 (11.78)
Topical steroid	25.89 (12.60)	22.16 (12.03)	21.00 (11.85)
Self-Efficacy			
GCBT	66.42 (13.89)	74.72 (14.84)	75.81 (15.86)
Topical steroid	61.30 (12.80)	68.43 (18.31)	71.39 (17.29)

Note. NRS = Numerical Rating Scale; GCBT = group cognitive-behavioral therapy; MPQ-PPI = McGill Pain Questionnaire–Present Pain Intensity; FSFI = Female Sexual Function Index; PCS = Pain Catastrophizing Scale; Self-Efficacy = Painful Intercourse Self-Efficacy Scale.

6-month-follow-up. There was a significant Time \times Group interaction, with GCBT participants reporting significantly more improvements in catastrophizing from pre- to posttreatment than the topical steroid participants. There were no interaction effects for pain self-efficacy. ANCOVA analyses did not show additional group differences.

Treatment Credibility and Adherence

At pretreatment, participants assigned to the topical steroid rated their confidence in this treatment significantly higher than those assigned to GCBT, $F(1, 73) = 3.83, p < .05$. Participants in the GCBT attended, on average, 82% of therapy sessions, and completed 62% of their homework exercises. Participants in the topical steroid arm completed, on average, 88% of the 13-week treatment, and applied the cream 75% of the time during those weeks. There were no significant correlations between treatment adherence and 6-month follow-up pain measures.

Global Participant Ratings of Improvement and Satisfaction

Participant ratings of satisfaction and global improvement by time of assessment and treatment group are shown in Table 4. As a whole, GCBT participants were significantly more satisfied with their treatment than the topical steroid participants. There were no significant differences between groups in terms of self-reported improvements in pain. GCBT participants reported significantly greater improvements in sexuality than the topical steroid participants.

Treatment success was defined as self-reported good to great improvement or complete relief of pain on the subjective improve-

ment measure of the participant ratings of global improvement for (a) pain (scores of 1, 2, or 3) and (b) sexuality (scores of 1 or 2). At 6-month follow-up, 68.6% of GCBT participants reported good improvement to complete relief of pain, compared to 44.8% of the topical steroid participants. Only 17.1% of GCBT participants reported no improvement in pain, in contrast to 48.3% of the topical steroid participants, $\chi^2(2, N = 64) = 7.26, p < .05$. As for sexuality, 71.4% of GCBT and 41.4% of the topical arm participants reported good to great improvements, whereas 11.4% of GCBT participants and 37.9% of the topical treatment participants reported no improvement, $\chi^2(2, N = 64) = 7.34, p < .05$.

Discussion

The aim of the present randomized clinical trial was to compare the efficacy of GCBT and a topical steroid in the treatment of PVD. Pain, sexuality and psychological adjustment outcomes at posttreatment and 6-month follow-up were examined using an intention to treat strategy, in addition to participant global ratings of improvement. Two main conclusions can be drawn from the results of this study: (a) GCBT and a topical steroid yield significant improvements in key outcomes at posttreatment and 6-month follow-up for women with PVD; (b) GCBT is significantly more successful regarding decreased pain at 6-month follow-up and pain catastrophizing at posttreatment, as well as better treatment satisfaction and global pain and sexuality-related improvements.

Pain and sexual function significantly improved from pre- to posttreatment and from pretreatment to 6-month follow-up for participants in both treatment conditions, suggesting that each modality was successful in alleviating the two main complaints of women with PVD—pain during intercourse and sexual dysfunction. The Initiatives on Methods, Measurements, and Pain Assess-

Table 3

Random Coefficient Analysis Models for the Outcome Measures at Pretreatment, Posttreatment, and at 6-Month Follow-Up; Group Comparison; and Interaction Effects ($N = 97$)

Variable	<i>b</i>	<i>SE</i>	<i>p</i>	<i>d</i>	95% CI
Model for pain during intercourse (NRS)					
Constant	7.841				
Time (t_1-t_2)	-2.805	.514	.000**	-1.06	[-3.82, -1.79]
Time (t_1-t_3)	-2.364	.527	.000**	-.86	[-3.40, -1.32]
Group	-.552	.553	.319	-.19	[-1.64, .54]
Time (t_1-t_2) × Group	.419	.694	.547	.14	[-.95, 1.79]
Time (t_1-t_3) × Group	-.283	.727	.698	-.09	[-1.72, 1.15]
Model for pain: MPQ-PPI					
Constant	3.582				
Time (t_1-t_2)	-.996	.226	.000**	-.85	[-1.44, -.55]
Time (t_1-t_3)	-.623	.231	.008**	-.50	[-1.08, -.17]
Group	-.031	.241	.899	-.02	[-.51, .45]
Time (t_1-t_2) × Group	.263	.304	.389	.21	[-.34, .86]
Time (t_1-t_3) × Group	-.663	.319	.039*	-.54	[-1.29, -.03]
Model for sexual function: FSFI					
Constant	20.079				
Time (t_1-t_2)	3.019	1.364	.028*	.41	[.32, 5.71]
Time (t_1-t_3)	3.833	1.395	.007**	.53	[1.08, 6.59]
Group	-1.287	1.450	.376	-.17	[-4.15, 1.57]
Time (t_1-t_2) × Group	2.086	1.854	.262	.28	[-1.58, 5.75]
Time (t_1-t_3) × Group	.945	1.941	.627	.13	[-2.89, 4.78]
Model for sexual function: Intercourse frequency					
Constant	2.384				
Time (t_1-t_2)	2.164	1.097	.050*	.38	[-.00, 4.33]
Time (t_1-t_3)	2.172	1.161	.064	.38	[-.12, 4.47]
Group	2.473	1.180	.038*	.43	[.14, 4.80]
Time (t_1-t_2) × Group	-1.908	1.493	.203	-.33	[-4.86, 1.04]
Time (t_1-t_3) × Group	.699	1.597	.662	.12	[-2.46, 3.86]
Model for psychological adjustment: PCS					
Constant	25.886				
Time (t_1-t_2)	-5.447	1.789	.003**	-.46	[-8.98, -1.91]
Time (t_1-t_3)	-6.836	1.811	.000*	-.59	[-10.42, -3.26]
Group	2.017	2.284	.379	.17	[-2.49, 6.53]
Time (t_1-t_2) × Group	-6.237	2.398	.010**	-.53	[-10.98, -1.50]
Time (t_1-t_3) × Group	-4.047	2.500	.108	-.34	[-8.99, .89]
Model for psychological adjustment: Self-Efficacy					
Constant	61.303				
Time (t_1-t_2)	10.534	2.636	.000**	-.67	[5.33, 15.74]
Time (t_1-t_3)	15.009	2.701	.000**	1.01	[9.67, 20.34]
Group	5.121	3.078	.098	.31	[-.96, 11.20]
Time (t_1-t_2) × Group	.798	3.561	.823	.05	[-6.24, 7.83]
Time (t_1-t_3) × Group	-2.233	3.735	.551	-.13	[-9.61, 5.15]

Note. NRS = Numerical Rating Scale; MPQ-PPI = McGill Pain Questionnaire–Present Pain Intensity; FSFI = Female Sexual Function Index; PCS = Pain Catastrophizing Scale; Self-Efficacy = Painful Intercourse Self-Efficacy Scale; t_1 = pre-treatment; t_2 = posttreatment; t_3 = 6-month follow-up; CI = confidence interval. All models had random intercepts. For FSFI, five couples who were sexually inactive in the last 4 weeks were excluded from analyses. * $p < .05$. ** $p < .01$.

ment in Clinical Trials recommendations for clinical trials in chronic pain state that changes in perceived pain intensity from baseline of approximately 2 points on a 0-to-10 NRS, or 30%, represent at least meaningful decreases in chronic pain (Dworkin et al., 2008). Based on these recommendations, the changes in pain during intercourse in the two conditions reflect a clinically significant improvement. GCBT also yielded significantly better outcomes on the Present Pain Intensity scale of the MPQ from

pretreatment to 6-month follow-up, as well as better self-reported global improvements in pain. Considering that a cognitive-behavioral treatment takes into account more dimensions of the pain experience including thoughts, emotions and behaviors—not to mention the important psycho-education component in the context of this misunderstood pain problem—it could contribute to break the negative cycle of pain by its focus on the multiple maintenance factors of PVD. Another mechanism of change could

Table 4
Participant Ratings of Satisfaction and Global Improvement by Time of Assessment and Treatment Group

Measure and group	Posttreatment <i>M</i> (<i>SD</i>)	Follow-up <i>M</i> (<i>SD</i>)	Group		Group × Time	
			<i>t</i>	<i>p</i>	<i>t</i>	<i>p</i>
Satisfaction			3.59	.001	.03	.975
GCBT	7.68 (1.44)	7.64 (1.72)	<i>d</i> = .88		<i>d</i> = -.01	
Topical steroid	5.32 (3.53)	5.26 (3.84)				
Improvement: Pain			-1.90	.061	1.66	.102
GCBT	3.37 (.97)	3.03 (1.34)	<i>d</i> = -.47		<i>d</i> = .29	
Topical steroid	3.58 (1.36)	3.62 (1.47)				
Improvement: Sexuality			-2.15	.034	-0.38	.707
GCBT	1.95 (.96)	2.00 (1.11)	<i>d</i> = -.53		<i>d</i> = -.08	
Topical steroid	2.68 (1.35)	2.62 (1.40)				

Note. GCBT = group cognitive-behavioral therapy.

be the group aspect of this treatment, whereby women's documented sense of isolation and invalidation may be significantly relieved by the support and empathy of other group members (Ayling & Ussher, 2008; Nguyen, Ecklund, Macle hose, Veasley, & Harlow, 2012; Nguyen, Turner, Rydell, Macle hose, & Harlow, 2013).

Sexual function was significantly more improved at 6-month follow-up in women in the GCBT group compared to those in the topical steroid group, as was their self-reported global improvement in sexuality. These findings suggest that making sexual dysfunction a target of intervention is clinically meaningful for women with PVD and necessary for significant improvements in this area of functioning. Nevertheless, the mean posttreatment and 6-month follow-up sexual function scores for both groups were still within the clinical range (Wiegel, Meston, & Rosen, 2005), and mean intercourse frequency was below that of population norms for women aged 25–29 (7.5 times/month; Laumann, Gagnon, Michael, & Michaels, 1994). Given the pervasive impairment in all phases of sexual function reported by women with PVD (Desrochers et al., 2008), it is possible that a group therapy intervention may not allow for enough individual patient-tailored strategies to be implemented, in particular those targeting partner and relationship variables, which have been shown to be important to women (Baumeister, 2000; Graham, 2010). Recent studies show that partner responses play a role in pain intensity and sexual function and satisfaction of women with PVD (N. Rosen, Bergeron, Glowacka, Delisle, & Baxter, 2012; N. Rosen, Bergeron, Leclerc, Lambert, & Steben, 2010; N. Rosen et al., 2014). Affective variables such as intimacy and romantic attachment have also been associated with sexuality outcomes in women with PVD (Bois, Bergeron, Rosen, McDuff, & Gregoire, 2013; Leclerc et al., 2014). Taken together, findings suggest that a group therapy, although helpful, may not be the optimal treatment for women with PVD, and efforts to engage the partner in future treatment developments should be made.

Although positive, improvements in sexuality outcomes over time for both groups may not solely be accounted for by reductions in pain, as pain and sexual function, including frequency of sex, are usually not highly correlated in this population (Bergeron et al., 2011), and sometimes not at all (Masheb et al., 2009). Women with vulvovaginal pain engage in sex for many different reasons independent of pain intensity, including to meet their partner's

sexual needs, maintain the image of an adequate sexual partner, and out of a sense of obligation (Ayling & Ussher, 2008; Brauer, Lakeman, van Lunsen, & Laan, 2014; Elmerstig, Wijma, & Swahnberg, 2013). It is also possible that taking part in a treatment study encouraged women and their partners to be more hopeful, less avoidant, and to engage in more intercourse attempts.

Pain catastrophizing and self-efficacy also significantly improved for both groups from pre- to posttreatment and from pretreatment to 6-month follow-up, with participants in the GCBT group reporting greater reductions in catastrophizing at posttreatment. Given that GCBT targets pain catastrophizing directly and is the most robust psychological predictor of pain and disability in other chronic pain samples (Sullivan et al., 2001), this finding is not surprising. In a cross-sectional study involving women with PVD, lower self-efficacy was found to explain a unique portion of the variance in sexual dysfunction, and together with higher catastrophizing, fear of pain, and hypervigilance, was associated with worse self-reported pain during intercourse (Desrochers et al., 2009). In a 2-year prospective study involving 222 women with PVD, Davis et al. (2014) found that participants who reported higher self-efficacy at time one reported greater declines in pain, greater increases in sexual satisfaction, and greater declines in sexual dysfunction over the two time points, and that the observed relationship between changes in self-efficacy and changes in pain was partially mediated by changes in avoidance (more intercourse attempts). Taken together, findings from the present study in conjunction with those from other cross-sectional and prospective studies suggest that pain catastrophizing and self-efficacy are relevant variables to target in psychological interventions for dyspareunia.

As for the clinical importance of individual patient improvements, these were captured using the participant ratings of treatment satisfaction and global self-reported improvements in pain and sexuality. Findings showed that participants in the GCBT condition were significantly more satisfied with their treatment than those in the topical steroid condition at posttreatment and 6-month follow-up, in addition to reporting significantly more improvements in their pain and sexuality. This high satisfaction with a cognitive-behavioral intervention for vulvovaginal pain is consistent with results of the two other randomized trials in this area (Bergeron et al., 2001b; Masheb et al., 2009), although

women having received a surgical intervention for this pain were also very satisfied (Bergeron et al., 2001b).

The present study is not without limitations. Only one subgroup of women with dyspareunia was included—PVD—which limits the generalizability of the findings. Depression and anxiety, common endpoints in randomized trials for chronic pain, were not measured. Given the multitude of medical management options available to women with PVD, our topical arm may not be representative of other medical treatments delivered by physicians. The inclusion of a placebo cream would have further strengthened the design of the study. Finally, our comparison group reflected standard care but did not control for professional attention, which could account for some of the findings, and the period during which the study took place is somewhat dated.

Strengths of this study include the use of a randomized trial design and intent to treat analyses, which are more conservative and preserve the presumed equivalency of both groups allowed by randomization, in addition to strict selection criteria and monitoring of treatment delivery, resulting in high internal validity. Using a wide range of outcome measures targeting the multiple dimensions of the pain experience and tapping into the different facets of change also represents a strength of the present trial.

Findings corroborate those of other studies demonstrating the efficacy of CBT for chronic pain, in particular dyspareunia (Masheb et al., 2009), yet are not in line with research showing that CBT only improves pain in the short-term, at posttreatment (Williams, Eccleston, & Morley, 2012). It is possible that dyspareunia is a unique pain problem, uncharacteristic of most musculoskeletal conditions. Indeed, PVD rarely involves any spontaneous pain but rather is provoked, and in that sense, somewhat predictable, making it potentially easier to manage than other forms of chronic pain. Clinically, the success of CBT in the present study warrants its recommendation as a first line treatment for PVD. This may prove challenging to implement in primary care and gynecology practices, although it could be delivered by nurse practitioners and other mental health professionals already present in some of these settings. Nevertheless, given that in comparison to the topical steroid, GCBT resulted in better treatment gains for pain, coping and sexuality, efforts to integrate this treatment into current best practices should be deployed.

In conclusion, results support a biopsychosocial model of pain where both medical and cognitive-behavioral treatments can improve various aspects of PVD. Findings suggest that GCBT may yield a positive impact on more dimensions of dyspareunia than does a topical treatment, in addition to participants being more satisfied with this intervention. Multimodal approaches incorporating medical and psychological treatments may target additional dimensions simultaneously and are in need of empirical validation.

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