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A Randomized Clinical Trial for Women with Vulvodynia: Cognitive-behavioral Therapy vs. Supportive Psychotherapy

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Abstract

Many treatments used for women with vulvodynia are based solely upon expert opinion. This randomized trial aimed to test the relative efficacy of cognitive-behavioral therapy (CBT) and supportive psychotherapy (SPT) in women with vulvodynia. Of the 50 participants, 42 (84%) completed 10-week treatments and 47 (94%) completed one-year follow-up assessments. Mixed effects modeling was used to make use of all available data. Participants had statistically significant decreases in pain severity ($p < .001$) with 42% of the overall sample achieving clinical improvement. CBT, relative to SPT, resulted in significantly greater improvement in pain severity during physician examination ($p = .014$), and greater improvement in sexual function ($p = .034$), from pre- to post-treatment. Treatment effects were well maintained at one-year follow-up in both groups. Participants in the CBT condition reported significantly greater treatment improvement, satisfaction and credibility than participants in the SPT condition ($p < .05$). Findings from the present study suggest that psychosocial treatments for vulvodynia are effective. CBT, a directed treatment approach that involves learning and practice of specific pain-relevant coping and self-management skills, yielded better outcomes and greater patient satisfaction than a less directive approach.

Keywords

vulvodynia; vulvar pain; vestibulitis; dysesthetic; cognitive-behavioral therapy

Introduction

Vulvodynia is generally regarded as an underdiagnosed, difficult-to-treat gynecological disorder characterized by chronic vulvar pain, physical disability, sexual dysfunction and affective distress [19]. Lifetime and point prevalence rates of chronic vulvar pain range from 10–16% and 4–7%, respectively [2,15]. While previously conceptualized as a condition with two subtypes (i.e., vulvar vestibulitis and dysesthetic vulvodynia, also referred to as localized and generalized vulvodynia), recent studies have called into question the validity of these subtypes [21,29]. The diagnosis is primarily based on exclusion of all other conditions (e.g.,

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infections, dermatoses) that may better account for the symptoms. Many factors (e.g., embryonic abnormalities, urinary oxalates, genetic factors, hormonal factors, inflammation, infection, and neurological factors) have been proposed as possible causal agents for vulvodynia, yet the etiology remains largely unknown and most likely there is not a single cause. Numerous medical treatments have been investigated but few controlled trials have been performed to verify the efficacy of these treatments [14].

Behavioral interventions for chronic pain that emphasize a self-management approach have become commonly available alternatives to more traditional medical and rehabilitation therapies [8,12]. In particular, cognitive-behavioral therapy (CBT) has been shown to be an effective treatment for chronic pain that assists the patient in developing a perspective of personal control of their condition through the use of self-management skills [31]. Significant reductions in pain severity, disability and affective distress, as well as significant reductions in healthcare use have been repeatedly documented in randomized controlled clinical trials [27]. Support for the efficacy of CBT for the treatment of vulvodynia has been investigated in two uncontrolled [1,32] and one well-controlled, randomized study [5]. When group CBT was provided to women with vulvar vestibulitis, a 21–38% decrease in pain severity was reported [5]. While reduction in pain severity was greater for surgery than CBT, improvements in psychological and sexual function were equivalent. CBT resulted in lower attrition and fewer complications than surgery. Despite these promising findings, the sheer paucity of research designed to evaluate the efficacy of psychological interventions for women with vulvodynia encourages further controlled investigation in this area. Efforts to examine the efficacy of a behaviorally oriented and coping skills based approach relative to a less directive psychological intervention may help to elucidate the role of such active interventions in promoting improved outcomes such as pain and sexual functioning.

To date, treatment decision making for vulvodynia is largely based on expert opinion. Preliminary evidence for the use of CBT in a subgroup of women with vulvodynia seems promising [6]. CBT has not been investigated with a more general sample of women with vulvodynia, and the treatment has not been tested against other psychosocial treatments. The purpose of the present study was to conduct a randomized controlled trial to evaluate the efficacy of CBT for the treatment of vulvodynia in comparison to another form of psychotherapy without behavioral interventions but matched for number and duration of treatment sessions.

Methods

Participants

Participants in the study were 50 women with vulvodynia who were enrolled from September 2000 until December 2004 at the Yale School of Medicine (YSM). Participants responded to advertisements in local newspapers or referrals from healthcare providers. Women with known or suspected vulvodynia, or with vulvar or vaginal itching, stinging or burning, and/or painful intercourse were sought through these recruitment mechanisms to participate in a 10-week treatment study to decrease pain, improve sexual functioning and enhance mood. Upon phone screening, potential participants who reported vulvar symptoms as described above and/or painful intercourse for at least a six-month duration, were 21-years or older, and were not pregnant were invited for an interview where the study was explained and written informed consent was obtained. The study was approved by the investigational review board at the YSM. No adverse events were reported as a consequence of this study. All assessments and treatments were provided at no costs to participants.

Doctoral-level research psychologists conducted two semi-structured interviews. Each participant's social history, psychiatric and medical histories, and history and current status of

vulvar symptoms (e.g., age of onset of symptoms) were obtained from a semi-structured biopsychosocial interview developed for this study. The Structured Clinical Interview for DSM-IV Axis I Disorders [10] was used to assess for psychiatric exclusions and history of Axis I psychiatric comorbidity. Potential participants were excluded at this point in the assessment if they were psychotic, suicidal, or substance dependent. Also excluded were individuals with a life-threatening illness, or potential participants who had initiated psychotherapy, psychopharmacologic treatment or pain medication within one month prior to the assessment.

Participants were independently evaluated by two study gynecologists according to methods used in previous studies [20,21]. Each evaluation included a standardized medical history, pelvic examination and bimanual palpation, and laboratory findings. Diagnosis of either vulvar vestibulitis (also referred to as localized or provoked vulvodynia) or dysesthetic vulvodynia (also referred to as generalized vulvodynia or unprovoked vulvodynia) by both gynecologists was needed using information from the existing literature at the time the study was developed [11,24]. Gynecologists were blind to findings from the other evaluation. Laboratory tests included vaginal culture, DNA probe, pap smear and urinalysis. Diagnoses ruled out included candida, herpes, trichomoniasis, bacterial vaginosis, gonorrhea, chlamydia, condyloma and pregnancy. Persons with other diagnoses known to cause vulvar pain were excluded (e.g., dermatoses, infection, recurrent candida, or other gynecologic conditions). Potential participants who had a treatable vaginal infection at the time of assessment were eligible to participate if they were treated, and continued to report vulvar symptoms after reevaluation. Atrophy as a primary cause of vulvar symptoms was ruled out by a minimum six-week trial of hormone replacement therapy or topical estrogen.

Figure 1 summarizes the recruitment and flow of participants throughout the study. Telephone screening was conducted on 234 individuals. Of those screened, 114 met the initial screening criteria and were further evaluated in-person. Of the 114 who began in person evaluations, 15 were not eligible for the following reasons: asymptomatic upon gynecological examination (n=4), contact dermatitis (n=2), lichen sclerosis (n=2), psoriasis (n=1), pain located in the pelvis (n=1), episiotomy scarring successfully treated with topical estrogen (n=1), menopausal symptoms (i.e., atrophy and dryness) successfully treated with topical estrogen (n=2), Bartholin cyst (n=1), and visible lesions (n=1); 24 were not interested for the following reasons: time commitment (n=7), travel to study location (n=4), already receiving talk therapy (n=1), not interested in talk therapy (n=1), interested in medication treatment (n=1), changed pain/psychopharmacology medication regimen (n=1), husband did not want patient to participate (n=1), reason unknown (n=8); and 25 no showed or cancelled prior to the first appointment.

Fifty women met all eligibility criteria, completed assessments and were randomized to treatments from a computer generated randomization schedule created without any restrictions. Participants were randomized in the order in which they completed all assessments and assignment was not revealed until the assessments were completed. Study gynecologists performing follow-up examinations were blind to treatment assignment, however, participants and research therapists were not. Of the 50 randomized participants, 42 (84%) completed treatment and 8 (16%) dropped out. Despite these dropout rates, we were able to obtain post-treatment and follow-up assessments on a larger percentage of participants. Post-treatment evaluation was completed by 48 (96%) participants, and six- and twelve-month evaluations were completed by 47 (94%) participants.

Measures

Pain Measures - Physician Ratings—Study gynecologists obtained the following ratings intended to correspond with Friedrich's three criteria for vulvar vestibulitis: the Speculum Rating, the Cotton-swab Rating, and the Erythema (redness of the skin) Rating.

The Speculum Rating was a 4-point rating (i.e., absent (0), mild (1), moderate (2), and severe (3)), based on pain provoked at the introitus with speculum insertion. Narrow (two centimeter width), prewarmed, metal speculums were used. Scores were calculated by averaging the two baseline ratings. This measure has been shown to be valid and reliable [21].

The Cotton-swab Rating involved pain ratings of point tenderness provoked by cotton-swab palpation at each of six sites within the vulvar vestibule (i.e., clitoris, perineum, right and left labia minora, and right and left labia majora) and rated on a 4-point scale: absent (0), mild (1), moderate (2), and severe (3). Scores for the six sites were added and averaged for the two baseline ratings. The Cotton-swab Rating was performed before the Speculum Rating. This measure has been shown to be valid and reliable [21].

The Erythema Rating was a 4-point rating, using the same scale above, for the presence and degree of erythema.

Pain Measures – Self-report—The Pain Severity subscale of the West Haven-Yale Multidimensional Pain Inventory (MPI; [18]) is a widely used multidimensional self-report instrument designed to assess chronic pain that has demonstrated reliability and validity. The 3-item subscale contains items such as “Rate the level of your pain at the present moment” on a scale of 0 (no pain) to 6 (very intense pain) was used.

The McGill Pain Questionnaire (MPQ; [25]) is a widely used measure of pain severity. The questionnaire is comprised of 20 sets of three to five descriptive words placed in order of increasing severity or intensity. The measure is used to assess three domains of pain: sensory affective and evaluative. Subjects are instructed to circle one word within each set that best describes their pain. The measure has demonstrated acceptable reliability, and face, construct, discriminant and concurrent validity [28]. Total scores range from 0 to 78.

For both the MPI and MPQ subjects were instructed to respond to items based on their vulvar pain; higher scores reflected greater pain severity.

Sexual Function—The Female Sexual Function Index (FSFI; [30]) is a 19-item multidimensional, self-report measure of sexual function. The measure has received empirical support for its reliability in several patient samples and for its ability to discriminate between samples of women with sexual dysfunction and healthy samples [20,26,30]. The FSFI includes both frequency items (“Over the past 4 weeks, how **often** did you experience discomfort or pain during vaginal penetration?”) and intensity items (“Over the past 4 weeks, how would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration?”). The FSFI Full scale and Pain subscale (i.e., measures of overall sexual function and dyspareunia (i.e., painful sexual intercourse), respectively) were used in this study. Higher scores reflect better functioning.

Emotional Function—The Beck Depression Inventory (BDI; [3]) is a psychometrically sound, widely used inventory of the cognitive, affective, motivational and somatic symptoms of depression with adequate internal consistency, acceptable short-term test-retest reliability and good convergent validity with clinician ratings of depressive symptoms [4]. Higher scores reflect greater depressive symptom severity.

The Pain Anxiety Symptoms Scale (PASS; [23]) is a 40-item measure of fear of pain intended to measure four aspects of anxiety associated with clinical pain symptoms: cognitive anxiety, fear of pain, escape and avoidance, and physiological anxiety. The measure has been shown to be internally consistent and valid [23]. The frequency of each item (e.g., I think that if my pain gets too severe, it will never decrease) is rated on a 6-point scale from 0 (never) to 5

(always). Higher scores reflect more frequent and more numerous anxiety responses. For the purposes of this study, subjects were instructed to respond to items based on their vulvar pain and the total score was used.

Treatment Acceptability—Global Treatment Improvement was measured with the single-item, “Up to what point do you feel your vulvar pain has improved following the treatment you received in this study?” Responses included: 0=worse, 1=no improvement, 2=little improvement, 3=moderate improvement, 4=great improvement, and 5=complete cure.

Treatment Satisfaction was measured with the single-item, “On a scale of 0 to 10, how would you rate your overall satisfaction with the treatment you received?” Responses ranged from “completely dissatisfied” to “completely satisfied.”

Treatment Credibility was measured with a 5-item scale adapted from Borkovec and Nau [7] and completed after treatment sessions one and ten (i.e., post-treatment). Items such as, “How logical does the treatment seem to you?” were rated from 0 to 10.

Treatments

Treatments were administered in 10 weekly individual 60-minute sessions by doctoral level research therapists experienced in delivering these therapies. Treatment manuals were developed specifically for this study and are described below. Therapists conducted an equal number of CBT and SPT treatments, and training and supervision in the delivery of these treatments involved weekly face-to-face meetings with the two study investigators (RM and RK). All treatment sessions were audio-taped. Audio-tapes for each therapist’s first two cases of CBT and first two cases of SPT were reviewed by the principal investigator (RM) for training purposes. Additional tapes were reviewed in supervision on an ad hoc basis to monitor that treatment manuals were being followed. Finally, one tape from each participant’s treatment (i.e., 50 tapes or 10% of treatment sessions) was chosen at random and rated by a blind tape rater. The rater was asked to decide whether each tape was a CBT or SPT session, and then rate her confidence in the decision on a scale from 0 to 10 ($M=9.9$, $SD=0.4$). 100% of the tapes were correctly identified as CBT or SPT.

Cognitive-behavioral Therapy (CBT)—Therapists followed a CBT treatment manual for chronic pain that was developed by Kerns and colleagues [17] and adapted for women with vulvodynia. The goal of the treatment was to assist participants in taking personal control of their vulvar pain by creating an understanding of the relationship of among thoughts, feelings and behaviors, on pain, and sexual and emotional function. Participants were taught self-management skills that alter thoughts, feelings and behaviors. The treatment involved three overlapping phases: orientation to a self-management approach, skills acquisition, and skills practice. The structure of sessions was similar across all sessions. An agenda was made explicit by the therapist at the beginning of each session with the patient having an opportunity to add items to the agenda. Sessions then typically proceeded with a brief review of the prior session and a review of intersession homework and goals. The majority of the sessions involved the introduction of new information and/or pain coping skills (described in the next paragraph), and practice of skills in session. In addition to providing the structure of sessions and teaching of skills, therapists used motivational enhancement, role-playing, problem-solving, and contingent reinforcement to increase patient adherence. The final component of each session involved session review and collaboration in the development of goals and homework for the coming week.

Self-management skills included behavioral, sex therapy, cognitive, and relaxation skills that were practiced both in session and at home. Behavioral skills included the following: gate-control, activity pacing, and goal setting. The *gate-control skill* involved identifying and

eliminating behaviors that initiated or increased vulvar pain (gate-opening behaviors such as wearing tight clothing), and increasing behaviors that eliminated or reduced vulvar pain (gate-closing behaviors such as relaxation). *Activity pacing* involved altering and/or limiting activities that initiated or increased vulvar pain (such as taking breaks when sitting for long periods). *Goal setting* involved identifying observable behaviors (e.g., exercising 30 minutes three times per week) and setting weekly goals to attain the desired duration and/or frequency by the end of treatment. Sex therapy skills included sensate focus (that could be done alone or with a partner) and assertive communication regarding sexual relations. The cognitive component of the treatment involved a series of cognitive skills. This included identifying triggers for negative mood states (e.g., increased vulvar pain following a gynecologic visit), identifying automatic negative thoughts (e.g., this vulvar pain will never go away), identifying the cognitive distortion associated with the automatic negative thought (e.g., all-or-nothing thinking), challenging negative thoughts (e.g., I have had terrible vulvar pain following exams before and it eventually subsides), and finally restructuring the negative thought (e.g., the increased level of vulvar pain I have now is uncomfortable, but it is also time-limited and manageable). A series of relaxation skills were taught in a stepwise fashion beginning with diaphragmatic breathing, progressive muscle relaxation, and finally relaxation that was specific to the pelvic floor musculature.

Supportive Psychotherapy (SPT)—SPT, a non-directive talk therapy, was chosen to control for the amount of treatment (number and duration of sessions) and therapist contact while providing a contrast to the directed approach of CBT. SPT was specifically chosen because it lacks specific behavioral interventions that have shown to be effective in other forms of short-term talk therapies such as interpersonal psychotherapy. SPT in the present study followed a patient-centered approach. Therapists were trained to assist participants in expressing their feelings while not making specific suggestions for how the person might wish to change. The therapist's role was three-fold: 1) to have unconditional positive regard (i.e., a positive, accepting attitude toward wherever the patient was at that moment), 2) to engage in empathic understanding (i.e., the ability to listen to and sense both the verbal and non-verbal communication of the patient's thoughts, feelings and personal meanings), and 3) to mirror (i.e., the technique of communicating this understanding back to the patient thus helping them to explore and understand their feelings for themselves).

SPT sessions in the present study were initiated by the therapist who began with, "How has your week been generally and with regard to your vulvar pain?" The remainder of each session was directed by the participant and unstructured, and generally focused on the woman's complaints of vulvar pain and associated problems. Therapists were instructed not to make interpretations, problem-solve, challenge or restructure cognitions, or initiate goal-setting.

Overview of Analyses

Participants randomized to CBT (25/50) were compared to those randomized to SPT (25/50) on demographic, descriptive, psychiatric, and clinical variables at baseline using chi-square analysis for categorical variables and analysis of variance (ANOVA) for dimensional variables. A correlation analysis was conducted on the outcome measures of pain severity, sexual function and emotional function at baseline. These measures were administered at five assessment points (baseline, post-treatment, and three-month, six-month and one-year follow-ups) and maximum likelihood mixed model analysis, performed with SPSS 14.0 Linear Mixed Models, was performed to assess changes over time in these outcomes. An a priori power analysis suggested that 25 participants per group, taking into account a 15% dropout rate, were needed to detect medium effect sizes with power of .89 using two-tailed tests ($\alpha = .05$). This power analysis was conservative as the original plan was to perform intent-to-treat, as opposed to maximum likelihood, analysis. Physician outcome measures of pain severity were

administered at only three assessment points (baseline, post-treatment and six-month follow-up) to reduce participant burden and discomfort. Analyses for the sexual function outcome measures (FSFI Pain subscale and FSFI Full scale) were performed only on the 42 participants who reported having a sexual partner. Main effects for time (baseline to post-treatment), and interaction effects for time by treatment condition, were examined to evaluate the acute treatment effects. Main effects for time (post-treatment to one-year follow-up), and interaction effects for time by treatment condition, were analyzed to examine the maintenance effects of these treatments. Three-month and six-month follow-up data were included in the analyses for maintenance effects. Global measures of treatment improvement and satisfaction, and a measure of treatment credibility, were analyzed with ANOVA.

Results

Demography, Descriptive Characteristics and DSM-IV Psychiatric Comorbidity

Table 1 summarizes the demography of participants randomized to each treatment condition. The mean age of subjects was 43.0 years, and age ranged from 21 to 68. Overall, of the 50 randomized participants, 82% (N=41) were Caucasian, 66% (N=33) were college graduates, 68% (N=34) were married, and 76% (N=38) were working. Analyses revealed no significant differences between the treatment groups on age, ethnicity, education, marital status and employment status.

Table 2 summarizes the descriptive characteristics of participants randomized to each treatment condition. ANOVAs revealed no significant differences between groups on age of onset, number of years with vulvar pain, or age at first intercourse or menses. Age of onset of vulvar pain ranged from 13 to 63.5 years, and vulvar pain had been present from six months to 32 years. Chi-square analyses revealed no significant differences between the treatments on type of onset (sudden or gradual), presence of lifelong dyspareunia, family history of vulvar pain, parity, number of chronic pain sites, sexual abuse history or current major depressive disorder.

The bottom of Table 2 shows results of chi-square analysis for DSM-IV comorbidity. No significant differences were found between the treatment conditions for any Axis I disorder, major depressive disorder, anxiety disorders and substance use disorders. Overall, 66% (n=33) of the sample reported at least one lifetime DSM-IV Axis I psychiatric diagnosis. Major depressive disorder was the most frequently reported disorder (n=23, 46%) followed by anxiety disorders (n=21, 42%). Sixteen percent (n=8) reported a history of substance abuse.

Associations among Outcome Variables

A correlation analysis was performed with the outcome measures of pain severity, sexual function and emotional function at baseline (see Table 3). The physician ratings of pain (cotton-swab and speculum) were significantly correlated to each other ($r=.64$, $p<.001$) whereas the self-report measures of pain severity (MPI and MPQ) were not. The cotton-swab rating was significantly related to the MPQ ($r=.29$, $p=.044$), while the correlations between the speculum rating and the MPQ and MPI were not statistically significant.

Both measures of sexual function (i.e., dyspareunia and overall sexual function) were significantly correlated with each other ($r=.52$, $p<.001$). Only dyspareunia (FSFI pain subscale) was related to the speculum rating ($r=-.46$, $p=.002$) suggesting that these two measures were representative of introital pain, especially given that dyspareunia was not related to the self-report measures of pain, or to symptoms of depression (BDI) and anxiety (PASS). In contrast, overall sexual function was related to symptoms of depression and anxiety ($r=-.46$, $p=.002$, and $r=-.41$, $p=.007$, respectively). However, overall sexual function was not related to the physician or self-report measures of pain.

As expected, the measures of emotional function (i.e., the BDI and the PASS) were significantly related to each other ($r=.54$, $p<.001$).

Baseline Clinical Characteristics and Retention Rates

Table 4 summarizes the baseline clinical characteristics for the overall sample and statistical tests for differences between the treatment groups at baseline for measures used to assess treatment outcome. Results of ANOVA revealed no significant differences between groups on any of the measures for pain severity, sexual function and emotional function. Of the 50 participants randomized to treatment, 84% were retained ($n=42$). Eighty-eight percent ($n=22$) completed CBT and 80% ($n=20$) completed SPT. Fisher's Exact Test revealed no significant difference in the retention rates for each treatment condition ($p=.702$). Treatment completers were not significantly different from dropouts on the demographic characteristics (ethnicity, education, marital status, and employment status), descriptive characteristics (years with vulvar pain, age of first intercourse, age of first menses, sudden onset, family history of vulvar pain, parity, other chronic pain sites, and childhood sex abuse history), DSM-IV comorbidity (any DSM-IV Axis I disorder, major depressive disorder, anxiety disorders and substance use disorders), and main outcomes (pain severity, sexual function, and emotional function) at baseline ($p's>.05$). Of the treatment completers ($n=42$), 39 (93%) attended all ten sessions, 2 attended nine sessions, and 1 attended eight sessions. Thus, treatment completers attended at least 80% of sessions. The two treatments did not differ significantly in session attendance ($F(1, 49)=1.49$, $p=.228$). Participants were asked not to initiate psychotherapy, psychopharmacologic treatment or pain medication, or other medical or alternative treatments for vulvodynia during the 10-week treatment. All participants complied with this request.

Acute Dimensional Treatment Outcomes: Pain severity, Sexual Function, and Emotional Function

Table 5 summarizes results of mixed effects ANOVAs performed to evaluate the immediate effects of treatment on dimensional measures of pain severity, sexual function, and emotional function. At the end of treatment participants reported significantly less pain on both physician measures of pain severity (physician cotton-swab and physician speculum; $p's<.001$) and self-report measures of pain severity (MPI pain severity and MPQ; $p's<.001$). Overall sexual function (FSFI Full scale) and dyspareunia (FSFI pain subscale) significantly improved from pre to post-treatment ($p's<.001$). At the end of treatment participants also reported improved emotional function as scores of depressive symptomatology (BDI) and pain anxiety (PASS) were significantly lower from pre- to post-treatment ($p's<.05$).

A significant interaction effect was found for the physician cotton-swab rating ($F(1, 49)=6.52$, $p=.014$). Figure 2 (top graph) shows the physician cotton-swab ratings from baseline to post-treatment by participants who received CBT compared to participants who received SPT. The slopes in this figure depict a sharper decline in pain severity on cotton-swab palpation for CBT suggesting a greater rate of improvement than SPT. A significant interaction effect was also found for the FSFI Full scale ($F(1, 41)=7.99$, $p=.007$). Figure 2 (bottom graph) shows the FSFI Full scale ratings from baseline to post-treatment by participants who received CBT compared to participants who received SPT. The slopes in this figure depict a sharper rate of improvement in overall sexual function for CBT than SPT. In addition, participants who received CBT reported significantly better sexual function at the end of treatment compared to participants who received SPT ($F(1, 40)=6.28$, $p=.017$).

Acute Categorical Treatment Outcome: 33% Reduction in Pain Severity

In the present study we found a mean 35.8% reduction in pain severity as measured by the pain severity subscale of the MPI, and a mean 37.7% reduction in pain severity as measured by the MPQ. A 33% decrease in pain severity has been shown to be clinically meaningful [9]. Thus,

participants in the present study were then categorized as having at least a 33% reduction in pain severity on both the MPI pain severity and MPQ, or not. Overall, 41.7% (20/48) of participants achieved at least a 33% reduction in pain severity on both self-report measures. For the CBT condition 39.1% (9/23), and for the SPT condition 44.0% (11/25), of participants achieved a 33% reduction in pain severity on both self-report measures. The two treatment groups did not differ in the percentage of participants who achieved this reduction versus those who did not ($\chi^2=0.12$, $p=.732$).

Maintenance Outcomes: Post-treatment to One-year Follow-up

To test for maintenance effects, self-report measures of pain severity, sexual function and emotional function were analyzed with data from four assessment points (post-treatment, and three-month, six-month and one-year follow-ups), and physician measures of pain severity at two assessment points (post-treatment and six-month follow-up). Table 6 summarizes results of mixed effects ANOVAs. A significant main effect was found for the pain severity subscale of the MPI (EMM=1.7, SE=0.2 vs. EMM=1.3, SE=0.2; $F(3, 141)=3.51$, $p=.017$) and the PASS (EMM=63.5, SE=5.0 vs. EMM=60.3, SE=5.0; $F(3, 141)=4.25$, $p=.007$) such that continued improvements in pain severity and pain anxiety were observed during the follow-up period. No significant main effects were found on any of the other outcome measures. Thus, improvements in pain severity, sexual function, and emotional function were maintained or continued to improve.

Treatment Acceptability

Participants in the CBT condition (Mean=3.0, SD=0.7) reported significantly greater global improvement than participants in the SPT condition (Mean=2.0, SD=1.3; $F(1, 46)=8.5$, $p=.005$) as well as greater treatment satisfaction (Mean=8.0, SD=1.8 vs. Mean=6.3, SD=3.0; $F(1, 45)=5.3$, $p=.027$).

Participants also completed a measure of treatment credibility at the end of treatment sessions one and ten (e.g., How logical does the treatment seem to you? Rated from 0 to 10). Participants scores on the measure indicated that the rationale for using CBT (M=33.2, SD=40.1) and SPT (M=28.1, SD=37.0) for the treatment of vulvodynia were equally credible ($F(1, 49)=2.28$, $p=.138$) at the beginning of treatment. By the end of treatment, however, the CBT group (M=34.9, SD=43.0) reported the treatment was significantly more credible than the SPT group (M=20.5, SD=32.7; $F(1, 45)=12.1$, $p=.001$).

Discussion

The present study evaluated the efficacy of two psychosocial treatments, CBT (a behaviorally oriented and coping skills based approach) and SPT (a non-directive, patient-centered, supportive approach), in the treatment of women with chronic vulvar pain. Fifty women with independently diagnosed vulvodynia were randomized to treatments at a medical school facility. Women were predominately Caucasian, college educated and married, with a mean age of 43 years and a duration of symptoms from six months to 32 years (approximately 8 ½ on average). In addition to the diagnosis of vulvodynia, well over half the sample (66%) reported a lifetime history of psychiatric comorbidity, with major depressive disorder and anxiety disorders being the most frequently cited (46% and 42%, respectively).

Forty-two percent (42%) of participants achieved clinically meaningful improvement using the conservative estimate of a 33% reduction in pain severity [9]. More importantly, however, was that participants in both treatments were significantly improved on all key dimensional outcome measures (pain severity, sexual function and emotional function). Less pain severity on both physician and self-report measures was reported; sexual function was improved and

dyspareunia reduced; and emotional function was improved as a result of a reduction in symptoms of depression and anxiety. Based upon findings from the present study we know that these specific areas of function were also distinct, as results of the correlation analysis revealed that for the most part measures within each key domain were moderately related to each other, while few measures were related across domains.

While the two treatments produced clinically meaningful improvements in all domains, greater rates of improvement in pain severity on the physician reports of cotton-swab palpation and overall sexual function were found in the CBT condition compared to the SPT condition. We hypothesize that some specific behavioral strategies used in the CBT condition may have been more beneficial in reducing pain that was provoked by touch and in improving overall sexual function, compared to a talk therapy without behavioral interventions.

In addition, participants in the CBT condition reported greater rates of improvement in overall sexual function, but not dyspareunia, compared to participants in the SPT condition. One hypothesis is that sex therapy skills such as sensate focus and assertive sexual communication may work better at addressing overall sexual satisfaction and function, but not the specific problem of dyspareunia. One limitation of the current study was that the use of vaginal dilators, a common intervention for vaginismus (i.e., an involuntary spasm of the pelvic floor musculature that prevents intercourse and is associated with dyspareunia) was not used.

While it could be argued that the equivalent findings for CBT and SPT on self-report measures of pain, measures of introital pain, and emotional function suggest that there is not a clear advantage of CBT over SPT, findings from the present study also demonstrated that participants who received CBT reported greater global treatment satisfaction. To better understand the relationship between study outcomes and patient satisfaction, a correlation analysis was run between the post-treatment outcome measures and treatment satisfaction. Only measures of pain on cotton-swab palpation and overall sexual function were significantly correlated with treatment satisfaction ($r = -.49$, $p = .001$, and $r = .33$, $p = .039$, respectively). Thus, patient satisfaction was significantly associated with improvement in these two outcomes suggesting that they may carry more weight in determining global satisfaction. Research is needed to determine what variables predict, moderate and mediate successful outcome and patient satisfaction for women with vulvodynia.

Also, of note was that participants receiving CBT felt it was equally credible to participants receiving SPT before treatment, but more credible at the end of treatment. It may be that greater improvements and satisfaction with CBT, compared to SPT, adds to its credibility over time. Alternatively, or in conjunction with the aforementioned hypothesis, it may be that after being exposed to the treatments, participants receiving CBT had a better understanding of how interventions would be relevant to their condition. It is interesting to note that women with vulvodynia treated in the Bergeron et al. [5] study were significantly more confident in vestibulectomy than group CBT before treatment yet significantly more women assigned to the vestibulectomy group did not proceed with the surgery compared to the number of pretreatment dropouts for the group CBT condition.

There were several areas in which CBT and SPT performed equally well, and it is unclear whether the treatments were truly comparable in these areas or whether the number of subjects in the present study was not sufficient to detect differences between treatments on these measures. While it could be that improvements found in the present study had to do with the non-specific effects of talking about the problem and being in the care of providers knowledgeable about vulvodynia, there were clear advantages of CBT over SPT. A larger scale study comparing psychosocial treatments with a no treatment or wait list control group would extend this line of research.

Co-morbid major depressive disorder has been shown to be related to greater pain severity and worse functioning in women with vulvodynia [22]. Thus, another potential confound considered was whether the improvements seen in the present study could be accounted for by improvement in symptoms of depression that in turn accounted for improvements in other areas. To test this hypothesis, we conducted the treatment outcome analyses a second time with BDI score as a covariate. The pattern of findings remained unchanged suggesting that findings were specific to treatments used in the present study.

Overall, improvements observed for psychosocial treatments of vulvodynia were also well maintained. In fact, scores on outcome measures used in the present study either remained at about the same level from post-treatment to one-year follow-up or improved. Continued improvements during the follow-up phase were observed on the self-report pain severity measure and the pain anxiety measure, but not measures for dyspareunia or overall sexual function. Some continued short-term improvements, and longer term maintenance of improvements, is consistent with findings by Bergeron and colleagues [6].

Vulvodynia is a difficult-to-treat diagnosis exclusive to women that has received scant attention in the literature and has been the subject of few randomized controlled treatment trials [14]. Our findings for individual CBT treatment of vulvodynia are consistent with a previous study of group CBT for the treatment of dyspareunia resulting from vulvar vestibulitis [5]. In both the present study and the Bergeron et al. [5] study statistically and clinically significant improvements were observed for both pain severity and sexual function. The current study builds upon previous work by investigating CBT in individual format, examining the relative efficacy of CBT compared to a treatment matched for number and length of sessions, therapist contact and mode of delivery (i.e., talk therapy), and recruiting a more heterogeneous sample of women with vulvodynia.

We note other potential limitations to consider. Findings in the present study pertain to women with vulvodynia who participated in a study of psychosocial treatments at a university medical center and may not generalize to other behavioral, medical or nutritional treatments that have been used for this condition. It is unknown how these findings may generalize to women with vulvodynia who seek care from their gynecologist or at specialized clinics for vulvovaginal diseases. Finally, the majority of participants in this study were Caucasian (82%) although the racial and ethnic diversity was representative of New Haven County and the state of Connecticut.

A number of important clinically relevant findings emerged from this study and warrant replication with a larger sample. Results suggest that psychosocial treatments for vulvodynia are well-tolerated and efficacious for producing clinically meaningful improvements in pain severity that are maintained through one-year follow-up. A particular strength of this study was the use of standardized measures and a rigorous threshold of 33% reduction on two measures of self-reported pain severity to evaluate successful outcome. We also observed incremental effects of CBT over SPT, something that has not been consistently demonstrated in the chronic pain literature [16]. Another potential advantage for CBT over SPT is that CBT has been successfully used in self-help formats for other disorders [e.g. 13]. The efficacy of a self-help approach may be an appropriate target for future research.

Despite ample evidence for the efficacy of psychosocial treatments for pain conditions in general, reviews of the treatment outcome literature for vulvodynia mention such treatments as an afterthought, if at all, and recommend other treatments that have not been rigorously evaluated. Our results indicate that psychosocial treatments for vulvodynia are effective and well-tolerated, and that CBT, a directed treatment approach that involves the acquisition of

specific pain-relevant coping and self-management skills, may yield better outcomes and greater patient satisfaction than a less directive approach.

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Figure 1.
Recruitment and study flow of participants

Figure 2. Interaction effects of time (baseline and post-treatment) by treatment condition (CBT and SPT) shown for the Physician Cotton-swab rating (top graph) and the Female Sexual Function Index (FSFI) Full scale (bottom graph).

Table 1
Demographic characteristics of participants randomized to treatment conditions

Measure	Overall (N=50)	CBT (n=25)	SPT (n=25)	F or χ^2	P
Age, <i>M</i> (<i>SD</i>)	43.0 (12.1)	43.4 (13.9)	42.6 (10.3)	0.05	.818
Ethnicity, (<i>n</i> , %)				3.39	.066
Caucasian	41 (82)	18 (72)	23 (92)		
Non-Caucasian	9 (18)	7 (28)	2 (8)		
Education, (<i>n</i> , %)				0.80	.370
College graduate	33 (66)	15 (60)	18 (72)		
Less than College	17 (34)	10 (40)	7 (28)		
Marital Status, (<i>n</i> , %)				5.88	.053
Single, Never Married	8 (16)	2 (8)	6 (24)		
Married	34 (68)	21 (84)	13 (52)		
Divorced/Widowed	8 (16)	2 (8)	6 (24)		
Employed, (<i>n</i> , %)				1.11	.574
Full/Part-time Paid Employment	36 (72)	17 (68)	19 (76)		
No Paid Employment	10 (20)	5 (20)	5 (20)		
Disability	4 (8)	3 (12)	1 (4)		

Note: CBT=cognitive-behavioral therapy; SPT=supportive psychotherapy.

Table 2
Age variables, descriptive characteristics, and DSM-IV psychiatric comorbidity of participants randomized to treatment conditions (N=50)

	Overall	CBT	SPT	
Descriptive Characteristics	M (SD)	M (SD)	M (SD)	F
Age of Onset	34.6 (13.7)	34.4 (14.7)	34.9 (12.2)	0.02
Yrs with Vulvar Pain	8.4 (7.8)	9.0 (8.2)	7.7 (7.5)	0.34
Age 1 st Intercourse [†]	18.4 (2.6)	18.8 (2.7)	18.1 (2.5)	0.76
Age 1 st Menses	12.5 (1.0)	12.4 (1.1)	12.6 (1.0)	0.38
	n (%)	n (%)	n (%)	χ²
Sudden Onset	25 (50%)	12 (48%)	13 (52%)	0.08
Lifelong Dyspareunia	10 (20%)	7 (28%)	3 (12%)	2.00
Family History of Vulvar Pain	7 (14%)	4 (16%)	3 (12%)	0.17
Nulliparous	23 (46%)	9 (36%)	14 (56%)	2.01
Multiple Pain Sites	39 (78%)	18 (72%)	21 (84%)	1.05
Sex Abuse History	18 (36%)	8 (32%)	10 (40%)	0.35
Major Depressive Disorder (current)	9 (18%)	4 (16%)	5 (20%)	0.14
DSM-IV Lifetime Diagnoses	n (%)	n (%)	n (%)	χ²
Any Axis I Disorder	33 (66%)	16 (64%)	17 (68%)	0.09
Major Depressive Disorder	23 (46%)	10 (40%)	13 (52%)	0.73
Anxiety disorders	21 (42%)	11 (44%)	10 (40%)	0.08
Substance use disorders	8 (16%)	2 (8%)	6 (24%)	2.38
				p

[†]N=49.

Note: *Multiple Pain Sites*=chronic pain (at least 6 months) in an anatomical site other than the vulva (including fibromyalgia); *Sex Abuse History*=met threshold for sexual abuse on the Childhood Trauma Questionnaire; *CBT*=cognitive-behavioral therapy; *SPT*=supportive psychotherapy.

Table 3
Correlation coefficients for outcome variables at baseline (N=50)

Constructs Measures	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Pain Severity								
(1) Physician Cotton-swab	-							
(2) Physician Speculum	.64***	-						
(3) Self-report MPI Pain Severity	.03	.02	-					
(4) Self-report MPQ	.29*	.27	.25	-				
Function: Sexual								
(5) FSFI Pain/Dyspareunia [†]	-.24	-.46**	-.20	-.16	-			
(6) FSFI Full Scale [†]	-.25	-.23	-.12	-.22	.52***	-		
Function: Emotional								
(7) BDI Depressive Symptoms	-.05	-.13	.45**	.23	-.27	-.46**	-	
(8) PASS Pain Anxiety	.15	.09	.27	.53***	-.35	-.41**	.54***	-

[†]Analyses performed only for participants with a sexual partner (n=42). Higher scores reflect better functioning.

* p<.05

** p<.01

*** p<.001

Table 4
Baseline clinical characteristics for the overall sample and statistical tests for differences between treatment groups (N=50)

Constructs Measures	Overall Sample M (SD)	CBT n=25 M (SD)	SPT n=25 M (SD)	F	p	Eta ²
Pain Severity						
Physician Cotton-swab	4.7 (3.1)	5.5 (3.4)	3.9 (2.7)	3.36	.073	.065
Physician Speculum	1.2 (0.9)	1.3 (1.0)	1.0 (0.8)	1.50	.227	.030
Self-report MPI Pain Severity	2.8 (1.3)	2.6 (1.2)	3.0 (1.3)	1.29	.261	.026
Self-report MPQ	25.7 (13.1)	29.1 (13.8)	22.2 (11.6)	3.67	.061	.071
Function: Sexual[†]						
FSFI Pain/Dyspareunia	4.3 (4.1)	5.3 (4.4)	3.2 (3.4)	2.99	.091	.070
FSFI Full Scale	17.1 (7.6)	15.9 (7.7)	18.4 (7.5)	1.09	.303	.027
Function: Emotional						
BDI Depressive Symptoms	12.3 (9.1)	12.1 (10.2)	12.5 (8.1)	0.02	.886	.000
PASS Pain Anxiety	72.8 (34.2)	72.6 (35.3)	73.0 (33.9)	0.00	.969	.000

[†] Analyses performed only for participants with a sexual partner (n=42). Higher scores reflect better functioning.

Note: *Physician Cotton-swab*=pain ratings of palpation at six sites in the vulva vestibule each rated on a 4-point scale: absent (0), mild (1), moderate (2), and severe (3). Scores for the six sites were added and averaged for the two physicians at pretreatment; *Physician Speculum*=4-point pain rating taken for pain with speculum insertion. Scores were averaged for the two physicians at pretreatment; *MPI*=Multidimensional Pain Inventory; *MPQ*=McGill Pain Questionnaire; *FSFI*=Female Sexual Function Index; *BDI*=Beck Depression Inventory; *PASS*=Pain Anxiety Symptom Scale; *CBT*=cognitive-behavioral therapy; *SPT*=supportive psychotherapy.

Table 5
Clinical characteristics and statistical tests for acute treatment effects (baseline to post-treatment) by treatment condition (CBT and SPT)

Constructs Measures	Overall Sample		CBT		SPT		Time		Time × Condition	
	Baseline EMM (SE)	Post-treatment EMM (SE)	Baseline EMM (SE)	Post-treatment EMM (SE)	Baseline EMM (SE)	Post-treatment EMM (SE)	F	p	F	p
Pain Severity										
Physician Cotton-swab	4.7 (0.4)	2.8 (0.4)	5.5 (0.6)	2.3 (0.6)	3.9 (0.6)	3.3 (0.6)	14.62	.000	6.52	.014
Physician Speculum	1.2 (0.1)	0.5 (0.1)	1.3 (0.2)	0.6 (0.2)	1.0 (0.2)	0.5 (0.2)	19.67	.000	0.72	.400
Self-report MPI Pain Severity	2.8 (0.2)	1.8 (0.2)	2.6 (0.2)	1.6 (0.3)	3.0 (0.2)	1.9 (0.2)	30.47	.000	0.08	.776
Self-report MPQ	25.7 (1.8)	16.3 (1.9)	29.1 (2.6)	18.5 (2.7)	22.2 (2.6)	14.0 (2.6)	18.25	.000	0.30	.589
Function:Sexual[†]										
FSFI Pain/Dyspareunia	4.2 (0.7)	6.8 (0.7)	5.3 (1.0)	8.1 (1.0)	3.2 (1.1)	5.6 (1.1)	14.84	.000	0.06	.804
FSFI Full Scale	17.2 (1.2)	20.7 (1.2)	15.9 (1.7)	21.9 (1.7)	18.4 (1.7)	19.5 (1.7)	17.37	.000	7.99	.007
Function:Emotional										
BDI Depressive Symptoms	12.3 (1.3)	10.3 (1.3)	12.1 (1.8)	10.7 (1.8)	12.5 (1.8)	9.9 (1.8)	5.92	.019	0.59	.445
PASS Pain Anxiety	72.8 (4.7)	65.3 (4.8)	72.6 (6.7)	67.7 (6.8)	73.0 (6.7)	62.8 (6.7)	4.10	.049	0.51	.480

[†]Analyses performed only for participants with a sexual partner (n=42). Higher scores reflect better functioning.

Note: *Physician Cotton-swab*=pain ratings of palpation at six sites in the vulva vestibule each rated on a 4-point scale: absent (0), mild (1), moderate (2), and severe (3). Scores for the six sites were added and averaged for the two physicians at pretreatment; *Physician Speculum*=4-point pain rating taken for pain with speculum insertion. Scores were averaged for the two physicians at pretreatment; *MPI*=Multidimensional Pain Inventory; *MPQ*=McGill Pain Questionnaire; *FSFI*=Female Sexual Function Index; *BDI*=Beck Depression Inventory; *PASS*=Pain Anxiety Symptom Scale; *CBT*=cognitive-behavioral therapy; *SPT*=supportive psychotherapy; *EMM*=estimated marginal mean; *SE*=standard error.

Table 6
Clinical characteristics and statistical tests for maintenance effects (post-treatment to one-year follow-up) by treatment condition (CBT and SPT)

Constructs Measures	Overall Sample			CBT		SPT		Time		Time × Condition	
	Post- treatment EMM (SE)	One-year Follow-up EMM (SE)	Post- treatment EMM (SE)	Post- treatment EMM (SE)	One-year Follow-up EMM (SE)	Post- treatment EMM (SE)	One-year Follow-up EMM (SE)	F	p	F	p
Pain Severity											
Physician Cotton-swab [†]	2.8 (0.4)	2.4 (0.4)	2.3 (0.6)	2.3 (0.6)	2.3 (0.6)	3.3 (0.6)	2.4 (0.6)	1.14	.291	1.23	.274
Physician Speculum [†]	0.6 (0.1)	0.5 (0.1)	0.6 (0.2)	0.6 (0.2)	0.7 (0.2)	0.5 (0.2)	0.4 (0.2)	0.21	.653	1.24	.272
Self-report MPI Pain Severity	1.7 (0.2)	1.3 (0.2)	1.5 (0.3)	1.5 (0.3)	1.3 (0.3)	1.9 (0.3)	1.3 (0.3)	3.51	.017	2.63	.053
Self-report MPQ	16.2 (2.0)	13.4 (2.0)	18.3 (2.9)	18.3 (2.9)	13.5 (3.0)	14.0 (2.8)	13.3 (2.8)	1.10	.351	1.05	.372
Function:Sexual^{††}											
FSFI Pain/Dyspareunia ^a	6.8 (0.9)	7.5 (0.9)	8.1 (1.3)	8.1 (1.3)	8.1 (1.3)	5.6 (1.3)	7.0 (1.3)	0.43	.731	0.94	.422
FSFI Full Scale ^a	20.8 (1.5)	20.6 (1.5)	22.1 (2.2)	22.1 (2.2)	22.6 (2.2)	19.5 (2.2)	18.6 (2.2)	2.05	.110	0.28	.837
Function:Emotional											
BDI Depressive Symptoms	9.9 (1.4)	9.4 (1.4)	9.9 (2.0)	9.9 (2.0)	7.3 (2.0)	9.9 (1.9)	11.5 (1.9)	0.45	.721	1.87	.138
PASS Pain Anxiety	63.5 (5.0)	60.3 (5.0)	64.2 (7.2)	64.2 (7.2)	55.3 (7.2)	62.8 (6.9)	65.2 (6.9)	4.25	.007	2.56	.058

[†]Analyses are from post-treatment to six-month follow-up.

^{††}Analyses performed only for participants with a sexual partner (n=42). Higher scores reflect better functioning.

Note: *Physician Cotton-swab*=pain ratings of palpation at six sites in the vulva vestibule each rated on a 4-point scale: absent (0), mild (1), moderate (2), and severe (3). Scores for the six sites were added and averaged for the two physicians at pretreatment; *Physician Speculum*=4-point pain rating taken for pain with speculum insertion. Scores were averaged for the two physicians at pretreatment; *MPQ*=Multidimensional Pain Inventory; *MPQ*=McGill Pain Questionnaire; *FSFI*=Female Sexual Function Index; *BDI*=Beck Depression Inventory; *PASS*=Pain Anxiety Symptom Scale; *CBT*=cognitive-behavioral therapy; *SPT*=supportive psychotherapy; *EMM*=estimated marginal mean; *SE*=standard error.