A RANDOMIZED COMPARISON OF INDIVIDUAL COGNITIVE-BEHAVIOURAL THERAPY AND PELVIC FLOOR REHABILITATION IN THE TREATMENT OF PROVOKED VESTIBULODYNIA

by

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Abstract

Provoked vestibulodynia (PVD) is the most common condition leading to painful intercourse and is currently best understood within a biopsychosocial framework. Although the usefulness of non-medical treatment options for vulvar pain is recognized by many, there is limited research investigating the effectiveness of these treatments using a biopsychosocial approach to outcome measurement. Furthermore, there is little evidence to support the mechanisms by which these treatments lead to pain reduction. This study aimed to address these gaps by investigating two non-medical treatment options: individual cognitive-behavioural therapy (ICBT) and pelvic floor rehabilitation (PFR). Twenty women with PVD were randomly assigned to eight sessions of either ICBT or PFR. Participants were assessed at pre-treatment, post-treatment, and 6-month follow-up via gynecological examination, structured interviews and standardized questionnaires measuring pain, psychological, and sexual variables, quantitative sensory testing, and a pelvic floor muscle (PFM) evaluation. The primary outcome was change in intercourse pain intensity. Secondary outcomes included changes in other features of vestibular pain (e.g., frequency), cotton-swab test pain intensity, vestibular sensitivity, sexual functioning, PFM functioning, and pain cognitions. Changes in psychosexual and PFM functioning were investigated as predictors of treatment outcome. Results indicated no differences in the effectiveness of the treatment groups with respect to pain outcomes, with both groups demonstrating significant reductions in pain. Between-group differences were minimal in other areas, with some suggestion that participants in the ICBT group fared better with respect to sexual functioning, while participants in the PFR group demonstrated more improvements in PFM tone. Participants in both groups demonstrated meaningful improvements in pain cognitions, with the ICBT group demonstrating greater changes in rumination. The study was not able to detect significant predictors of treatment outcome. The results of the study suggest that both ICBT and
PFR may lead to clinically meaningful improvements in pain, as well as in other areas of psychosexual functioning. Future treatment studies should consider incorporating general chronic pain clinical trial recommendations to allow for better comparison of outcomes with other studies.
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Chapter 1
Introduction

Provoked vestibulodynia (PVD) is the most common form of vulvodynia (i.e., chronic vulvar pain), estimated to affect approximately 12% of women (Harlow & Stewart, 2003). It is commonly described as a sharp or burning pain at the entrance of the vagina in response to contact or pressure to the vulvar vestibule and thus, can be experienced during both sexual (e.g., intercourse) and non-sexual activities (e.g., tampon insertion). PVD is known to be associated with a wide range of negative outcomes including depressive and anxious symptoms, negative pain cognitions, and poorer sexual functioning and satisfaction (e.g., Desrochers, Bergeron, Landry, & Jodoin, 2008; Gates & Galask, 2001; Payne, Binik, Amsel, & Khalifé, 2005; Pukall, Binik, Khalifé, Amsel, & Abbott, 2002). Etiological theories are numerous, with researchers and clinicians speculating possible roles of genetic susceptibility, inflammation, infection, hormonal changes, as well as dysfunction of both the central and peripheral nervous systems. Although it is difficult to determine the etiological pathway for each affected woman, PVD is understood to be multifactorial for most. In addition to the biological factors thought to trigger the onset of PVD, psychological, physiological, and sexual factors are recognized as playing a role in the maintenance of the condition. Specifically, negative pain cognitions such as pain catastrophizing and hypervigilance, pelvic floor muscle dysfunction, and reduced sexual desire and arousal are believed to maintain and exacerbate the pain of PVD (Pukall, Payne, Kao, Khalifé, & Binik, 2005a; Reissing, Brown, Lord, Binik, & Khalifé, 2005).

Based on these findings, several studies have investigated the effects of pelvic floor rehabilitation (PFR) and cognitive-behavioural therapy (CBT) for women with PVD and found improvements in pain and psychosexual correlates of pain. To date, PFR has yet to be included in
any randomized treatment studies, despite showing considerable improvements in both retrospective (Bergeron, Brown, Lord, Oala, Binik, & Khalifé, 2002) and prospective studies (Goldfinger, Pukall, Gentilcore-Saulnier, McLean, & Chamberlain, 2009). Group CBT has been included in several randomized and controlled studies (Bergeron et al., 2001b; Desrochers, Bergeron, Khalifé, Dupuis, & Jodoin, 2010; ter Kuile & Weijenborg, 2006); however, individual CBT (ICBT) has only been included in one treatment outcome study (Masheb, Kerns, Lozano, Minkin, & Richman, 2009), and it was with a group of women with various subtypes of vulvodynia. No studies have compared the relative effectiveness of PFR and ICBT, despite these options being the most commonly provided non-medical treatments for PVD.

Therefore, the purpose of this study was to compare the effectiveness of ICBT and PFR in treating various components of PVD using an effectiveness or pragmatic approach. This study situated PVD within a biopsychosocial framework. This view highlights the importance of biological, psychological, and social factors in understanding the effects and etiology of PVD. Furthermore, this study investigated biological as well as psychosexual outcomes before and after treatment, as well as 6 months following treatment. This randomized study was concerned with determining the effectiveness of each treatment, comparing the effectiveness of the two treatment modalities, and determining predictors of treatment outcome.

The study results contribute to our understanding of the effectiveness of ICBT and PFR in the treatment of PVD. The findings also speak to the process of change of these two treatment modalities and to the importance of determining clinically meaningful methods of measuring treatment progress. The results will help clinicians in treatment planning to meet specific needs of affected women.
Chapter 2

Literature Review

Although the experience of vulvar pain without any known underlying cause was documented as early as the late 19th century, recognition by researchers and clinicians did not truly begin until the creation of the International Society for the Study of Vulvovaginal Disease (ISSVD) in the 1970s (Moyal-Barracco & Lynch, 2004). Provoked vestibulodynia (PVD), previously called vulvar vestibulitis syndrome (VVS), is one subtype of chronic vulvar pain and is currently considered to be the most common reason for women’s experience of dyspareunia, or painful sexual intercourse (Meana, Binik, Khalifé, & Cohen, 1997).

Classification and Diagnosis

Currently, the existence of distressing dyspareunia would be classified as genito-pelvic pain/penetration disorder subsumed within the sexual dysfunctions in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013). Given that dyspareunia can be produced by numerous disorders, some of known cause and others considered idiopathic, all of these conditions, including PVD, would be considered to fit within this diagnostic category. There has been considerable backlash against the classification of dyspareunia more generally, and PVD specifically, as a sexual dysfunction. Reasons for this criticism include, but are not limited to the fact that: (1) women with dyspareunia often experience pain with non-sexual activities such as tampon insertion, (2) the diagnostic taxa used by pain experts (i.e., anatomical region, organ system, temporal characteristics of pain and pattern of occurrence, patient’s statement of intensity and time since onset of pain, etiology) more adequately accounts for the variance among women with dyspareunia than the DSM-5’s diagnostic taxa for sexual dysfunction (i.e., lifelong versus acquired), and (3) outcome studies
demonstrate that whereas traditional sex therapy is not effective for dyspareunia, pain-focused treatments such as surgery, cognitive-behavioural therapy, and biofeedback are (Binik, 2005; Binik, Pukall, Reissing, & Khalifé, 2001; Pukall, Kao, & Binik, 2004b). Proponents of these criticisms suggest that dyspareunia be classified as a pain disorder that interferes with sexuality rather than a sexual disorder that is characterized by pain. This change, however, was not made within the DSM-5.

Fortunately, another classification system exists with a focus on pain rather than on sex. In 2003, the ISSVD (Haefner, 2007) came to a consensus on the terminology and classification of vulvar pain with two broad categories: (1) vulvar pain related to a specific disorder and (2) vulvodynia. Vulvar pain due to a specific disorder can be categorized as infectious (e.g., candidiasis), inflammatory (e.g., lichen planus), neoplastic (squamous cell carcinoma), or neurologic (e.g. herpes neuralgia). Vulvodynia, alternatively, is defined as “vulvar discomfort, most often described as burning pain, occurring in the absence of relevant visible findings or a specific, clinically identifiable, neurologic disorder” (pp. 49). Vulvodynia is further classified into subtypes depending on (1) the location of the pain (i.e., generalized—pain affecting the whole vulva; localized—pain affecting a portion of the vulva), and (2) the temporal characteristics of the pain (i.e., provoked—pain triggered by physical contact; unprovoked—pain occurs spontaneously without a specific physical trigger; mixed—combination of provoked and unprovoked pain), with provoked pain being elicited in sexual and/or non-sexual situations. Although this classification system is limited to pain experienced at the vulva, and does not include conditions that cause non-vulvar dyspareunia (e.g., pelvic pain during intercourse), the classification does promote pain-focused research and treatment.

PVD is the most common form of vulvodynia and is characterized as pain experienced at the vulvar vestibule that occurs upon physical contact to the area (i.e., localized and provoked). The vulvar vestibule is the area of the vulva that extends from the base of the inner labia minora
inward to the introitus, or the border with the vagina (Friedrich, 1983). Friedrich (1987) outlined three diagnostic criteria for PVD: (1) severe pain upon vestibular touch or attempted vaginal entry, (2) tenderness to pressure localized within the vulvar vestibule, and (3) physical findings limited to vestibular erythema (i.e., redness) of various degrees. Only the first two criteria, however, have demonstrated reliability and validity and significantly contribute to diagnostic decision making (Bergeron, Binik, Khalifé, Pagidas, & Glazer, 2001a). Although not part of the diagnostic criteria of PVD, the pain is typically described as having thermal (e.g., hot, burning) and incisive (e.g., sharp, cutting) qualities (Bergeron et al., 2001a). Furthermore, the pain should be present for a minimum of 6 months, the general duration criteria for chronic pain. Currently, a diagnosis of PVD is based upon a combination of the woman’s self-report of vulvar pain (e.g., location, temporal pattern, duration, quality) and the presence of pain localized to the vestibule during a cotton-swab test carried out by a gynecologist. Given that vulvodynia is considered present only in the absence of relevant findings, ruling out other causes for the pain (e.g., sexually transmitted infections [STIs], dermatological conditions) through a gynecological examination is typical as well. Though the ISSVD does not outline specific subtypes of PVD, women with this condition are often categorized as having primary PVD (i.e., the onset of pain is at first intercourse attempt or first attempt at tampon insertion) or secondary PVD (i.e., the pain develops after some period of pain-free intercourse).

Research studies suggest that a significant number of women who experience chronic vulvar pain do not seek treatment. Rates of seeking help from a healthcare professional ranged between 50% and 71% in three studies (Arnold, Bachmann, Rosen, & Rhoads, 2007; Harlow & Stewart, 2003; Reed, Haefner, Harlow, Gorenflo, & Sen, 2006). Among those who do consult a health professional, a significant portion does not receive a diagnosis for their pain (39% and 44%; Harlow & Stewart, 2003; Reed et al., 2006), and many are either misdiagnosed or told that their pain is “all in their head” (Sackett, Gates, Heckman-Storm, Kobus, & Galask, 2001).
Whether this is due to a paucity of understanding of the condition among health professionals or the difficulties in assessing for pain etiology is unclear.

**Prevalence**

Although there have been a number of studies designed to determine prevalence rates of vulvodynia, numerous methodological issues limit the accuracy of prevalence estimates. Specifically, the studies often do not take into account the location of pain, the presence of pain during penetrative activities, or whether the individual has received a medical explanation for their pain (e.g., infection, endometriosis) when reporting prevalence estimates, despite reporting on some of these variables in their papers (e.g., Arnold et al., 2007; Harlow & Stewart, 2003; Landry & Bergeron, 2009; Reed, Haefner, Sen, & Gorenflo, 2008). The inability to rule out alternative causes for pain is a major limitation of the studies relying on questionnaire data. Studies including a gynecological examination have demonstrated that between 75% and 88% of women predicted to have PVD or other forms of vulvodynia based on self-report were confirmed to have the diagnosis following a physical examination (Goetsch, 1991; Harlow, Vazquez, MacLehose, Erickson, Oakes, & Duval, 2009; Masheb, Lozano, Richman, Minkin, & Kerns, 2004b; Reed et al., 2006). Another limitation of many prevalence studies is that a 3 month, rather than 6 month, duration criteria for vulvar pain symptoms is used. Research using this duration criteria has demonstrated that between 22% and 26% of women who report 3 months of vulvodynia symptoms will later report full remission of their vulvar pain symptoms (Reed et al., 2006; Reed et al., 2008). These numbers suggest that for a significant number of women, the experience of vulvar pain for 3 months is not indicative of a chronic course of pain. No studies investigating spontaneous remission of vulvar pain symptoms lasting at least 6 months were found in the literature.

Based on these various limitations, the lifetime prevalence of PVD that is often
documented at 12.4% (Harlow & Stewart, 2003) is most likely an overestimate of the proportion of women who would meet criteria for PVD based on more conservative criteria. Based on the data available in these studies, the prevalence rate of PVD is more likely closer to 7-10%.

**Proposed Etiological, Maintaining, and Consequent Factors of PVD**

Although a plethora of etiological theories has been proposed for PVD, there is no single factor that has proven itself as the cause of PVD. Alternately, research has revealed myriad factors that potentially contribute to the onset and maintenance of pain in women with PVD. In fact, a clinical diagnosis of PVD may result from various disorders with multiple etiologies. Currently, a multidimensional viewpoint in which biological, psychological, and sexual factors are all seen as fundamental to understanding and treating PVD is accepted by most researchers and clinicians (Goldstein & Burrows, 2008; Weijmar Schultz, Basson, Binik, Eschenbach, Wesselmann, & van Lankveld, 2005).

**Medical factors.** The large majority of research supports the role of biological factors in initiating the pain of PVD. Specifically, the literature focuses on inflammatory and infectious factors, hormonal factors, and the peripheral and central nervous systems.

**Inflammatory and infectious factors and genetic predisposition.** Early findings that women with PVD are more likely to have a history of infection of the urogenital tract or vulvar area (e.g., Mann, Kaufman, Brown, & Adam, 1992) led researchers to investigate a possible link between infection and the development of chronic vulvar pain. Although there are inconsistent findings with respect to some infections (e.g., human papilloma virus, STIs), more recent research continues to demonstrate higher rates of a history of candida infections, bacterial vaginosis, and urinary tract infections among women with PVD than non-affected women (Bazin, Bouchard, Brisson, Morin, Meisels, & Fortier, 1994; Danielsson, Sjöberg, & Wikman, 2000; Edgardh & Abdelnoor, 2007; Smith, Ritchie, Galask, Pugh, Jia, Ricks-McGillan, 2002). Researchers and
Clinicians purported for many years that infection, and particularly chronic infection, led to an inflammatory response that was the main cause of the symptoms of PVD. There is inconsistent evidence, however, for an inflammatory role in PVD. While some research has demonstrated significantly greater signs of chronic inflammation in affected versus non-affected women (Bornstein, Goldshmid, & Sabo, 2004; Bornstein, Maman, & Abromovici, 2001; Goetsch, Morgan, Korcheva, Li, Peters, & Leclair, 2010), other studies have found no between-group differences; in fact, some groups have found great variability in the presence of inflammation among women with PVD (Bohm-Starke, Falconer, Rylander, & Hilliges, 2001; Halperin, Zehavi, Vaknin, Ben-Ami, Pansky, & Schneider, 2005). This variability may suggest that although inflammation—that may or may not be triggered by infection—may play a role for some women, PVD differs from chronic inflammatory diseases and active inflammation is not the sole cause of patients’ symptoms.

The role of infection and inflammation for some women with PVD is also supported by genetic research demonstrating that women with PVD have a higher incidence of a number of alleles associated with abnormal regulation of inflammation and immune defense against fungal, bacterial, and viral pathogens than non-affected women (Babula, Danielsson, Sjöberg, Ledger, & Witkin, 2004; Babula, Linhares, Bongiovanni, Ledger, & Witkin, 2008; Gerber, Bongiovanni, Ledger, & Witkin, 2002; Gerber, Bongiovanni, Ledger, & Witkin, 2003; Jeremias, Ledger, & Witkin, 2000). Overall, the study findings suggest that some women with PVD have a relative inability to launch an effective antimicrobial immune response and/or a reduced capacity to terminate pro-inflammatory immune activity. It has been speculated, therefore, that these women have an increased susceptibility to lower genital tract infections, and that infection triggers an inflammatory response that becomes chronic and leads to the painful symptoms of PVD, even once the infection is gone.

**Hormonal factors.** In addition to a possible genetic susceptibility to vulvar infection and
inflammation, researchers have investigated the role of hormones in increasing these vulnerabilities in women with PVD. Specifically, they have looked at hormonal contraceptives (HC) as a risk factor for PVD. There is inconsistent evidence in the literature with respect to whether the use of HC and the onset of HC use are related to a greater risk for PVD (Bazin et al., 1994; Berglund, Nigaard, & Rylander, 2002; Bouchard, Brisson, Forier, Morin, & Blanchette, 2002; Danielsson, Sjöberg, Stenlund, & Wikman, 2003; Danielsson et al., 2000; Sutton, Pukall, & Chamberlain, 2009a). The fact that earlier age of HC use, and earlier age of menarche (Bazin et al., 1994) have both been associated with increased risk of PVD have led authors to speculate that the hormonal impact on the genital mucosa and the mucosal secretions makes the tissue more vulnerable to irritants and increases the local inflammatory response, leading to increased vulvar sensitivity. Although one study did find that among women with PVD, those who were using HCs had greater pain sensitivity at the vulvar vestibule than those not using HCs (Bohm-Starke, Johannesson, Hilliges, Rylander, & Torebjörk, 2004), another study found no differences between these two groups (Heddini, Bohm-Starke, Grönbladh, Nyberg, Nilsson, & Johannesson, 2012). The variable findings and anecdotal evidence of women developing vulvar pain after starting or changing HCs suggests that hormonal factors may play a role in the development of PVD for a subset of women. It is still unclear whether the impact of hormonal changes on the vulva is that of mucosal changes that affects the local tissue sensitivity.

**Peripheral and central nervous system.** There is ample evidence demonstrating altered peripheral nervous system functioning at the vulvar vestibule leading to heightened sensitivity. Specifically, women with PVD show greater vestibular innervation as compared to non-affected women (Bohm-Starke, Hilliges, Falconer, & Rylander, 1998; Bohm-Starke, Hilliges, Falconer, & Rylander, 1999; Goetsch et al., 2010; Tympanidis, Terenghi, & Dowd, 2003). This increased innervation allows for the summation of impulses, thus resulting in lower tactile thresholds, as well as lower thresholds to pressure and heat pain at the vestibule among women with PVD as
compared to controls (Bohm-Starke, Hilliges, Brodda-Jansen, Rylander, & Torebjörk, 2001; Giesecke, Reed, Haefner, Giesecke, Clauw, & Gracely, 2004; Lowenstein et al., 2004; Pukall et al., 2002; Sutton et al., 2009a). Lower tactile and pain thresholds among women with PVD have also been documented at various non-genital sites, suggesting that there may be some dysregulation at the level of the central nervous system (Giesecke et al., 2004; Granot, Friedman, Yartnitsky, & Zimmer, 2002; Granot, 2005; Granot & Lavee, 2005; Pukall et al., 2002). The possible role of central sensitization also has some preliminary support from brain imaging studies. Research studies have found increased grey matter in brain areas known to be involved in pain modulation and in stress-induced disorders, as well as higher overall neural activation in response to pain, among women with PVD compared to controls (Pukall, Strigo, Binik, Amsel, Khalifé, & Bushnell, 2005b; Schweinhardt, Kuchinad, Pukall, & Bushnell, 2008). The possible role of central nervous system dysregulation is also supported by research demonstrating that women with PVD are more likely than non-affected women to report more instances of non-vulvar pain. This was true both with respect to having more painful areas and more severe pain upon a tender point examination, as well as self-reported regularly experienced non-vulvar pains (Pukall, Baron, Amsel, Khalifé, & Binik, 2006).

Overall, research supports the role of various biomedical factors in the development of PVD. Given the great variability in the inflammatory, hormonal, and nervous system factors among women with PVD, and the fact that not all women with PVD demonstrate dysfunction in all of these areas, PVD is understood to be a symptom profile with multiple etiological pathways. It is therefore likely that there exist subsets of women with PVD that have similar etiological pathways. Women with primary PVD, for instance, have been found to have significantly more neural hypertrophy and hyperplasia and lower pain thresholds than women with secondary PVD (Leclair, Goetsch, Korcheva, Anderson, Peters, & Morgan, 2011; Sutton, Pukall, & Chamberlain, 2009b). There is also research demonstrating that women with PVD who have a history of
recurrent vulvovaginal candidiasis experience more persistent pain and are more likely to have vaginal discharge and dysuria, suggesting that this etiological pathway may lead to a slightly different symptom profile (Witkin, Gerber, & Ledger, 2002).

**Non-medical, psychological, and sexual factors.** Within the biopsychosocial framework, researchers have looked to investigate non-medical factors important to the conceptualization of the development and maintenance of PVD. Three broad areas have been explored: psychological, sexual, and pelvic floor muscle (PFM) functioning. As with the research on biomedical factors, the studies are all cross-sectional in nature, and thus, these non-medical factors may be understood to play a predisposing or perpetuating role in PVD, or are proposed to be mere consequences of the pain of PVD. Whereas there is considerable consensus among clinicians and researchers that the biomedical factors likely act as predisposing and/or precipitating factors of PVD pain, there is less consensus regarding the role of non-medical factors.

**Psychological factors.** The importance of investigating the role of psychological factors in pain initially grew out of Melzack and Wall’s (1965) Gate Control Theory of Pain that proposed that the experience of pain is based on an integration of ascending and descending central nervous system activity. This meant that psychological factors (e.g., attention, affect, attitudes) are capable of influencing the experience of pain. Although more up-to-date theories of pain have been developed, these theories also support the role of psychological factors in pain perception.

Many studies comparing women with PVD and non-affected women demonstrate significantly higher levels of depressive and anxious symptomatology, as well as greater percentages of women with PVD meeting clinical cut-off scores in both areas (Gates & Galask, 2001; Granot et al., 2002; Johannesson, Nygren de Boussard, Brodda Jansen, & Bohm-Starke, 2007; Nylander Lundqvist & Bergdahl, 2003). Vulvodynia has been found to be associated with
new or recurrent onset of a mood or anxiety disorder, and is also much more prevalent among
women with pre-existing mood or anxiety diagnoses (Khandker, Brady, Vitonis, MacLehose, Stewart, & Harlow, 2011). It has been speculated that the link between these conditions is
inflammation, with psychological stressors leading to physiological changes in the central
nervous, endocrine, and immune systems. Another possible explanation is a common feature of a
general pattern of catastrophic or negativistic thinking in response to stressful events or
experiences. A considerable number of women who experience vulvar pain for even up to 3
months, for instance, report full remission of their pain (Reed et al., 2008). It is possible that those
women who are prone to responding to normal experiences of vulvar pain with maladaptive
cognitive and behavioural patterns (the same ones who may be more likely to have mood or
anxiety disorders) may more frequently develop chronic vulvar pain.

This possible connection is consistent with research demonstrating that women with PVD
differ from control women, on average, in cognitive responses to pain, as well as in personality
profile. For instance, women with PVD demonstrate higher levels of hypervigilance to pain
(Payne et al., 2005), score higher on pain catastrophizing for non-vulvar pain, report greater
levels of distress with the same intensity of experimentally delivered vulvar pain (Pukall et al.,
2002), and rate the degree of interference of their non-genital pain higher (Payne, Binik, Pukall,
Thaler, Amsel, & Khalifé, 2007) than control women. Women with PVD are also known to
catastrophize more about their vulvar pain than their worst non-vulvar pain (Pukall et al., 2002;
Schweinhardt et al., 2008). These findings may suggest that women with PVD respond to pain
with more salient negative affect and less adaptive coping mechanisms. This speculation is
supported by findings that women with PVD are more likely to have personality traits (e.g., trait
anxiety, pessimism) that would result in such outcomes (Granot & Lavee, 2005; Granot,
Friedman, Yarnitsky, Tamir, & Zimmer, 2004a; Granot et al., 2002; Nylander Lundqvist &
Bergdahl, 2005; Pukall et al., 2006).
Consistent with the notion that psychological factors contribute to the experience of pain, numerous variables, including hypervigilance to pain, pain anxiety, pain catastrophizing, pain self-efficacy, and harm avoidance, have demonstrated significant correlations with both intercourse pain intensity and experimental vulvar and non-vulvar pain sensitivity and intensity among women with PVD (Desrochers, Bergeron, Khalifé, Dupuis, & Jodoin, 2009; Granot, 2005; Granot & Lavee, 2005; Sutton et al., 2009a). Thus, the differences in cognitive and personality profiles in women with PVD compared to controls likely contribute to the pain of PVD, either as predisposing or perpetuating factors, or both. However, as with the biomedical factors, not all affected women present with these features. For instance, in one study, 52% of the women with PVD had low levels of anxiety, somatization, and catastrophizing (Granot & Lavee, 2005). These results suggest that although psychological factors may play a role in the pathogenesis of PVD for some women, it does not for all. This conclusion was also drawn by authors of an early review on the topic, who stated that “there is no reason to suggest that there is a specific psychological profile associated with [PVD] or that psychological factors such as anxiety, depression and somatization are a necessary part of the etiology of the disorder, although as with other pain conditions they might possibly make the experience of pain worse” (Green & Hetherton, 2005, pp. 103-104).

**Sexual factors.** Given that the pain of PVD is most often experienced in the context of sexual activity, a number of studies have investigated sexual correlates of the pain. Specifically, as compared to women without PVD, affected women demonstrate significantly reduced sexual functioning, including lower sexual desire, arousal, lubrication, and ability to reach orgasm (Desrochers et al., 2008; Payne et al., 2007; Sutton et al., 2009a; White & Jantos, 1998). It has been suggested that when attention is focused on pain during sexual stimulation, there are fewer attentional resources devoted to the processing of sexually arousing stimuli, thus resulting in possible exacerbation of pain (Payne et al., 2005). This postulation is supported by findings that
women with PVD who were more anxious before watching an erotic film demonstrated less physiological arousal during the film (Payne et al., 2007). Furthermore, lack of significant differences between affected and unaffected women on objective or subjective measures of physiological arousal during the erotic film suggest that outside of the context of experienced pain, women with PVD are able to focus on arousing stimuli as much as women without pain.

The fear-avoidance model, originally developed by Lethem and colleagues (Lethem, Slade, Troup, & Bentley, 1983), purports that negative appraisals about pain and its consequences (e.g., catastrophizing), results in pain-related fear and hypervigilance, and thus in avoidance and/or safety behaviours to reduce the pain (Vlaeyen & Crombez, 2007). Although there is some support for this model among women with PVD, with some suggestions of greater sexual avoidance (Brotto, Basson, & Gehring, 2003; Desrochers et al, 2008; Marriott & Thompson, 2008; Sutton et al., 2009a; White & Jantos, 1998), some studies do not find less frequent sexual activity among women with PVD compared to controls (Sutton et al., 2009a), and some women with PVD report enduring the pain of sex to avoid rejecting their partner or avoid feelings of guilt (Marriott & Thompson, 2008). Thus, although the fear-avoidance model of pain may fit for some affected women, some women with PVD appear not to avoid pain-provoking activities.

Although it is not possible to definitively state whether sexual difficulties are a cause or a consequence of the pain of PVD, research findings suggest that the difficulties likely develop after pain onset (Sackett et al., 2001; Sutton et al., 2009a). Interestingly, despite the significant impacts of PVD on women’s sexual lives, controlled studies using validated scales do not indicate significantly reduced relationship adjustment among women with PVD compared to either control women or scale norms (Smith & Pukall, 2011).

**Pelvic floor muscle functioning.** The PFMs refer to all of the supportive structures within the pelvic cavity and play a number of roles including 1) support of the uterus, bladder, urethra, and rectum, 2) sphincteric control of continence, 3) orgasmic response, and 4) support of
the trunk. Thus, dysfunction of the muscles can contribute to weakness, incoordination, spasm, and hypertonicity, or increased tone (Hartmann, 2010). Research into the role of the PFMs in PVD is based on the knowledge that heightened muscle tension is understood as a form of inefficient peripheral response to hyperalertness that is frequently seen in chronic pain patients (Jantos, 2008). Both the superficial PFMs, as well as the levator ani group of muscles, have been investigated as playing potential roles in the pain of PVD. Specifically, heightened PFM resting tone has been found using both manual examination and surface electromyographic (sEMG) recordings among women with PVD (Gentilcore-Saulnier, McLean, Goldfinger, Pukall, & Chamberlain, 2010; Reissing, Binik, Khalifé, Cohen, & Amsel, 2004; Reissing et al., 2005; White, Jantos, & Glazer, 1997). Interestingly, studies have found less consistent findings of muscle tone at the deeper PFMs, as well as a lack of increased tone in areas of the muscles that would be typical of long-term changes in patients with chronic overall increased tone (Gentilcore-Saulnier et al., 2010; Reissing et al., 2005). These results have led authors to speculate that muscle tension begins as a protective guarding response to some initial pain experience, and that over time the response results in increased tone even when the pain is no longer present. This increased resting tone would subsequently increase pressure at the vestibule upon attempted vaginal penetration, and thus, increase the experience of pain. Thus, the increased PFM tone is understood to maintain and exacerbate the pain of PVD, rather than cause it.

In addition to findings of increased PFM tone, women with PVD also demonstrate dysfunction of the muscles in other arenas, including greater superficial muscle reactivity in response to pain; less flexibility of the PFMs at the vaginal entrance; greater muscle instability; less contractile strength, particularly when more pain is present; and less, and slower, ability to relax the muscles following a contraction as compared to non-affected women (Gentilcore-Saulnier et al., 2010; Reissing et al., 2004; Reissing et al., 2005; White et al., 1997). Overall, compared with 7% of non-affected women, 90% of women with PVD demonstrate PFM
pathology (Reissing et al., 2005), suggesting that treatment should target this dysfunction and that other treatments for the pain may be less likely to result in complete pain relief if the protective response of muscle guarding is not addressed.

**PVD and the biopsychosocial model.** All of the findings discussed are consistent with the biopsychosocial model of PVD, in that the experience of pain is associated with a number of biomedical, physiological, psychological, and sexual factors. Although the cross-sectional nature of the studies does not allow for firm conclusions to be made about the causal relationship among the factors, most researchers and clinicians agree that whereas the biomedical factors are more likely to result in the onset of pain, psychological factors may act to maintain and exacerbate pain. This was aptly described by one group of authors: “The clinical manifestations of vestibulitis may result from the convergence of a variety of pathophysiological mechanisms, including a predisposition of the mucosa toward heightened inflammatory response, pelvic muscle dysfunction, previous trauma (e.g., childbirth, pudendal nerve injury, vaginitis), intrinsic CNS dysregulation, and modulation by psychologic traits” (Zolnoun, Hartmann, Lamvu, Assanie, Maixner, & Steege, 2006, pp. 396).

Theoretical models driving treatment for PVD reflect the cyclical nature of pain in affected women (e.g., Pukall et al., 2005a; ter Kuile, Both, & van Lankveld, 2010). These models focus on a number of key factors: (1) the maintaining and exacerbating role of psychological variables such as pain catastrophizing, fear of pain, and hypervigilance to pain, (2) the involvement of the PFMs, specifically the heightened muscle tone, and (3) sexual difficulties (see Figure 1). Given the cyclical nature of these models, these components can all be understood as both contributors to, and outcomes of, the pain itself and thus can be considered targets of the treatment of PVD. The diagnostic criteria for genito-pelvic pain/penetration disorder in the DSM-5, in fact, include both fear and anxiety about pain, as well as PFM tensing or tightening, as possible features (APA, 2013).
**Treatment Options for PVD**

Given that there is no single, verifiable cause for PVD, treatment options vary greatly. Treatments have attempted to target both the biomedical factors thought to initiate pain onset, as well as those factors thought to maintain the pain of PVD.

**Medical and surgical treatment options.** Medical interventions for PVD include topical interventions (e.g., antifungals, corticosteroids, estrogen creams, anesthetics), injectable medical treatments (e.g., corticosteroids, anesthetics, interferon, botulinum toxin), and systemic medications (e.g., antifungals, antidepressants, anticonvulsants). A recent review of various treatment options for PVD found success rates for medical treatments—including topical, injectable, and systemic medications—ranging from 13 to 67% (Landry, Bergeron, Dupuis, &
Desrochers, 2008). There are significant methodological issues with a majority of the studies, however, as well as no consistent definition of treatment success. Four studies investigating medical treatment options (i.e., cromolyn cream, oral fluconazole, botulinum toxin, lidocaine cream and desipramine) have included placebo control groups and all found no significant difference in treatment response between the active treatment and the placebo (Bornstein, Livnat, Stolar, & Abramovici, 2000; Foster, et al., 2010; Nyirjesy, Sobel, Weitz, Leaman, Small, & Gelone, 2001; Petersen, Giraldi, Lundvall, & Kristensen, 2009). In addition to a lack of benefit over and above placebo, a number of medical treatments have undesirable side effects such as a burning sensation upon application of some topical options and reduced sexual arousal with antidepressants. Although a subset of women with PVD will respond to some of these treatment options, typically, medical treatment providers will try several different treatments unsuccessfully before offering a more invasive, surgical treatment option.

The surgical treatment of PVD, known as vestibulectomy, involves the surgical excision of vestibular tissue. Various techniques have been developed, with the most common being the modified perineoplasty, which consists of the excision of the posterior hymen and of the painful mucosa of the posterior and anterior vestibule to a depth of 2 to 5mm. Reviews of the literature have determined that vestibulectomy has the highest success rates of any treatment option, ranging from 61 to 83% among prospective studies (Andrews, 2011; Bergeron, Binik, Khalifé, & Pagidas, 1997; Landry et al., 2008). The studies use various different definitions of success, however, and thus it is difficult to quantify the size of the effect. A recent systematic review estimated the absolute effect of vestibulectomy (i.e., the effect above and beyond the predicted placebo effect) to be 30% (Andrews, 2011). Minor to moderate postsurgical complications (e.g., heavy bleeding, local infection) are found in some women with PVD and others require an additional surgery (Schneider, Yaron, Bukovsky, Soffer, & Halperin, 2001). Furthermore, there is a total lack of effectiveness or a worsening of pain in a subset of affected women (Landry et al.,
2008). Thus, surgical treatment is generally only recommended after the failure of less invasive treatments (Haefner et al., 2005).

Although few treatment studies investigating medical and surgical treatment options have included outcome measures other than pain reduction or ability to resume sexual intercourse, there are some indications that these treatments can lead to improvements in the areas of sexuality and emotional well-being (Bergeron et al., 2001b; Bergeron, Khalifé, Glazer, & Binik, 2008; Bohm-Starke & Rylander, 2008; Goldstein, Klingman, Christopher, Johnson, & Marinoff, 2006; Pelletier, Parratte, Penz, Moreno, Aubin, & Humbert, 2011; Peterson et al., 2009; Rapkin, McDonald, & Morgan, 2007). Despite findings that treatments aimed at targeting the presumed etiology of the pain can be successful for some women, and can even lead to improvements in psychosexual functioning in some cases, there are also treatment options aimed at addressing the maintaining and exacerbating factors of PVD. These non-medical treatment options are specifically geared toward targeting not only the pain of PVD, but also the psychosexual correlates of pain.

**Treatments targeting the pelvic floor muscles.** Given the proposed role of PFM dysfunction in maintaining and exacerbating the pain of PVD, treatment options targeting this dysfunction, particularly the heightened muscle tone, have been investigated as potential avenues for women with PVD. sEMG biofeedback is used in response to the findings of heightened PFM tone in women with PVD and has been the most widely studied PFM treatment for PVD. Four studies have examined the effectiveness of sEMG biofeedback for PVD. Although the protocols varied with respect to frequency of exercises, frequency of contact with a service provider, and duration of the treatment, all studies demonstrated significant improvements in pain following treatment, which were maintained up to 2.5 years (Bergeron et al., 2001b, 2008; Danielsson, Torstensson, Brodda-Jansen, & Bohm-Starke, 2006; Glazer, Rodke, Swencionis, Hertz, & Young, 1995; McKay, Kaufman, Doctor, Berkova, Glazer, & Redko, 2001). The studies also
demonstrated improvements in PFM functioning—including reduced resting tone, increased muscle strength, and increased muscle stability—and increases in measures of quality of life, sexual functioning and satisfaction, and psychological adjustment. In the most well-designed of these studies, Bergeron et al. (2001b, 2008) compared vestibulectomy, group CBT (GCBT), and pelvic floor sEMG biofeedback for the treatment of PVD. The average reduction in pain with intercourse at 6-month follow-up for those in the biofeedback group was 35% and at that time, 34.6% were considered to have had a successful treatment (i.e., subjective report of at least “great improvement”).

Support for pelvic floor treatment options has also been demonstrated in a number of small studies investigating other treatment modalities, including electrical stimulation and vaginal dilator therapy (Murina, Bernorio, & Palmiotto, 2008; Murina, Bianco, Radici, Felice, Di Martino, & Nicolini, 2008). In an attempt to increase success rates of treatments targeting the pelvic floor muscles, some clinicians use a comprehensive pelvic floor rehabilitation (PFR) program that includes multiple treatment modalities. The goals of such a comprehensive intervention according to Bergeron and Lord (2003) are to (1) increase awareness and proprioception of the pelvic floor musculature; (2) improve muscle discrimination and muscle relaxation; (3) normalize muscle tone; (4) increase elasticity of the tissue at the vaginal opening, as well as desensitize the painful area; and (5) decrease fear of vaginal penetration. To meet these goals, the intervention plan typically includes education about the role of pelvic floor hypertonicity in maintaining PVD, EMG biofeedback, electrical stimulation, stretching and other manual techniques, and insertion techniques such as the use of vaginal dilators.

Two treatment studies have investigated such a comprehensive PFR program; one retrospectively (Bergeron et al., 2002) and one prospectively (Gentilcore-Saulnier et al., 2010; Goldfinger et al., 2009). Both studies provide preliminary support for the usefulness of such a program in reducing the pain of PVD and in improving PFM, sexual, and emotional functioning.
The success rates found in these studies (51.5%, 77%) also suggest that a comprehensive program may lead to better outcomes than solely using biofeedback. Such a comprehensive program, however, has not been included in any randomized treatment studies to compare its effectiveness to other treatments.

**Cognitive behavioural therapy.** Cognitive-behavioural therapy (CBT) is a commonly used treatment option for the management of various chronic pain conditions, including PVD. Randomized controlled studies have consistently documented improvements in pain severity, mood/affect, cognitive coping and appraisal, pain behaviour and activity level, and social role functioning after CBT for individuals with varying chronic pain conditions (Morley, Eccleston, & Williams, 1999). As with a cognitive-behavioural understanding of other conditions such as depression or anxiety, PVD is conceptualized within this model as an interaction among thoughts, behaviours, emotions, and physical sensations that all interact with one another in a bidirectional manner within the context of one’s environmental circumstances (see Figure 2).

Because the pain is often triggered in sexual circumstances, and because it can be both affected by and affect sexual functioning, cognitive-behavioural interventions for PVD often include both cognitive-behavioural pain management and sex therapy techniques to target the pain and sexual functioning. According to Bergeron and Lord (2003), the goals of CBT for women with PVD are to aid them in: (1) reconceptualizing their pain as a multifactorial pain problem influenced by various factors including thoughts, emotions, behaviours, and couple interactions; (2) modifying the factors associated with pain during intercourse and increasing adaptive coping and decreasing pain intensity; (3) improving the quality of their sexual functioning, and (4) consolidating skills. Common techniques used in cognitive-behavioural pain management and sex therapy include: education about pain as a multifactorial condition and about how vulvar pain affects sexual desire and arousal, self-exploration of genitals, progressive muscle relaxation and/or suggestive relaxation, abdominal breathing, distraction techniques
usually focusing on sexual imagery, rehearsal of coping self-statements, communication skills training, cognitive restructuring, counseling aimed at improving self-image and body-image, Kegel exercises, and vaginal dilatation.

**Figure 2. Cognitive-behavioural model of PVD.**

Three studies to-date have investigated the effectiveness of GCBT for PVD. In the previously mentioned randomized treatment outcome study (Bergeron et al., 2001b, 2008), after eight sessions of GCBT over 12 weeks, women demonstrated significant improvements in pain, and sexual and psychological functioning. The average reduction in pain with intercourse at 6-month follow-up was 36.5% and at that time, 39.3% were considered to have had a successful treatment (i.e., subjective report of at least “great improvement”). Other studies investigating GCBT found similar positive outcomes following treatment, including improvements in PFM tone (Desrochers et al., 2010; ter Kuile & Weijenborg, 2006). Overall, the findings suggest that
GCBT results in improvements in pain during intercourse as well as in psychosexual functioning, and that these improvements are maintained over long periods of time.

There are a number of benefits to CBT being offered in a group format. The primary advantages are that the group format can provide normalization of the condition, that group participants can learn from the experiences and the homework review of others (vicarious learning), and that group treatment is more economical than individual treatment. However, a group format is not acceptable to all individuals, particularly those with social anxiety, or who have interpersonal deficits. Furthermore, scheduling of sessions is much more challenging with a group. CBT delivered on an individual basis has a number of advantages over GCBT, including having more time devoted to each individual and being able to tailor the treatment components to the specific needs of the individual. Moreover, for the specific case of PVD, CBT offered in a group format is likely to only be available to women living in large cities with a multidisciplinary pain centre, or a university with a research lab studying vulvar pain. It is therefore possible that the majority of women with PVD who are receiving CBT are doing so on an individual basis.

There has only been one study, however, investigating the use of individual CBT (ICBT), and it was with a group of women with different forms of vulvodynia (i.e., PVD and generalized vulvodynia). The randomized study compared the effectiveness of ICBT and individual supportive psychotherapy (Masheb et al., 2009) and demonstrated that women who received ICBT showed significantly greater improvements with respect to pain during the cotton-swab test and overall sexual functioning, greater ratings of global improvement and greater treatment satisfaction in comparison with the women who received the supportive therapy. These results indicate that a directive treatment approach including both cognitive and behavioural techniques for pain management may yield better outcomes and greater satisfaction than a less directive approach (Masheb et al., 2009). Because the study was comprised of women with various forms of vulvodynia, it is difficult to know whether these results would hold true for a group of women
with PVD.

**Comparing treatments.** The large majority of PVD treatment studies have investigated just a single treatment. There are a limited number of studies comparing the effectiveness of various treatments, three of which have included non-medical treatment options. Whereas one study comparing sEMG biofeedback and lidocaine demonstrated almost no differences in outcomes between the treatments (Danielsson et al., 2006), Desrochers et al. (2010) found GCBT to be superior to a corticosteroid cream in nearly all outcomes measured, including pain and psychosexual functioning.

The largest study comparing treatment options for PVD came from Bergeron et al.’s (2001b) study comparing vestibulectomy, sEMG biofeedback, and GCBT. Findings indicated that while vestibulectomy outperforms both other treatments on pain outcomes, all three groups demonstrated equally significant improvements in overall sexual functioning and in psychological adjustment. Furthermore, although a significantly higher percentage of those who received vestibulectomy had successful treatment than those who received biofeedback or GCBT, 9.1% of those who received vestibulectomy were worse, while none in the other groups reported a worsening of their condition. Gains were maintained in all groups at a 2.5 year follow-up and between group differences suggested that although the effects of CBT may take longer to present, it may be as effective as vestibulectomy in reducing intercourse pain (Bergeron et al., 2008).

Given the wide array of treatment options for PVD and limited well-controlled treatment outcome studies, clinicians have little guidance for treatment planning. A recent survey including a scenario of a woman presenting with PVD was sent to American clinicians known to treat women with PVD (e.g., gynecologists, dermatologists, family physicians) and asked them to identify what treatments they would use for the case (Updike & Wiesenfeld, 2005). Results from this study indicated much variability in the treatment of PVD across clinicians. Despite physical therapy being the fourth most commonly recommended treatment, and being recommended as...
first-line treatment by 19% of the clinicians, tricyclics, local anesthetics, and topical steroids were more frequently recommended as first-line options. Psychiatric care, alternatively, was only recommended by 10% of clinicians as first-line treatment, and in total was recommended by 23% of the clinicians. Given that no definition was provided for ‘psychiatric care’, it is unclear if these referral are made for psychotherapy aimed at pain management, or whether the clinicians assume the presence of a psychosomatic pain condition, and thus recommended psychiatric treatment. Overall, the findings suggest that clinicians are frequently recommending treatment options with little or no research evidence to support their effectiveness, and that non-medical treatment options are infrequently recommended, despite support for their effectiveness.

**Predicting Treatment Success**

As a result of the variability in response to treatment, numerous studies have attempted to determine the factors that are best able to predict who is most likely to benefit from treatment. The majority of the studies have investigated which baseline variables (i.e., those measured at pre-treatment) predict treatment outcome. Findings have varied considerably from study to study and it is difficult to draw overall conclusions since studies have used a variety of outcome measures and not all studies that included multiple treatments separated predictors by treatment modality. Medical or pain factors that have demonstrated significant correlations with more positive treatment outcomes include secondary rather than primary PVD (Bornstein, Goldik, Stolar, Zarfati, & Abramovici, 1997; Brotto et al., 2003), not experiencing vestibular pain outside of the context of sexual intercourse (Bornstein et al., 1997), a shorter pain duration (Goetsch, 2007), fewer other pain disorders or complaints outside of PVD (Granot et al., 2004b; Heddini, Bohm-Starke, Nilsson, & Johannesson, 2012), and the absence of other concomitant vulvar disease (Zolnoun et al., 2003). Alternatively, some studies have found no association between PVD subtype or pain duration and treatment outcome (Bergeron et al., 2008; Bornstein et al.,
Psychological and PFM variables have also been investigated as potential predictors of treatment outcome. Some studies find that pre-treatment variables such as greater levels of phobia toward vaginal penetration and avoidance of sexual activity (Brotto et al., 2003), more erotophobia (Bergeron et al., 2008), and higher magnification of pain and lower self-efficacy (Desrochers et al., 2010) are associated with less improvement. Alternatively, other studies find that process variables (i.e., changes in variables from pre- to post-treatment) better account for changes in outcome variables. Greater improvements in perceived pain control, helplessness, sexual satisfaction, vaginal muscle tone, and PFM stabilization over the course of treatments have been associated with better treatment outcomes (Glazer et al., 1995; Goldfinger et al., 2009; ter Kuile & Weijenborg, 2006). Knowing which process variables predict treatment outcome provides information about mechanisms of change, and can aid clinicians in knowing which areas to target most in treatment.

Two additional factors that are important to investigate in treatment outcome studies are ratings of treatment credibility/expectations and adherence to homework. Treatment expectancy and credibility have demonstrated significant associations with outcomes and satisfaction of both physical treatment and CBT for chronic low back pain (Smeets, Beelen, Goossens, Schouten, Knottnerus, & Vlaeyen, 2008). Homework adherence has also shown to be associated with better pain outcomes within physical therapy, CBT, and multimodal treatment programs (Dobkin et al., 2010; Hicks et al., 2012; Nicholas et al., 2012). Unfortunately, few PVD treatment studies have looked at these measures. There are mixed findings regarding the association of credibility and expectancy predicting outcomes for PVD treatment (Bergeron et al., 2001b; ter Kuile & Weijenborg, 2006) and the only study to investigate homework adherence found no significant correlations between degree of adherence to homework and the follow-up pain measures.
(Bergeron et al., 2001b). The method of analysis used, however, considered only the final pain measure rather than the degree of improvement (i.e., the change in these pain measures).

**Current Study and Research Objectives**

Despite growing understanding of PVD as a multifactorial condition that is influenced by biological, psychological, and social factors, the treatment literature continues to be driven by a biomedical model. Compared to the number of studies investigating medical treatments for PVD, only a small number of studies have examined the effectiveness of non-medical treatment options for pain. Furthermore, outcomes in studies continue to be pain focused, to the exclusion of other factors known to be of relevance in this population (e.g., sexual and emotional functioning). Although vestibulectomy continues to be the most effective treatment for PVD, it cannot be recommended as a first line treatment due to its invasiveness and potential for negative side effects. Medical treatments, furthermore, are the most commonly used first line treatments despite a lack of evidence to support their use in the majority of women with PVD. Numerous researchers in the field have highlighted the need for more studies investigating the effectiveness of non-medical treatment options, and specifically, prospective comparative studies of treatment outcomes (Andrews, 2011; Landry et al., 2008; Updike & Weisenfeld, 2005).

The current study focuses on the two most frequently recommended non-medical treatment options for PVD: PFR and CBT. Although much of the research into treatments targeting the PFMs has focused on biofeedback, only 66% of physiotherapists treating women with PVD use biofeedback, with 10 alternative treatment modalities being used by a larger proportion of physiotherapists (Hartmann, Strauhal, & Carlotta, 2007). In addition to practicing physiotherapists using a comprehensive PFR approach for PVD, the Vulvar Pain Task Force of the American Physical Therapy Association’s treatment algorithm for vulvar pain includes multiple modalities that go far beyond the use of biofeedback (Strauhal et al., 2007). Despite this,
the task force points to how little data exists of the effectiveness of such a treatment. Although several studies have shown significant reductions in pain and improvements in psychosexual functioning following PFR, this treatment option has only been examined prospectively in one previous study and has not been systematically compared to any other treatment options. Additionally, the effectiveness of CBT offered in a group format has been demonstrated in a number of studies, including several randomized trials. As previously noted, however, access to group-based interventions is limited to a select few cities in North America, and thus, individuals referred for or choosing to seek psychologically-based treatments are most likely to receive this on an individual basis. The use of CBT offered on an individual basis has only been investigated in one previous study with a group of women with different forms of vulvodynia. There is thus a need for further investigation into both of these treatment options for PVD as they appear to be in most common use today. One Canadian centre, for instance, noted that following diagnosis of PVD, the gynecologists recommend that women choose between CBT and physiotherapy as a first line treatment (Bergeron, Binik, & Khalifé, 2002). To ensure the use of evidence-based practice, we must determine whether the practice that is already in use is, in fact, supported by data. Furthermore, there is very little research to guide clinicians in selecting the most appropriate treatment for women due to the lack of comparative studies in existence in the field.

The first aim of the current study, therefore, was to examine the effectiveness of each treatment independently on both pain and psychosexual correlates of pain. Given the promising findings in previous studies, it was hypothesized that both treatments would result in improvements in pain and in psychosexual functioning following treatment.

The second aim of the study was to compare the effectiveness of the two treatment groups on pain and psychosexual functioning. Given the limited research comparing non-medical treatment options for PVD, hypothesized differences between the treatment groups were based on the assumption that the greatest improvements in each treatment group would be consistent with
the treatment goals (as outline by Bergeron & Lord, 2003). Thus, because PFR aims to normalize
the function of the surrounding tissue, and desensitize the vestibular tissue itself, it was
hypothesized that women who completed PFR would have better outcomes with respect to pain
and PFM functioning than women who completed ICBT. Given that CBT aims to impact the
thoughts, emotions, and behaviours associated with pain, as well as to improve sexual
functioning, it was hypothesized that women who completed ICBT would have better outcomes
with respect to psychosexual functioning than women who completed PFR.

The third aim of the study was to determine predictors of treatment outcome.
Specifically, the study investigated which process variables (i.e., changes in variables over the
course of treatment) would predict changes in pain. Once more, based on the goals of the two
treatment groups, it was hypothesized that improvements in pain in the PFR group would be
accounted for by improvements in PFM functioning, whereas improvements in pain in the ICBT
group would be accounted for by improvements in psychosexual functioning. Furthermore, the
study aimed to determine whether treatment credibility/expectations and adherence to homework
predicted treatment outcome. It was hypothesized that greater treatment credibility and
expectations, as well as greater homework adherence, would predict more improvement in pain.

Given that both PFR and ICBT are currently used in clinical practice without
considerable amounts of research providing evidence of their relative benefits, this study hoped to
help inform relevant healthcare professionals (e.g., gynecologists, psychologists, sex therapists,
physiotherapists) about the effects of both of these treatment options to help plan treatment to
meet the needs of affected women. Lastly, the study aimed to demonstrate how expert
recommendations for chronic pain clinical trials can be adapted to be relevant for PVD.
Conducting PVD treatment studies that are more in line with the general chronic pain literature
may help to legitimize the condition among medical professionals and help make more direct
comparisons between the treatment for PVD and other pain conditions.
Chapter 3

Method

Participants

Women were eligible to participate in the study if they: (1) were 18 years of age or older, (2) were fluent in English, (3) experienced vulvar pain upon attempted vaginal penetration for a minimum of 6 months, and (4) met the diagnostic criteria for PVD during the study gynecological examination. Exclusion criteria for the study included: (1) women with other serious medical, psychiatric, or other pain conditions, (2) women with generalized vulvodynia and/or significant vaginismus (i.e., not able to have at least one finger inserted vaginally), (3) women who were pregnant, breastfeeding, or were less than 6 months postpartum, and (5) women who were unwilling to abstain from other treatments for their PVD pain during the course of the study.

Twenty women completed treatment—10 in each treatment group—and the post-treatment and 6-month follow-up assessments. Women completed all portions of the study between September 2009 and April 2012.

Procedures

Recruitment and screening. Women who had participated in previous studies carried out at the Sexual Health Research Laboratory (SHRL) and who gave permission to be contacted about future studies were contacted either by phone or email to inform them of the study. Flyers were posted on Queen’s University campus, as well as around the Kingston area (Appendix A). Electronic advertisements were posted on Facebook for women in the Kingston area. Women with vulvar pain who contacted the SHRL with interest in other lab studies were also informed of the study. Women interested in participating in the treatment study were provided with a detailed account of the study purpose and procedures and were screened for preliminary eligibility over
the telephone using a standardized script (Appendix B). Potentially eligible women were booked for an appointment with the study gynecologist.

**Participant disposition.** Of the 48 women who were screened over the telephone, 12 (25%) were ineligible while 16 (33%) were not interested in participating or were presumed to be uninterested due to an inability to contact them following their screening or gynecological exam. Reasons for ineligibility included pain presentation inconsistent with PVD (e.g., generalized, infrequent pain, \(n = 6, 50\%\)), severe physical or mental health problems interfering with daily life (e.g., fibromyalgia, obsessive compulsive disorder, \(n = 4, 33\%\)), leaving Kingston before treatment would be completed (\(n = 1, 8\%\)), and peri-menopausal onset pain with undetermined vaginal atrophy (\(n = 1, 8\%\)). Only 1 (8%) of these 12 women was determined to be ineligible for the study following the gynecological examination, while the others were ineligible following the screening. Reasons provided for not being interested in participating included being too busy (\(n = 4, 25\%\)), pain subsided (\(n = 1, 6\%\)), husband not wanting her to participate (\(n = 1, 6\%\)), and only wanting to participate in the PFR treatment option but being randomized to ICBT (\(n = 1, 6\%\)).

Given the high volume of women who contact the SHRL to participate in studies, it is not possible to determine how many other women with pain symptoms consistent with PVD were provided with information about the study and declined screening to determine eligibility. There were no significant differences between women who were not interested in participating or who were lost to follow-up and women who did participate in the study on the available demographic (i.e., age, relationship status), health (i.e., presence of physical or mental health problems, hormonal contraceptive use), or pain variables (i.e., pain subtype, duration of pain, percentage of painful intercourse attempts, worst and average intercourse pain intensity).

**Pre-treatment assessments.** Before beginning treatment, participants completed three assessments: (1) a gynecological examination to confirm the presence of PVD, (2) an interview, completion of standardized questionnaires, and vestibular quantitative sensory testing (QST), and
(3) a PFM evaluation.

**Gynecological examination.** A female member of the SHRL met with potentially eligible women at Kingston General Hospital to go over the Letter of Information, obtain informed consent (Appendix C), confirm the woman's medical history and vulvar pain characteristics, and explain the components of the gynecological examination. The pain intensity and unpleasantness numerical rating scales were explained to the women as follows: Pain intensity was described as the sensory component of the pain (i.e., how much the sensation physically hurts), whereas unpleasantness was described as the emotional component of the sensation (i.e., how bothersome or uncomfortable the sensation is). Women then underwent a physical examination by a female gynecologist while a female graduate student was present in the room to record information. The gynecologist visually and manually examined the internal and external genitalia and reproductive organs, and palpated the labia majora, labia minora, vulvar vestibule, perineum, and midline area of the vulva with a cotton-swab. The vulvar vestibule was palpated at five different sites (1, 4, 6, 8, and 11 o'clock, where 12 represents the anterior, and 6 represents the posterior, portion of the vaginal entrance) in a randomized order, rather than a clockwise fashion, to control for sensitization over time (Bergeron et al., 2001a; Pukall, Payne, Binik, & Khalife, 2003). After each palpation, women rated the intensity of their pain. The cotton-swab test is the standard gynecological method for diagnosing PVD (Friedrich, 1987) and one previous study using a similar cotton-swab examination found good inter-rater correlations and no significant differences between ratings at vestibular sites across two testing times (Bergeron et al., 2001a). The findings from the examination, along with the women's pain history, formed the basis for the diagnosis of PVD. Women who did not meet the diagnosis of PVD were debriefed and were not included in the study. Women who received a diagnosis of PVD were booked for an appointment for the pre-treatment testing.

**Interview, questionnaires, and quantitative sensory testing.** Participants completed a
semi-structured interview (Appendix D) that included questions in the following areas: sociodemographic information (e.g., age, ethnicity, education, employment status), sexual and relationship history (e.g., sexual orientation, relationship status, relationship length), medical and gynecological history (e.g., menstruation history, history of yeast infections, STIs, non-vulvar pain history), a comprehensive history of vulvar pain (e.g., onset of pain, diagnostic and treatment history, location and quality of pain, pain intensity and unpleasantness ratings, frequency of penetration attempts), and treatment goals. Participants then completed a number of standardized questionnaires via computer administration. Only those questionnaires analyzed for the purpose of this thesis are described below.

The QST session included the measurement of pressure pain thresholds (i.e., the point at which one first detects the sensation of pain) at the 3, 6, and 9 o’clock positions of the participant’s vulvar vestibule using a digital vulvalgesiometer. Participants were explained the details of the testing, shown the measurement tool, instructed on the use of the rating scales, and given the opportunity to ask any questions before testing began. A female member of the SHRL was present in the room to run the computer system and record pain ratings. The digital vulvalgesiometer consists of a single device that exerts pressures from 3 to 600 grams. A disposable cotton-swab is attached to one end of the device and is the only portion that comes into contact with the participant’s tissue. The other end of the device has a small cable consisting of coil wires and is connected to a laptop computer. This digital version of the device was adapted from the previous non-digital spring based vulvalgesiometers that have been shown to replicate the burning pain many women with PVD report experiencing during sexual intercourse (Pukall, Binik, & Khalifé, 2004a; Pukall, Young, Roberts, Sutton, & Smith, 2007). The cotton-swab tip was applied to the vestibule at one site and pressed slowly in a continuous manner. The participant held a buzzer in their dominant hand and pressed the buzzer, also connected to the laptop computer, when they first felt pain (i.e., their pain threshold). Computer software recorded
the amount of pressure applied by the digital vulvalgesiometer at the point at which the participant pressed the button. The pressure was removed from the vestibule as soon as the buzzer was pressed. Participants then rated the intensity and unpleasantness of the pain sensation on separate numerical rating scales. The digital vulvalgesiometer was applied at three different positions of the vestibule (i.e., 3, 6, and 9 o’clock) in a randomized order with an inter-stimulus interval of 10 seconds, or until the participant reported that pain had subsided. All sites were tested once before the procedure was repeated a second time.

**Pelvic floor muscle evaluation.** Participants subsequently saw a female rehabilitation science graduate student at the Pelvic Floor Laboratory, School of Rehabilitation Therapy, Queen’s University. The graduate student was also a registered physiotherapist with the College of Physiotherapists of Ontario and had two years of experience treating women with vulvar pain and other urogynecological conditions. The evaluation consisted of an interview, body measurements, manual examination of PFM functioning (i.e., contractile ability, contractile strength, tone, relaxation following contraction, and compliance of vaginal opening), and 4D ultrasound imaging of the PFM at rest and during various PFM tasks. For the purposes of this dissertation, two of the PFM measures were investigated: levator ani muscle tone and relaxation of the levator ani muscles following a muscle contraction.

The internal vaginal palpation for tone was performed with 1 digit and was assessed by a passive stretch of the muscle at 4, 6, and 8 o’clock. The muscle sites were tested in a randomized order at the superficial muscle layer. The digit was inserted vaginally to the section between the distal interphalangeal joint and the proximal interphalangeal joint.

The ability of the levator ani muscles to relax following a muscle contraction was assessed by measuring how closely the muscles returned to their pre-contraction state with 1 digit inserted vaginally.

Following the PFM evaluation, participants were randomized to one of two treatment
groups: PFR or ICBT. The order of randomization was determined by a computerized random number generator that produced digits 1 and 2, each identifying a treatment group, for the pre-identified number of participants required for the study.

**Treatments.** Both treatments consisted of eight 1.5-hour sessions of PFR or ICBT. Although sessions were meant to occur over a 12 week period, due to scheduling challenges, the time to complete all treatment sessions ranged from 8 to 24 weeks ($M = 14.19, SD = 3.90$).

Both treatments were standardized so that the same general components were included for all participants. The protocols, however, were flexible enough so as to be adaptable to participant’s specific situations (e.g., single versus being in a committed relationship, long-distance relationships, occurrence of vaginal infections, menstruation). The first session of both treatments included a summary of the treatment components followed by obtaining consent to treat (Appendix E) and the completion of a measure of the participant’s perception of the treatment’s credibility and their expectations for improvement.

**Pelvic floor rehabilitation.** The same physiotherapist who completed the pre-treatment PFM evaluation conducted all of the PFR treatment sessions. The treatment protocol was adapted slightly from one used in a previous treatment outcome study which resulted in positive outcomes (Goldfinger et al., 2009) and included the following procedures: (1) Education was provided to the participants regarding possible causes of PVD, PFM anatomy, and the role that the PFMs play in maintaining PVD. The same education was provided to all participants; however, based on individual participant’s questions about their bodies or about PVD, more or less additional education may have been provided. (2) PFM exercises (e.g., contract-relax) were taught and practiced in session and were assigned as homework. The goal of these exercises is to increase the participants’ awareness of and control over their PFMs. The exercises progressed over the course of treatment and the amount of time devoted to the exercises varied across participants depending on their progress. (3) PFM manual techniques were performed in session by the
physiotherapist and included such techniques as external pressures, “peace-sign” stretches involving passive stretch at the posterior regions of the vestibule, perineal massage, and trigger-point release. Although each technique has a specific aim, the general goals of the manual techniques are to increase proprioception and facilitate contraction and relaxation, mobilize the PFMs and soft tissue, normalize tone, desensitize the vulvar vestibule, and increase circulation. The techniques performed and the time devoted to each one varied across participants depending on their presentation and progress. (4) sEMG biofeedback was utilized in session with all participants until the point at which the participant had gained satisfactory muscle control. This was determined by the physiotherapist through observation of the biofeedback readings and through PFM palpation. (5) Silicone vaginal dilators (Come As You Are, Toronto, Ontario, Canada) were used both in session and by the participant at home as homework. Four dilators were provided to each participant and each participant progressed through the dilators over the course of treatment according to their own pace. The goals of the dilators are to increase the participants’ control over their PFMs during vaginal penetration, to decrease fear of penetration, and to stretch the vaginal opening. (6) Lower extremity stretches were taught in session and were assigned as homework between sessions. The goal of the stretches is to increase flexibility in the lower extremity muscles that are in close relationship with the PFMs. (7) Participants were instructed on how to use deep breathing exercises as a relaxation exercise before dilator insertions and/or intercourse. (8) Participants were provided with additional information regarding reducing genital pain including the application of a cold compress to the genital area following painful activities and attempting different sexual positions. In general, participants were encouraged to withhold from engaging in sexual activities that were not pain-free during the course of treatment to maximize progress. The components of the treatment were consistent with recommendations put forth by a Vulvar Pain Task Force of the American Physical Therapy Association (Strauhal et al., 2007).
Participants’ partners were invited to attend a portion of the last or second last treatment session; 4 partners attended a session. Participants whose partners attended a session provided the physiotherapist with information in advance regarding what they were comfortable sharing with the partner. The partners were provided with basic information about the role of PFMs in PVD, were given some information about their partners progress in treatment, and were shown exercises and stretches that they could perform with their partner to help reduce pain during sexual activity.

*Cognitive-behavioural therapy.* The ICBT program was adapted from a previously used GCBT program (Bergeron, Binik, & Larouche, 2002) to be applicable for the individual therapy format and included the following procedures: (1) Education was provided to participants about the epidemiology, etiology, effects, and treatment of PVD. Additionally, participants were provided with information about the myths about pain. The same education was provided to all participants; however, based on individual participant’s questions about PVD, more or less additional education may have been provided. (2) PVD was re-conceptualized as a multi-factorial pain condition through education about pain processing (e.g., Gate Control Theory of Pain), exploration of the participants’ varying levels of pain based on contextual factors, and building a unique cognitive-behavioural model of the participants’ pain. This re-conceptualization aimed to allow participants to see that they could be in control of their pain experience and to identify specific thoughts and behaviours that could be targeted throughout treatment. (3) Participants were instructed to explore their genitals at home and this experience was discussed in session. Furthermore, a desensitization exercise was conducted in session which involved observing photographs of women’s genitals. In addition to increasing the participants’ comfort level in discussing and observing their genitals, these exercises also aimed to dispel unrealistic ideas that participants’ held about their genitals. (4) Participants were educated about the role of stress/anxiety in triggering and perpetuating pain. Diaphragmatic breathing was taught and
practiced in session and was assigned as homework between sessions. Several different breathing and relaxation exercises were practiced over the course of treatment such that the participants could select ones that worked best. The participants were encouraged to use the relaxation techniques during formal practice time, before using their vaginal dilators, in anticipation of painful sexual activities, and at other times of stress. (5) The impact of pain on the participants’ sexual functioning was explored in session and techniques for increasing desire and arousal that were specific to each participant were brainstormed and implemented as homework. (6) Sexual communication skills training was conducted with participants and focused on their specific needs (e.g., sexual assertiveness, expressing sexual desires, informing new partners about pain). (7) Participants were educated about the role of the PFMs in exacerbating vulvar pain. PFM exercises (e.g., contract-relax) were taught and practiced in session and were assigned as homework. As in PFR, the goal of these exercises is to increase the participants’ awareness of and control over their PFMs. The exercises progressed over the course of treatment and the amount of time devoted to the exercises varied across participants depending on their progress. (8) Participants were instructed on the use of silicone vaginal dilators (Come As You Are, Toronto, Ontario, Canada) in session and the participants were provided with four dilators to progress through over the course of treatment. The goals of the dilators are to increase the participants’ control over their PFMs during vaginal penetration, to decrease fear of penetration, to stretch the vaginal opening, and to provide the participants with opportunities to practice cognitive techniques. (9) Informal and formal cognitive restructuring techniques were used in session to help participants identify their unrealistic or maladaptive thoughts regarding their pain and to replace them with more realistic and adaptive thoughts. Participants were also instructed to use the cognitive techniques outside of session for homework. Once participants identified realistic and helpful thoughts, coping self-statement were collaboratively developed for the participants to use within the context of painful activities or to reduce anticipatory anxiety.
Participants in both treatment groups were asked to keep logs that included pain diaries as well as their adherence to the homework exercises. At the end of treatment, each participant and their therapist built a collaborative maintenance plan.

**Post-treatment and 6-month follow-up assessments.** Within one month following, and six months after the participants completed their last treatment session, they returned to complete the previously described gynecological exam, an interview (Appendix F) and questionnaires, the QST session, and the PFM evaluation. During the interview, participants provided information about changes with respect to medical and gynecological concerns, relationship status, and pain. Participants were also asked global improvement and satisfaction questions related to the treatment they received, and how much progress they had made on each of the goals they set at the pre-treatment interview. The wording for questionnaires that did not previously have time frames was adapted for the post-treatment and 6-month follow-up sessions. Specifically, participants were asked to base their ratings on the last few instances of vaginal or attempted vaginal penetration. Participants who complete the post-treatment sessions were reimbursed $35 and participants who completed the 6-month follow-up sessions were reimbursed another $65 for their participation.

As per Lachlin (2000), participants who withdrew from treatment (i.e., who did not complete all treatment sessions) still completed the post-treatment and follow-up assessments to allow for an intent-to treat analysis.

The study received institutional approval from the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (Appendix G).

**Outcome Measures**

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations (Turk et al., 2003) for the core outcome domains for chronic pain
clinical trials are used to organize the outcome measures. These domains are: pain, physical functioning, emotional functioning, participant ratings of global improvement, symptoms and adverse events, and participant disposition. These guidelines provide a comprehensive and useful method of categorizing the outcomes measured in this study. They are also consistent with the biopsychosocial model in that they recognize that pain reduction and safety of treatment alone are not sufficient for a comprehensive evaluation of the benefit of treatment.

**Pain.** Variables related to pain experienced both in experimental (i.e., cotton-swab test, QST) and non-experimental situations (e.g., intercourse, finger insertion) were considered within this domain.

**Subjective ratings of the presence, frequency, and intensity of painful activities.** Self-report measures of pain are considered the ‘gold standard’ in pain assessment because they reflect the subjective nature of pain (Dworkin et al., 2005).

During the interviews, participants were provided with a list of seven sexual activities (i.e., intercourse, one finger inserted vaginally, two fingers inserted vaginally, manual stimulation, oral stimulation, masturbation with clitoral stimulation, masturbation with internal stimulation) and a list of six non-sexual activities (i.e., tampon insertion, tampon removal, friction with clothing, sitting for long periods of time, urinating after penetration, non-provoked pain) and asked if they regularly experienced vulvar pain during the activities. Their answer options were ‘yes’, ‘no’, ‘not applicable’, and ‘stopped due to pain’. Response options ‘yes’ and ‘stopped due to pain’ were coded as 1 while ‘no’ was coded as 0. Separate calculations were performed to compute proportions of applicable sexual and non-sexual activities that triggered vulvar pain. Participants also reported the percentage of intercourse attempts that resulted in pain. Research has demonstrated that pain frequency represents a distinct dimension of pain, separate from pain intensity (Jensen, 2003). Participants were asked what percentage of their intercourse attempts they were able to have to whatever they consider to be completion without having to terminate
Numerical rating scales (NRS) were used to assess pain intensity and unpleasantness for the cotton-swab test and intercourse. The scales ranged from 0 (no pain at all/not unpleasant at all) to 10 (worst pain ever felt/most unpleasant ever). A rating of 1-3 was identified as mild, 4-6 was identified as moderate, and 7-9 was identified as severe. For intercourse, participants were asked to provide average intensity and unpleasantness ratings. These 11-point NRS scales are recommended as the primary outcome measure in pain clinical trials (Dworkin et al., 2005); the change in average pain intensity rating was considered the primary outcome of this study. NRSs were chosen over the Visual Analogue Scale due to their ease of use within the context of ratings being provided while participants were on a gynecological table. Research has demonstrated the validity of NRSs based on significant positive correlations with other measures of pain intensity and pain affect and based on their sensitivity to treatments known to have an effect on pain intensity (Jensen, 2003). Although research has validated NRSs as having separate pain intensity and unpleasantness components and as internally consistent measures of both experimental and clinical pain, NRSs do not demonstrate ratio qualities (Hartrick, Kovan, & Shapiro, 2003; Price, Bush, Long, & Harkins, 1994).

At the post-treatment and follow-up interviews participants rated their degree of vulvar pain improvement (VPI) on a scale from 1 (complete cure) to 6 (the pain is worse). Of note is that despite the use of the word ‘cure’ in this previously developed outcome measure, participants in both groups were informed that both treatment modalities are management strategies for PVD rather than cures for the condition.

*The McGill Pain Questionnaire (MPQ).* The MPQ (Melzack, 1975) is a self-report checklist comprised of 78 words to describe the sensory, affective, and evaluative qualities of pain. The words are presented within 20 different sets with the words within each set reflecting
similar qualities of pain in increasing intensity. Participants were asked to select only those words that best describe their vulvar pain and to include only one word within each set. The pain rating index based on the rank values of the words [PRI(R)] was used such that the word in each set with the lowest intensity was provided a value of 1, the next word given a value of 2, and so on. The values of the words chosen by the participant were then summed separately for the sensory (0-42) and affective words (0-14). As recommended by Melzack (1975), instances in which no words were chosen in a given category (i.e., sensory, affective) for all three time points were excluded from the analyses. This occurred in 5 participants for the affective words. Participants completed the MPQ at pre-treatment, post-treatment, and follow-up during the interview to ensure appropriate completion of the questionnaire. The MPQ has demonstrated good test-retest reliability and is sensitive to change due to treatment (Melzack, 1975). The reliability of the groupings of words has been demonstrated in a number of research studies (Melzack & Katz, 1994). Due to the fact that responders are not required to select items from all word sets, and that the different sets of words describe different types of sensations or experiences, internal consistency of this measure was not calculated.

**Vestibular pain threshold.** The number of grams required to elicit pain during the QST was used as the measurement of vestibular pain threshold. Due to the 6 o’clock site being the only one to show reliable ratings at all three time points (α = .96, α = .87, α = .97), only this vestibular site was analyzed. The values for the two trials were averaged to obtain a single 6 o’clock rating.

**Physical functioning.** This domain typically includes measures related to broad health-related quality of life and disease-specific measures investigating the effects of a disorder on an individual’s ability to perform specific tasks or engage in routine, daily physical activities. Given the provoked nature of PVD, daily tasks and activities are frequently not impacted by vulvar pain. Sexual functioning and PFM functioning were therefore considered within this domain since these are the areas of functioning most affected by PVD.
The Female Sexual Function Index-Revised (FSFI-R). The FSFI (Rosen et al., 2000) is a 19-item questionnaire which assesses desire, subjective arousal, lubrication, orgasm, satisfaction, and pain over the past 4 weeks. The original version of this scale, and its subscales, demonstrated good internal consistency and was able to discriminate between women with vulvar pain and women without pain or without sexual dysfunction (Masheb, Lozano-Blanco, Kohorn, Minkin, & Kerns, 2004a; Rosen et al., 2000). Participants completed the revised version of the questionnaire based on the modification suggestions of Meyer-Bahlburg and Dolezal (2007) to correct for the statistical consequences of the original scoring techniques in populations with low sexual frequency. Although this resulted in smaller sample sizes for data analysis, it more accurately reflects the sexual functioning of participants. Participants completed the FSFI-R at pre-treatment (α = .90), post-treatment (α = .76), and follow-up (α = .93) and the total score (range: 7.2-36), as well as the desire (range: 1.2-6), arousal (range: 1.2-6), and satisfaction (range: 1.2-6) subscales were analyzed.

PFM functioning. PFM tone was rated on a scale ranging from -3 (very hypotonic) to +3 (very hypertonic), with 0 being normal muscle tone. This scale has been used in a number of previous studies including women with PVD and vaginismus and has demonstrated good inter-rater reliability as well as the ability to differentiate these clinical groups from each other and from pain-free controls (Reissing et al., 2004; Reissing et al., 2005). Given that the 4, 6, and 8 o’clock ratings of tone grouped together well at both pre-treatment (α = .88) and post-treatment (α = .85), and that the conclusions about changes did not differ whether the sites were investigated independently or when averaged, the tone ratings were averaged across the three muscle sites. PFM relaxation capacity was recorded on a scale ranging from 0 (returns to resting state) to 4 (remains fully contracted).

Emotional functioning. Variables related to pain cognitions were considered within this domain. These were assessed with standardized questionnaires.
**The Pain Catastrophizing Scale (PCS).** The PCS (Sullivan, Bishop & Pivik, 1995) consists of 13 items to which participants assign a frequency ranging from 0 (*not at all*) to 4 (*all the time*), which describe their thoughts and feelings experienced when they are in pain. Total scores range from 0 to 52, with a score of 30 or more indicating a clinically relevant level of catastrophizing (Sullivan, 2009). The scale consists of three components: rumination (i.e., increasing attentional focus on thoughts about pain), magnification (i.e., exaggerating the threat value of pain), and helplessness (i.e., adopting a helpless orientation to coping with pain). Acceptable internal reliability of the total PCS score and the subscales, temporal stability, and validity have been demonstrated in previous studies (Osman, Barrios, Gutierrez, Kopper, Merrifield, & Grittmann, 2000; Sullivan et al., 1995). Participants completed the PCS at pre-treatment ($\alpha = .91$), post-treatment ($\alpha = .94$), and follow-up ($\alpha = .94$).

**The Coping Strategies Questionnaire (CSQ).** The CSQ (Rosenstiel & Keefe, 1983) includes a single item assessing the degree to which one feels they are able to cope or deal with their pain from 0 (*no control*) to 6 (*complete control*). Participants completed the CSQ at pre-treatment, post-treatment, and follow-up. Only the perception of control item identified above was analyzed in the current study.

**The Beck Depression Inventory-II (BDI-II).** The BDI-II (Beck, Steer, Ball, & Ranieri, 1996) is a 21-item questionnaire which assesses the affective, motivational, cognitive, and somatic symptoms of depression over the past 2 weeks. Participants rated whether they experience the symptoms on a scale from 0 to 3, with total scores ranging from 0 to 63 (0-13 = minimal depression; 14-19 = mild depression; 20-28 = moderate depression; 29-63 = severe depression). Participants completed the BDI-II at pre-treatment ($\alpha = .88$) to help characterize the sample and to exclude those with significant mood disturbance or suicidal ideation.

**The Beck Anxiety Inventory (BAI).** The BAI (Beck, Epstein, Brown, & Steer, 1988) is a 21-item questionnaire which assesses physical, cognitive, and emotional symptoms of anxiety
over the past 2 weeks. Participants indicated the extent of their symptoms on a scale from 0 (*not at all*) to 3 (*severely*), with total scores ranging from 0 to 63 (0-7 = minimal anxiety; 8-15 = mild anxiety; 16-25 = moderate anxiety; 26-63 = severe anxiety). Participants completed the BAI at pre-treatment (*α* = .91) to help characterize the sample.

**The Credibility/Expectancy Questionnaire (CEQ).** The CEQ (Devilly & Borkovec, 2000) is a 6-item questionnaire which assesses a person’s evaluation of the credibility of a treatment they are receiving and their expectations for change due to the treatment. The wording of the questionnaire is flexible to enable the items to reflect the specific intent of the therapy, in this case, pain reduction. Participants respond to items on a scale from 1 to 9 with higher scores representing greater perception of credibility or greater expectancy. Factor analysis supports a two-factor model (Devilly & Borkovec, 2000, Smeets et al, 2008), and thus, separate mean scores were computed for credibility and expectancy. Both factors have demonstrated good internal reliability (Devilly & Borkovec, 2000, Smeets et al, 2008). Participants completed the CEQ at their first treatment session after the discussion of the treatment outline and rationale but before any intervention was provided (Credibility: *α* = .78; Expectancy: *α* = .84). The therapy providers were kept blind to the CEQ results until after treatment was completed to encourage honest responding on the part of the participant and to prevent bias in treatment on the part of the therapist.

**Participant ratings of global improvement.** At the post-treatment and follow-up interviews participants rated their global impression of overall improvement (i.e., including pain, emotional and sexual functioning, etc.) on a scale from 0 (*no better*) and 100 (*completely better*), their overall satisfaction with the treatment they received on a scale from 0 (*completely dissatisfied*) to 10 (*completely satisfied*), and how much progress they had made on each of the goals they set at the pre-treatment interview from 0 (*no progress toward goal*) to 10 (*goal was attained*). The three goal progress values were averaged to create an overall goal progress score.
Participants were given privacy while completed these items on a handout to encourage honest reporting.

**Symptoms and adverse events.** The percentage of participants who experienced any adverse events during the course of treatment was recorded.

**Participant disposition.** Descriptions of the participants screened for the study as well as the reasons for non-participation, changes to treatment provided including protocol deviations and premature withdrawal, as well as issues of homework adherence were considered within this domain. Adherence to homework was assessed at sessions 2 through 8 by the therapist providing treatment. The therapists recorded an adherence score based on the following guidelines: 0 (*no homework attempted, 0%*), 1 (*some homework attempted, 25%*), 2 (*half of the homework attempted, 50%*), 3 (*most homework attempted, 75%*), 4 (*all homework attempted, 100%*). This scale was adapted from one suggested by Primakoff, Epstein and Covi (1986). These scores were based on what participants attempted compared to what they were instructed to complete between each session. The importance of the activity at that particular time in the process of treatment was taken into account when assigning a score. For instance, regular breathing exercises may have been of key importance early on in CBT treatment when the skill was first being learned; however, it became less important later on in treatment when the participant had already attained an adequate ability to perform the skill and when the dilator insertion homework was of greater focus.

**Methodological Limitations**

Before presentation of the study results, it is important to point out the major methodological limitations that must be considered for careful interpretation of the findings. First, the study did not include a randomly assigned control group. Although the inclusion of such a group would have been ideal to make more firm conclusions about the reason for any changes
over the course of treatment, there were a number of practical limitations that prevented its inclusion. Namely, the length of time to complete all of the treatment and post-treatment assessments was limited by the availability of the physiotherapist who was conducting the PFM evaluations and treatment. Given the small size of the Kingston community, and thus the small number of women available to participate in the study, the inclusion of a randomized control group would have lengthened the duration of the study considerably beyond the period of time that the physiotherapist was available. The lack of control group makes it not possible to evaluate whether changes are attributable to the treatments themselves or natural history (i.e., other factors that have occurred over the same period of time).

The very small sample size, and thus low power, is the second major methodological limitation of the current study. An a priori power analysis identified a required total sample size of 42 (21 per treatment group) to detect moderate effect sizes for between-group differences. Unfortunately, due to time restrictions and limited availability of the treating physiotherapist, study recruitment was terminated without sufficient sample size. The low study power limits the ability to detect potentially meaningful changes over time and between group differences. Particularly given the small sample size, there were also numerous outcome measures investigated, and error rates were not altered to account for the number of tests conducted. There was, therefore, a highly inflated Type I error rate in the current study.

These limitations should be kept in mind while reviewing the results of the present study.


Chapter 4

Results

Data Cleaning and Considerations

Missing data. Given that all participants completed the interview at all three time points, and due to the structured nature of the interview, there were no missing data on any of the variables assessed during the interviews. Although all 20 participants completed all portions of the pre-treatment testing, due to technical difficulties with the questionnaire software and with the QST software, one participant’s data for both the questionnaires and QST were not properly retrieved and therefore these data were not included in the analyses.

The questionnaire data (including those questionnaires not analyzed) were assessed for missing data at each time point. The FSFI items were not included in the missing values analysis because, based on each participant’s sexual activities over the previous 4 weeks and the presence or absence of a sexual partner, many items are not applicable. Data were considered missing completely at random at pre-treatment \( \chi^2(409) = 0.00, p = 1.00 \), with 0.40% of the questionnaire data missing. At post-treatment, 4.60% of the questionnaire data were missing and it was not missing completely at random \( \chi^2(425) = 9599.64, p < .001 \). An inspection of the missing data revealed that items closer to the end of the questionnaire were more likely to be missing. The last three questionnaires presented to participants, which is where the majority of the missing data was found, were not analyzed in this thesis. At the 6-month follow-up, 2.83% of the data were missing completely at random \( \chi^2(336) = 0.00, p = 1.00 \). When over 20% of a questionnaire’s items were missing, the last observation carried forward (LOCF) method was used such that the participant’s score on that measure at the previous time point was imputed for the missing value. When less than 20% of a questionnaire’s items were missing, means imputation was used such
that the mean of that participant’s score on the completed questionnaire items was imputed for the missing values. There was a total of 12 LOCFs for the questionnaire data and approximately 0.1% of the questionnaire data was imputed through means replacement.

Not all women were able to complete all portions of the post-treatment and 6-month follow-up sessions. Two participants, both in the ICBT group, were not able to complete the post-treatment gynecological exam or QST session. This was due to having moved out of town for one participant and due to an ongoing vaginal infection for the other participant. Four participants, three in the ICBT group and one in the PFR group, were not able to complete the 6-month follow-up gynecological examination. This was due to scheduling conflicts for two participants, having moved out of town for one participant, and due to being pregnant for another participant. The latter two of these participants also did not complete the 6-month follow-up QST session. The LOCF method was used to handle these missing data. A significant number of participants did not complete the 6-month follow-up PFM evaluation due to an extended absence of the physiotherapist; these data were therefore not analyzed. Raw data for all participants for all outcome variables is presented in Appendix H.

Assessing assumptions. Outcome measures were explored at each time point for normality and univariate outliers through examination of z scores, histograms, and P-P plots. Significant skewness was identified by testing the observed skewness value against the null hypothesis of zero using the following equation: 
$$z = \frac{S - 0}{\sqrt{6/N}}$$, while significant kurtosis was identified in a similar manner using the following equation: 
$$z = \frac{S - 0}{\sqrt{24/N}}$$. Only four univariate outliers were identified; three of these indicated significantly poorer functioning at post-treatment and follow-up for one participant who presented as significantly more vaginismic than other participants (i.e., she had much more difficulty with vaginal penetration). The other outlier reflected better functioning in one participant at pre-treatment in one specific pain domain,
despite the other pain measures being in line with the other participants. Outliers were not removed from the analyses so as to accurately estimate the effectiveness of the treatments. A small number of variables were not normally distributed. In most cases, these deviations from normality represented clinically meaningful deviations (e.g., significant negative skewness for percentage of painful intercourse attempts at pre-treatment, significant positive skewness for average intercourse pain intensity at 6-month follow-up). Variables with significant outliers and/or that were not normally distributed were transformed until normality was reached. Analyses were performed both with and without the transformed variables. Where the conclusions reached were the same with both methods, the un-transformed data are presented for purposes of increasing interpretability. Where the conclusions differed, the transformed data are presented.

**Clinical significance.** It is recommended that in addition to reporting statistical significance, chronic pain clinical trials include the clinical significance of the findings (Dworkin et al., 2008; Robinson et al., 2005). Effect sizes are reported for all analyses and are interpreted where statistically significant effects occurred. Effect sizes for t-tests are reported in the form of Cohen’s $d$ using the pooled standard deviation as the denominator. To avoid issues of overestimation of effect size for repeated measures t-tests due to high correlations between time points, the independent-groups method of $d$ calculation was utilized for repeated measures, as well as for independent group t-tests (Becker, 2000; Morris & DeShon, 2002). Effect sizes for chi-square tests are reported in the form of phi ($\phi$) and partial eta squared ($\eta_p^2$) for ANOVAs. Cohen’s $d$ values of 0.2, 0.5, and 0.8, phi values of .10, .30, and .50, partial eta squared values of 0.01, 0.06, and 0.14, and Pearson correlation coefficient values of .10, .30, and .50 are considered small, medium, and large, respectively (Cohen, 1988). As Cohen (1988) notes, the guidelines used to identify small, medium, and large effect sizes are arbitrary (as is the use of the .05 significance criterion), yet required for consistent presentation and interpretation across scientists. For the purposes of this study, effect sizes that are medium or large following a statistically
significant analysis are considered to have clinical meaningfulness, while those with less than medium effect sizes are interpreted as insignificant changes or differences. Medium effect sizes are conceptualized as those that are “large enough to be visible to the naked eye” (Cohen, 1988, pp. 26). The use of applying this arbitrary guideline of interpreting medium effect sizes as clinically meaningful is further necessary given that, other than for the pain numerical rating scale, there are no pre-determined amounts of change in the study outcome measures that indicate clinically meaningful change.

Based on research utilizing both anchor-based and distribution-based approaches to assessing clinical meaningfulness, IMMPACT recommendations identify a change in the 11-point NRS for pain of 30% or more as indicative of a ‘moderate clinically important difference’ while a change of 50% or more is considered a ‘substantial clinically important difference’ (Dworkin et al., 2008). The 30% change identifies an amount of pain reduction that is perceived by patients as noticeable after treatment (Farrar, Young, LaMoreaux, Werth, & Poole, 2001).

Do Pain Ratings Spontaneously Change Over Time?

Unfortunately, studies investigating vulvar pain symptoms over time have used a 3 month criterion for chronic pain rather than a 6 month criterion (Reed et al., 2006, 2008). Thus, there is no research documenting the course of PVD in women with at least 6 months pain duration to determine the rate of spontaneous improvement or remission. In order to account for the possibility that vulvar pain may change over time, 10 women with PVD who had participated in other studies being conducted by the SHRL, but who did not participate in the current treatment study, were contacted between 3 and 19 months ($M = 9.20$, $SD = 5.31$) after their participation to receive an update about their pain symptoms and any access to treatment. Reasons for not participating in the current study included: not residing in Kingston ($n = 6$, 60%), being too busy ($n = 2$, 20%), and receiving another treatment ($n = 1$, 10%). No reason was provided for one
participant for not participating in the treatment study. Table 1 presents a summary of background and pain variables for the 20 participants who completed the treatment study and the 10 participants who did not complete the study (i.e., no treatment group). The information for the no treatment participants was obtained from their screening interview and face-to-face interview for the SHRL study in which they participated. Treatment participants were significantly more likely to have another medical condition than no treatment participants; however, this difference was not clinically meaningful.

Table 1

*Demographic, Relationship, and Health and Pain Variables for Treatment and No Treatment Groups*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Treatment ($n = 20$)</th>
<th>No Treatment ($n = 10$)</th>
<th>$t (df)$</th>
<th>$\chi^2 (df)$</th>
<th>$p$</th>
<th>$d$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ($M (SD; range)/n (%)$)</td>
<td>26.44 (8.86; 18.00–56.00)</td>
<td>22.74 (2.59; 19.00–26.00)</td>
<td>1.73</td>
<td>(24.54)</td>
<td>.097</td>
<td>0.50</td>
</tr>
<tr>
<td>Caucasian ($n (%)$)</td>
<td>15 (75)</td>
<td>7 (70)</td>
<td>.09 (1)</td>
<td>.770</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Using hormonal contraceptive</td>
<td>12 (60)</td>
<td>8 (80)</td>
<td>1.20 (1)</td>
<td>.273</td>
<td>0.20</td>
<td></td>
</tr>
<tr>
<td>Current medical condition</td>
<td>7 (35)</td>
<td>0 (0)</td>
<td>4.57 (1)</td>
<td>.033</td>
<td>0.39</td>
<td></td>
</tr>
<tr>
<td>Current psychological condition</td>
<td>6 (30)</td>
<td>2 (20)</td>
<td>0.34 (1)</td>
<td>.559</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>Primary PVD ($n (%)$)</td>
<td>10 (50)</td>
<td>5 (50)</td>
<td>0.00 (1)</td>
<td>1.00</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Pain duration (years) ($M (SD; range)/n (%)$)</td>
<td>4.78 (3.27; 0.67–13.25)</td>
<td>2.51 (1.93; 0.05–6.00)</td>
<td>2.02 (28)</td>
<td>.054</td>
<td>0.78</td>
<td></td>
</tr>
<tr>
<td>Average intercourse pain intensity ($M (SD; range)/n (%)$)</td>
<td>5.13 (1.60; 2.50–9.00)</td>
<td>6.20 (1.69; 3.00–8.00)</td>
<td>1.70 (28)</td>
<td>.100</td>
<td>0.66</td>
<td></td>
</tr>
<tr>
<td>% painful intercourse ($M (SD; range)/n (%)$)</td>
<td>90.75 (20.21; 15.00–100.00)</td>
<td>90.30 (12.90; 60.00–100.00)</td>
<td>0.06 (28)</td>
<td>.950</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td># of treatments attempted ($M (SD; range)/n (%)$)</td>
<td>0.85 (1.18; 0.00–4.00)</td>
<td>0.90 (1.45; 0.00–4.00)</td>
<td>0.10 (28)</td>
<td>.920</td>
<td>0.04</td>
<td></td>
</tr>
</tbody>
</table>
The follow-up telephone interview for the no treatment participants asked questions about any treatment received for their vulvar pain, changes in hormonal contraceptive use, changes in medical status or gynecological conditions (e.g., presence of vaginal infections, change in physical or mental health), and changes in vulvar pain intensity, temporal pattern, quality, location, or frequency. Of the 10 no treatment participants, 2 (20%) had sought treatment for their vulvar pain since the time of their initial participation in an SHRL study. One of them underwent physiotherapy and another used a topical cream. Four participants (40%) stopped taking hormonal contraceptives, although only one of these did this for the purposes of vulvar pain reduction. Only one participant (10%) reported any change in her vulvar pain symptoms. This was the participant who stopped hormonal contraceptives and who used the topical cream. In addition to a reduction in her average intercourse pain intensity (from 4 to 3, a 25% reduction), she reported a frequency reduction from 90% to 50% of intercourse attempts, and indicated that the pain lasted for a shorter duration of time during intercourse. Thus, whereas 85% of the treatment study participants had at least a moderate clinically important change in average intercourse pain intensity from pre-treatment to 6-month follow-up (\(M = 10.80, SD = 1.82\) months), none of the no treatment participants met the 30% pain reduction criteria, \(\chi^2(1) = 19.62, p < .001, \phi = .81\).

The findings from this small sample provide some preliminary information about the course of vulvar pain in women who have experienced their pain for at least 6 months. However, there are a number of limitations of the no treatment group that do not allow for the conclusion to be drawn that the differences in pain reduction between the treatment and no treatment groups signifies that changes in the treatment group are not due to passage of time. Namely, the lack of random assignment of the no treatment group, the fact that very few in the group sought treatment, and the differences in the methods by which women were asked for pain updates (no
treatment group: “has there been an increase or decrease in the intensity of your intercourse
pain?” followed by pain ratings provided if they responded ‘yes’; study participants: pain ratings
provided at each time point).

Participant Disposition and Characteristics

Twenty participants suffering from PVD completed ICBT or PFR as well as assessments at pre-
treatment, post-treatment, and 6 months following treatment completion. During the pre-
treatment interview and questionnaires, participants provided information about socio-
demographics, relationship factors, health, and mental health. Table 2 summarizes these features
within each treatment group. The majority of participants were Caucasian, in heterosexual
relationships, and well-educated with both treatment groups having a mean age of mid-twenties.
Seventy percent of participants were in a committed relationship at the time of the pre-treatment
interview. Thirteen participants’ relationship status and partner did not change over the course of
the study. Three participants changed from being non-partnered to being partnered by the post-
treatment assessment and another two participants by the 6-month follow-up assessment. Two
participants broke up with their partner during treatment, and while one resumed the relationship
by the follow-up, the other entered into a new relationship. Nine participants were in a long-
distance relationship at the time of at least one of the assessment points. Despite the fact that
serious medical or psychiatric conditions were exclusionary criteria, over half of the participants
(60%) had at least one well-managed physical or mental health condition.
<table>
<thead>
<tr>
<th>Variable</th>
<th>ICBT (n = 10)</th>
<th>PFR (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>27.40 (11.05; 18.00–56.00)</td>
<td>25.48 (6.45; 19.00–36.00)</td>
</tr>
<tr>
<td>Caucasian&lt;sup&gt;a&lt;/sup&gt;</td>
<td>9 (90)</td>
<td>6 (60)</td>
</tr>
<tr>
<td>Years of schooling</td>
<td>16.60 (2.32; 13.00–20.00)</td>
<td>15.70 (2.00; 13.00–19.00)</td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed full-time</td>
<td>2 (20)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Student full-time</td>
<td>7 (70)</td>
<td>6 (60)</td>
</tr>
<tr>
<td>Parenting full-time</td>
<td>1 (10)</td>
<td>1 (10)</td>
</tr>
<tr>
<td>Relationship factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partnered&lt;sup&gt;b&lt;/sup&gt;</td>
<td>7 (70)</td>
<td>7 (70)</td>
</tr>
<tr>
<td>Health and mental health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using hormonal contraceptive</td>
<td>7 (70)</td>
<td>5 (50)</td>
</tr>
<tr>
<td>Repeated yeast infections</td>
<td>2 (20)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Current medical condition&lt;sup&gt;c&lt;/sup&gt;</td>
<td>4 (40)</td>
<td>5 (50)</td>
</tr>
<tr>
<td>Current psychological condition&lt;sup&gt;d&lt;/sup&gt;</td>
<td>2 (20)</td>
<td>4 (40)</td>
</tr>
<tr>
<td>Number of regular pain problems</td>
<td>1.50 (1.17; 0.00–3.00)</td>
<td>2.30 (0.95; 1.00–4.00)</td>
</tr>
<tr>
<td>Beck Depression Inventory-II</td>
<td>7.60 (6.47; 0.00–19.00)</td>
<td>10.35 (7.67; 0.00–24.15)</td>
</tr>
<tr>
<td>Beck Anxiety Inventory</td>
<td>12.30 (8.10; 4.00–28.00)</td>
<td>11.71 (11.79; 0.00–38.00)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Non-Caucasian participants identified as Middle Eastern (n = 2), Latin American (n = 1), South Asian (n = 1), and East Asian (n = 1).  
<sup>b</sup> All participants engaging in sexual activity at pre- and post-treatment had male sexual partners while one participant at follow-up had a female partner.  
<sup>c</sup> Medical conditions included chronic/recurrent gastrointestinal, endocrinological, dermatological, immunological, neurological, musculoskeletal, and cardiovascular problems.  
<sup>d</sup> Psychological conditions included well-managed mood and anxiety disorders.
Table 3 summarizes the pain characteristics of the participants at the time of the pre-treatment interview within each treatment group. Half of the participants (50%) had experienced their pain since their first attempt at sexual intercourse. For those with secondary PVD, many were able to identify a possible trigger for the onset of their pain. Only a small percentage (10%) perceived their pain to start ‘out of the blue.’ Of the identifiable triggers, the majority (63%) was biological in nature (e.g., childbirth) while the remaining (37%) triggers were psychosocial in nature (e.g., stressful event). One quarter of the participants had never consulted a health professional about their pain and over half (55%) had never attempted any treatment for their pain. Treatments that had been attempted included: cromolyn cream, estrogen cream, lidocaine jelly, antifungal cream, gentian violet, changing or discontinuing hormonal contraceptives, changing psychotropic medications, amitriptyline, naproxen, abdominal/pelvic massage, dilation with dilators or fingers, and psychotherapy.

Independent sample $t$-tests were conducted to compare the two treatment groups on the demographic and pre-treatment relationship, health and mental health, and pain variables. There were no statistically significant differences between the treatment groups on any of the variables investigated.

With respect to changes to the treatment provided, in addition to the large variability in the number of weeks to complete the sessions, three participants did not complete all eight treatment sessions. One participant in the PFR group only completed six sessions due to a combination of scheduling difficulties and her not feeling the need to continue treatment since her progress had plateaued and she was satisfied with her progress. One participant in each of the treatment groups only completed seven sessions, one due to scheduling difficulties and the other due to a premature move out of Kingston. Despite early withdrawal from the treatment, all three of these participants returned to complete the post-treatment and follow-up assessments.
Table 3
Pain Characteristics by Treatment Group

<table>
<thead>
<tr>
<th>Pain Characteristic</th>
<th>ICBT (n = 10)</th>
<th>PFR (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD; range) / n (%)</td>
<td>M (SD; range) / n (%)</td>
</tr>
<tr>
<td>Primary PVD</td>
<td>4 (40)</td>
<td>6 (60)</td>
</tr>
<tr>
<td>Event occurring near onset of secondary PVD pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeated yeast infections</td>
<td>1 (17)</td>
<td>2 (50)</td>
</tr>
<tr>
<td>Childbirth</td>
<td>1 (17)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Gynecological surgery</td>
<td>1 (17)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Change of partner</td>
<td>1 (17)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Stressful life event</td>
<td>1 (17)</td>
<td>1 (25)</td>
</tr>
<tr>
<td>No identifiable reason</td>
<td>1 (17)</td>
<td>1 (25)</td>
</tr>
<tr>
<td>Pain duration (years)</td>
<td>4.33 (2.87; 0.67–9.00)</td>
<td>5.23 (3.73; 0.83–13.25)</td>
</tr>
<tr>
<td>Pre-treatment average IPI</td>
<td>5.20 (1.40; 3.00–7.00)</td>
<td>5.05 (1.86; 2.50–9.00)</td>
</tr>
<tr>
<td># of professionals consulted</td>
<td>2.10 (1.52; 0.00–5.00)</td>
<td>1.60 (2.41; 0.00–8.00)</td>
</tr>
<tr>
<td># of pain treatments attempted</td>
<td>1.00 (1.05; 0.00–3.00)</td>
<td>0.70 (1.34; 0.00–4.00)</td>
</tr>
</tbody>
</table>

*Note.* IPI = intercourse pain intensity.

Although all participants reported not attempting to treat or alleviate the vulvar pain in any way other than the treatment they received in the study, there were some changes in hormonal contraceptive and antidepressant use that were unrelated to treatment for pain. Changes in hormonal contraceptive and antidepressant use can both impact pain processing (Bohm-Starke, Johannesson, Hilliges, Rylander, & Torebjörk, 2004; Lynch, 2001). Whereas one participant discontinued hormonal contraceptive use, another participant began hormonal contraceptives during the course of treatment. One participant discontinued her antidepressants while another started an antidepressant and another increased her dosage. No other violations to the treatment protocol occurred.
Homework adherence scores were not significantly different between participants in the ICBT ($M = 3.02, SD = 0.70$) and PFR ($M = 2.60, SD = 1.18$) groups, $t(14.72) = 0.96, p = .354, d = 0.43$.

**Effectiveness and Comparison of ICBT and PFR on the Outcome Variables**

In order to address the study aim of comparing the effectiveness of the two treatments at improving the pain, physical functioning, and emotional functioning of study participants, mixed-model analyses of variance (ANOVAs) were conducted with time as the within-subject variable (pre-treatment, post-treatment, 6-month follow-up) and treatment as the between-subjects variable (ICBT, PFR). The interaction effect was used to determine whether there was a difference between the two treatment groups. Where there were significant time by treatment interaction effects, subsequent mixed-model ANOVAs were conducted to compare the effectiveness of the treatments from each time point to the other. Where there were no significant interactions, time and treatment effects are reported. To address the study aim of determining whether each treatment leads to improvements in each of the major outcome measures, paired-sample $t$-tests were conducted from each time point to the other within each treatment. Where assumptions of sphericity were violated according to Mauchly’s Test of Sphericity, the Greenhouse-Geisser correction was used when analyzing and reporting the time by treatment interaction effects. Significant findings from the Levene’s Test of Equality of Error Variances were followed up by a comparison of the largest and smallest variance within each time point using Hartley’s $F_{\text{max}}$ test. No $F$ ratios exceeded the critical values.

Although clustering outcomes by conceptual domains and running two-way repeated measures ANOVAs (MANOVAs) are typically suggested for the purposes of reducing Type I error rates, the small sample size in this study discounts the usefulness of this approach. Furthermore, experts in the area of chronic pain clinical trials highlight that combining outcomes
in a statistical manner results in the loss of important information about specific treatment effects (Turk et al., 2008a).

Means and standard deviation for the main pain, physical functioning, and emotional functioning measures at pre-treatment, post-treatment, and 6-month follow-up are presented in Table 4, Table 6, and Table 7, respectively. The significance level and Cohen’s $d$ values for the paired-sample $t$-tests are also presented in these tables. The results from the ANOVAs are delineated in the following sections.

**Credibility and expectancy ratings.** Results from an independent sample $t$-test indicated that the credibility ratings of ICBT participants ($M = 7.57, SD = 0.97$) were significantly and meaningfully higher than those of PFR participants ($M = 6.60, SD = 1.09$), $t(18) = 2.10, p = .050, d = 0.95$. Alternatively, the ratings of expectancy were not significantly higher among ICBT participants ($M = 6.27, SD = 0.77$) than PFR participants ($M = 5.70, SD = 1.39$), $t(18) = 1.13, p = .274, d = 0.51$. 

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Table 4

*Means, Standard Deviations, and Post-Hoc Analyses for the Pain Outcomes*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-Treatment</th>
<th>Post-Treatment</th>
<th>Follow-up</th>
<th>Pre → Post</th>
<th>Post → Follow-up</th>
<th>Pre → Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
<td>M (SD)</td>
<td>p (d)</td>
<td>p (d)</td>
<td>p (d)</td>
</tr>
<tr>
<td>Average IPI</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>5.20 (1.40)</td>
<td>2.60 (1.43)</td>
<td>2.10 (1.37)</td>
<td>.004 (1.84)</td>
<td>.397 (0.36)</td>
<td>.001 (2.24)</td>
</tr>
<tr>
<td>PFR</td>
<td>5.05 (1.86)</td>
<td>2.70 (2.36)</td>
<td>2.40 (2.63)</td>
<td>&lt; .001 (1.11)</td>
<td>.279 (0.12)</td>
<td>&lt; .001 (1.16)</td>
</tr>
<tr>
<td>Average IPU</td>
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<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>4.90 (1.66)</td>
<td>2.00 (1.05)</td>
<td>1.40 (1.65)</td>
<td>.005 (2.09)</td>
<td>.297 (0.43)</td>
<td>.002 (2.11)</td>
</tr>
<tr>
<td>PFR</td>
<td>5.10 (1.85)</td>
<td>2.70 (1.77)</td>
<td>2.30 (2.16)</td>
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<td>.423 (0.20)</td>
<td>.003 (1.39)</td>
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<tr>
<td>% painful intercourse</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>ICBT</td>
<td>94.00 (9.94)</td>
<td>67.10 (31.98)</td>
<td>41.00 (37.33)</td>
<td>.036 (1.14)</td>
<td>.012 (0.75)</td>
<td>.002 (1.94)</td>
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<tr>
<td>PFR</td>
<td>87.50 (27.21)</td>
<td>60.50 (42.91)</td>
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<td>.026 (0.79)</td>
<td>.001 (1.83)</td>
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<tr>
<td>% intercourse completed</td>
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<tr>
<td>ICBT</td>
<td>57.50 (34.90)</td>
<td>97.00 (7.89)</td>
<td>93.50 (8.83)</td>
<td>.017 (1.49)</td>
<td>.306 (0.46)</td>
<td>.027 (0.87)</td>
</tr>
<tr>
<td>Transformed</td>
<td>0.23 (0.41)</td>
<td>0.82 (0.38)</td>
<td>0.62 (0.48)</td>
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<tr>
<td>PFR</td>
<td>59.00 (42.61)</td>
<td>88.00 (31.20)</td>
<td>90.00 (31.62)</td>
<td>.033 (0.87)</td>
<td>.168 (0.47)</td>
<td>.005 (1.46)</td>
</tr>
<tr>
<td>Transformed</td>
<td>0.32 (0.47)</td>
<td>0.72 (0.45)</td>
<td>0.90 (0.31)</td>
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<tr>
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<td>ICBT</td>
<td>PFR</td>
<td>ICBT</td>
<td>PFR</td>
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</tr>
<tr>
<td>Proportion sexual activities painful</td>
<td>.58 (.16)</td>
<td>.48 (.33)</td>
<td>.20 (.23)</td>
<td>.418 (0.39)</td>
<td>.024 (0.98)</td>
<td>.002 (1.92)</td>
</tr>
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<td></td>
<td>.56 (.23)</td>
<td>.27 (.23)</td>
<td>.18 (.19)</td>
<td>.001 (1.26)</td>
<td>.097 (0.43)</td>
<td>.001 (1.80)</td>
</tr>
<tr>
<td>Proportion non-sexual activities painful</td>
<td>.53 (.26)</td>
<td>.32 (.23)</td>
<td>.16 (.15)</td>
<td>.034 (0.86)</td>
<td>.066 (0.82)</td>
<td>.009 (1.74)</td>
</tr>
<tr>
<td></td>
<td>.47 (.34)</td>
<td>.21 (.25)</td>
<td>.11 (.15)</td>
<td>.013 (0.87)</td>
<td>.087 (0.49)</td>
<td>.002 (1.37)</td>
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<td>MPQ PRI(R)-Sensory</td>
<td>19.00 (6.67)</td>
<td>11.70 (7.60)</td>
<td>11.90 (7.49)</td>
<td>.059 (1.02)</td>
<td>.935 (0.03)</td>
<td>.024 (1.00)</td>
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<td>17.70 (7.85)</td>
<td>10.10 (7.02)</td>
<td>11.10 (9.42)</td>
<td>.018 (1.05)</td>
<td>.667 (0.12)</td>
<td>.089 (0.78)</td>
</tr>
<tr>
<td>MPQ PRI(R)-Affective</td>
<td>3.13 (3.04)</td>
<td>1.38 (1.51)</td>
<td>1.00 (2.07)</td>
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<tr>
<td></td>
<td>1.53 (0.94)</td>
<td>0.89 (0.81)</td>
<td>0.56 (0.89)</td>
<td>.224 (0.73)</td>
<td>.433 (0.39)</td>
<td>.007 (1.06)</td>
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<td>2.71 (1.70)</td>
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<td>1.14 (2.19)</td>
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<tr>
<td></td>
<td>1.58 (0.50)</td>
<td>0.78 (0.89)</td>
<td>0.64 (0.93)</td>
<td>.092 (1.11)</td>
<td>.356 (0.15)</td>
<td>.057 (1.26)</td>
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<tr>
<td>Cotton-swab test</td>
<td>3.94 (2.3)</td>
<td>3.26 (2.69)</td>
<td>2.62 (2.88)</td>
<td>.144 (0.27)</td>
<td>.104 (0.23)</td>
<td>.009 (0.51)</td>
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<tr>
<td></td>
<td>4.16 (1.53)</td>
<td>1.28 (1.05)</td>
<td>1.86 (2.22)</td>
<td>.001 (2.19)</td>
<td>.464 (0.33)</td>
<td>.008 (1.21)</td>
</tr>
<tr>
<td>Pain threshold (g)</td>
<td>ICBT</td>
<td>Transformed</td>
<td>PFR</td>
<td>Transformed</td>
<td>.767 (0.11)</td>
<td>.006 (0.76)</td>
</tr>
<tr>
<td>-------------------</td>
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</tr>
<tr>
<td></td>
<td>39.35 (29.43)</td>
<td>1.46 (0.40)</td>
<td>59.35 (70.18)</td>
<td>1.58 (0.41)</td>
<td>.465 (0.32)</td>
<td>.415 (0.15)</td>
</tr>
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<td></td>
<td>31.18 (17.20)</td>
<td>1.42 (0.28)</td>
<td>111.69 (155.14)</td>
<td>1.74 (0.55)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>59.12 (47.11)</td>
<td>1.66 (0.34)</td>
<td>78.73 (71.88)</td>
<td>1.66 (0.55)</td>
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<tr>
<td></td>
<td>.767 (0.11)</td>
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<td>.465 (0.32)</td>
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</table>

*Note. MPQ = McGill Pain Questionnaire; PRI(R) = Pain Rating Index; IPI = intercourse pain intensity; IPU = intercourse pain unpleasantness.*
Pain. The following section outlines the results from the mixed-model ANOVAs and paired-samples t-tests conducted to determine and compare the effectiveness of ICBT and PFR in treating the pain of PVD. It was expected that both treatment groups would result in pain improvements, with PFR leading to greater improvement in these outcomes. Results from the mixed-model ANOVAs indicated significant and meaningful time effects with non-significant time by treatment interaction and treatment effects for average intercourse pain intensity \( \text{T: } F(2, 36) = 39.11, p < .001, \eta_p^2 = .68; \text{Time by Treatment (TbT): } F(2, 36) = 0.21, p = .816, \eta_p^2 = .01 \), average intercourse pain unpleasantness \( \text{T: } F(2, 36) = 27.13, p < .001, \eta_p^2 = .60; \text{TbT: } F(2, 36) = 0.31, p = .737, \eta_p^2 = .02 \), the percentage of painful intercourse attempts \( \text{T: } F(2, 36) = 25.11, p < .001, \eta_p^2 = .58; \text{TbT: } F(2, 36) = 0.07, p = .936, \eta_p^2 = .004 \), the percentage of completed intercourse attempts \( \text{T: } F(2, 36) = 12.04, p < .001, \eta_p^2 = .40; \text{TbT: } F(2, 36) = 1.34, p = .276, \eta_p^2 = .07 \), and the proportion of sexual \( \text{T: } F(2, 36) = 19.35, p < .001, \eta_p^2 = .52; \text{TbT: } F(2, 36) = 1.67, p = .203, \eta_p^2 = .09 \) and non-sexual activities that result in vulvar pain \( \text{T: } F(2, 36) = 19.46, p < .001, \eta_p^2 = .52; \text{TbT: } F(2, 36) = 0.17, p = .847, \eta_p^2 = .01 \). Paired-sample t-tests demonstrated significant and meaningful reductions in intercourse pain intensity and unpleasantness from pre- to post-treatment in both treatments. These reductions were maintained at follow-up, with no further significant changes from post-treatment to follow-up, in both treatment groups (see Figure 3 for depiction of effect with intercourse pain intensity).
There were also significant and meaningful decreases in the percentage of intercourse attempts that resulted in pain from pre- to post-treatment and from post-treatment to follow-up in both treatment groups (Figure 4). Participants in both groups also had significant and meaningful reductions in the number of non-sexual activities resulting in regularly experienced vulvar pain that were maintained at follow-up (Figure 5). The same pattern was seen for the percentage of intercourse attempts that participants were able to complete, with participants in both treatment groups demonstrating significant and meaningful improvements from pre- to post-treatment that were maintained from post-treatment to follow-up (Figure 6).
Figure 4. Results from mixed-model ANOVA assessing changes in percentage of intercourse attempts resulting in pain over time. Error bars represent standard errors.

Figure 5. Results from mixed-model ANOVA assessing changes in proportion of non-sexual activities resulting in pain over time. Error bars represent standard errors.
Figure 6. Results from a mixed-model ANOVA assessing changes in the percentage of intercourse attempts participants were able to complete without having to stop due to pain over time. Error bars represent standard errors. The data shown are transformed data.

For the proportion of sexual activities resulting in vulvar pain, paired-sample *t*-tests indicated that whereas only those in the PFR group showed significant and meaningful reductions from pre- to post-treatment, only those in the ICBT group showed significant and meaningful reductions from post-treatment to follow-up. From pre-treatment to follow-up, both groups demonstrated significant and meaningful improvements (Figure 7).
When the subjective pain experience was measured via the MPQ, there were significant and meaningful time effects for both the sensory $[F(2, 36) = 8.61, p = .001, \eta^2_p = .32]$ (Figure 8) and affective $[F(2, 26) = 7.24, p = .003, \eta^2_p = .36]$ (Figure 9) pain rating indices with non-significant treatment and time by treatment interaction effects [Sensory: $F(2, 36) = 0.02, p = .980, \eta^2_p = .001$; Affective: $F(2, 26) = 0.08, p = .925, \eta^2_p = .01$]. Paired-sample t-tests demonstrated significant and meaningful reductions in the sensory pain rating index from pre-treatment to follow-up in the ICBT group. Alternatively, although there were significant and meaningful reductions in the sensory pain rating index from pre- to post-treatment in the PFR group, these reductions were not maintained at follow-up. Participants in the ICBT groups also had significant and meaningful reductions in the affective pain rating index from pre-treatment to follow-up, while participants in the PFR group did not demonstrate significant changes on this measure.
Figure 8. Results from mixed-model ANOVA assessing changes in McGill Pain Questionnaire Pain Rating Index (PRI) for sensory qualities of pain over time. Error bars represent standard errors.

Figure 9. Results from mixed-model ANOVA assessing changes in McGill Pain Questionnaire Pain Rating Index (PRI) for affective qualities of pain over time. Error bars represent standard errors. The data shown are transformed data.
The results from the mixed-model ANOVA for the pain experienced during the cotton-swab test demonstrated a significant and meaningful time by treatment interaction effect, $F(2, 36) = 3.88, p = .030, \eta_p^2 = .17$ (Figure 10). Subsequent mixed-model ANOVAs indicated that there was a significant and meaningful time by treatment interaction from pre- to post-treatment [$F(1, 18) = 8.71, p = .009, \eta_p^2 = .33$] and a non-significant interaction from post-treatment to follow-up [$F(1, 18) = 2.12, p = .162, \eta_p^2 = .11$]. Paired-sample $t$-tests indicated that only those in the PFR group showed significant and meaningful reductions in pain during the cotton-swab test from pre-to post-treatment. Although neither of the groups demonstrated significant changes from post-treatment to follow-up, the direction of change was different, with those in the ICBT group showing reductions in pain, and those in the PFR group showing increases in pain. When looking at changes from pre-treatment to follow-up, there was a non-significant time by treatment interaction [$F(1, 18) = 1.55, p = .229, \eta_p^2 = .08$]. The paired-sample $t$-tests demonstrated that both treatment groups had significant and meaningful changes from pre-treatment to follow-up.

![Figure 10](image-url)  
*Figure 10.* Results from a mixed-model ANOVA assessing changes in the average intensity of pain experienced during the cotton-swab test over time. Error bars represent standard errors.
The results from the mixed-model ANOVA for the vestibular pain threshold demonstrated non-significant time [$F(1.30, 22.01) = 0.79, p = .461, \eta^2_p = .06$], treatment, and time by treatment interaction effects [$F(1.30, 22.01) = 1.10, p = .324, \eta^2_p = .06$] (Figure 11).

Paired-sample $t$-tests indicated that participants in the ICBT group had significant and meaningful increases in the number of grams required to reach pain threshold (i.e., less sensitivity) from post-treatment to follow-up. Those in the PFR group did not have significant changes.

![Figure 11](image). Results from a mixed-model ANOVA assessing changes in the average number of grams required to reach pain threshold at the 6 o’clock vestibular position over time. Error bars represent standard errors. The data shown are transformed data.

The following section outlines the results from further analyses conducted to determine and compare the effectiveness of ICBT and PFR in treating the pain of PVD. These analyses were based on participant ratings of vulvar pain improvement at post-treatment and follow-up, and on percentage change in pain ratings. As with the other pain measures, it was expected that both treatment groups would result in improvements with PFR leading to greater improvements in pain.
than ICBT. At post-treatment, on the vulvar pain improvement scale, 9 participants in the PFR group reported ‘great improvement’ while 1 reported ‘some improvement.’ Alternatively, 6 ICBT participants reported ‘great improvement’, 3 reported ‘some improvement’, and 1 reported ‘little improvement.’ Participants in the PFR group \((M = 2.10, SD = 0.32)\) did not have a significantly greater amount of reported vulvar pain improvement than the ICBT group \((M = 2.5, SD = 0.70)\), \(t(12.46) = 1.63, p = .127, d = 0.73\). At follow-up, 1 participant in the PFR group reported a ‘complete cure’, 7 reported ‘great improvement’, and 2 reported ‘some improvement’, while in the ICBT group 8 reported ‘great improvement’ and 2 reported ‘some improvement.’ At the follow-up, therefore, the PFR \((M = 2.10, SD = 0.32)\) and ICBT \((M = 2.30, SD = 0.42)\) groups did not differ from each other in terms of reported vulvar pain improvement, \(t(18) = 0.45, p = .660, d = 0.20\).

Results from an independent-sample \(t\)-test indicated that there was no significant difference in the percentage of change in the average intercourse pain intensity rating from pre- to post-treatment between participants in the ICBT group \((M = -45.00, SD = 36.95)\) and the PFR group \((M = -54.44, SD = 27.19)\), \(t(18) = 0.65, p = .523, d = 0.29\). This was also the case from pre-treatment to follow-up (ICBT: \(M = -55.50, SD = 34.49\); PFR: \(M = -60.67, SD = 30.18\)), \(t(18) = 0.36, p = .726, d = 0.16\). According to chi-square tests, as seen in Table 5, there were no significant differences between the percentage of participants in each treatment group who had at least a 30% or a 50% reduction in average intercourse pain intensity from pre- to post-treatment, or from pre-treatment to follow-up.
Table 5

Chi-Square Tests for the Percentage of Participants in Each Treatment Group with at Least a 30 Percent and a 50 Percent Reduction in Average Intercourse Pain Intensity

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%) in ICBT</th>
<th>n (%) in PFR</th>
<th>$\chi^2$ (1)</th>
<th>$p$</th>
<th>$\Phi$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Treatment to Post-Treatment</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>$\geq 30 %$ reduction</td>
<td>7 (70)</td>
<td>8 (80)</td>
<td>0.27</td>
<td>.606</td>
<td>.12</td>
</tr>
<tr>
<td>$\geq 50 %$ reduction</td>
<td>5 (50)</td>
<td>7 (70)</td>
<td>0.83</td>
<td>.361</td>
<td>.20</td>
</tr>
<tr>
<td>Pre-Treatment to Follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\geq 30 %$ reduction</td>
<td>8 (80)</td>
<td>9 (90)</td>
<td>0.39</td>
<td>.531</td>
<td>.14</td>
</tr>
<tr>
<td>$\geq 50 %$ reduction</td>
<td>6 (60)</td>
<td>8 (80)</td>
<td>0.95</td>
<td>.329</td>
<td>.22</td>
</tr>
</tbody>
</table>

In summary, participants in both treatment groups demonstrated significant improvements in the majority of pain measures assessed. The only significant difference between the two groups was on the pain experienced during the cotton swab test, with PFR participants demonstrating greater improvements from pre- to post-treatment. However, the treatment difference was no longer present when looking at changes to follow-up.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-Treatment $M (SD)$</th>
<th>Post-Treatment $M (SD)$</th>
<th>Follow-up $M (SD)$</th>
<th>Pre $\rightarrow$ Post $p (d)$</th>
<th>Post $\rightarrow$ Follow-up $p (d)$</th>
<th>Pre $\rightarrow$ Follow-up $p (d)$</th>
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<tr>
<td>ICBT</td>
<td>22.26 (5.57)</td>
<td>27.37 (4.61)</td>
<td>29.69 (5.12)</td>
<td>.091 (1.00)</td>
<td>.305 (0.43)</td>
<td>.013 (1.48)</td>
</tr>
<tr>
<td>PFR</td>
<td>22.59 (7.20)</td>
<td>27.06 (4.25)</td>
<td>24.29 (7.18)</td>
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<td>.160 (0.38)</td>
<td>.518 (0.24)</td>
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<td>FSFI-R Desire</td>
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</tr>
<tr>
<td>ICBT</td>
<td>3.24 (0.99)</td>
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<td>5.10 (0.81)</td>
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<td>PFR</td>
<td>3.33 (1.50)</td>
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<td>4.13 (1.31)</td>
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<td>4.80 (1.29)</td>
<td>5.20 (1.41)</td>
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<td>.671 (0.27)</td>
</tr>
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<td>4.00 (1.85)</td>
<td>5.03 (1.20)</td>
<td>4.11 (2.09)</td>
<td>.125 (0.66)</td>
<td>.023 (0.60)</td>
<td>.859 (0.06)</td>
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<td>PFR</td>
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<tr>
<td><strong>PFM Tone</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>1.57 (0.45)</td>
<td>1.33 (0.54)</td>
<td>-</td>
<td>.298 (0.48)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>PFR</td>
<td>1.62 (0.79)</td>
<td>0.70 (0.62)</td>
<td>-</td>
<td>.004 (1.30)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td><strong>PFM Relaxation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>2.33 (0.71)</td>
<td>1.33 (1.32)</td>
<td>-</td>
<td>.027 (1.05)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Transformed</td>
<td>1.51 (0.25)</td>
<td>0.92 (0.75)</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PFR</td>
<td>2.40 (0.97)</td>
<td>0.70 (0.67)</td>
<td>-</td>
<td>.027 (1.05)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Transformed</td>
<td>1.52 (0.33)</td>
<td>0.64 (0.57)</td>
<td>-</td>
<td>&lt; .001 (1.89)</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

*Note.* FSFI-R = Female Sexual Functioning Index-Revised, PFM = pelvic floor muscle.
Physical functioning. The following section outlines the results from the mixed-model ANOVAs and paired-samples \( t \)-tests conducted to determine and compare the effectiveness of ICBT and PFR in treating the physical functioning aspects of PVD, namely, sexual functioning and PFM functioning. It was expected that both treatment groups would result in improvements, with ICBT leading to greater improvements in sexual functioning and PFR leading to greater improvement in PFM functioning.

With respect to sexual functioning, there was a significant and meaningful time effect \([F(2, 24) = 5.62, p = .010, \eta^2_p = .32]\) and non-significant time by treatment interaction \([F(2, 24) = 1.89, p = .172, \eta^2_p = .14]\) and treatment effects for the FSFI Total score (Figure 12). Paired-sample \( t \)-tests demonstrated that neither treatment group had significant increases in overall sexual functioning from pre- to post-treatment or post-treatment to follow-up. From pre-treatment to follow-up, those in the ICBT group had significant and meaningful improvements in sexual functioning, while there were no significant changes for the PFR group.

![Figure 12](image.png)

*Figure 12.* Results from mixed-model ANOVA assessing changes in Female Sexual Function Index-Revised (FSFI-R) Total scores over time. Error bars represent standard errors.
The FSFI Desire subscale had a significant and meaningful time effect \(F(1.52, 25.75) = 6.82, p = .003, \eta^2_p = .29\) with non-significant time by treatment interaction \(F(1.52, 25.75) = 3.25, p = .067, \eta^2_p = .16\) and treatment effects (Figure 13). Paired-sample \(t\)-tests demonstrated that participants in the ICBT group demonstrated significant and meaningful improvements in desire from all time points to the next. Participants in the PFR group, alternatively, did not demonstrate significant changes in desire.

**Figure 13.** Results from mixed-model ANOVA assessing changes in Female Sexual Function Index-Revised (FSFI-R) Desire scores over time. Error bars represent standard errors.

The FSFI Arousal subscale also had a significant and meaningful time effect \(F(2, 26) = 4.31, p = .024, \eta^2_p = .25\) with non-significant time by treatment interaction \(F(2, 26) = 2.22, p = .129, \eta^2_p = .15\) and treatment effects (Figure 14). Paired-sample \(t\)-tests demonstrated that those in the ICBT group had significant and meaningful improvements in sexual arousal from pre- to post-treatment; however, the change from pre-treatment to follow-up was not significant. Those in the PFR group demonstrated no significant changes from any time point to another.
Figure 14. Results from mixed-model ANOVA assessing changes in Female Sexual Function Index-Revised (FSFI-R) Arousal scores over time. Error bars represent standard errors.

The FSFI Satisfaction subscale had non-significant time $[F(2, 22) = 0.48, p = .623, \eta^2_p = .04]$, time by treatment $[F(2, 22) = 1.04, p = .372, \eta^2_p = .09]$, and treatment effects (Figure 15). Paired-sample $t$-tests showed that participants in the ICBT group had no significant changes in satisfaction from any time point to another. Participants in the PFR group had no significant overall change from pre-treatment to follow-up.

When investigating physical functioning with respect to PFM functioning, there was a significant and meaningful time by treatment interaction with respect to PFM tone, $F(1, 18) = 4.52, p = .048, \eta^2_p = .20$ (Figure 16). Those in the ICBT group did not have significant reductions in their PFM tone from pre- to post-treatment. Participants in the PFR group demonstrated a significant and meaningful reduction in PFM tone from pre- to post-treatment.
The mixed-model ANOVA for PFM relaxation capacity had a significant and meaningful time effect \( F(1, 17) = 34.28, p < .001, \eta_p^2 = .67 \) with non-significant time by treatment.
interaction \[ F(1, 17) = 1.26, p = .277, \eta^2 = .07 \] and treatment effects (Figure 17). Participants in both treatment groups demonstrated significant and meaningful improvements in their ability to relax their PFMs following a contraction from pre- to post-treatment.

![Figure 17. Results from mixed-model ANOVA assessing changes in PFM relaxation capacity over time. Error bars represent standard errors. The data shown are transformed.](image)

In summary, the only significant between-group difference in physical functioning outcomes was with respect to changes in PFM tone, with participants in the PFR group showing improvements while those in the ICBT group did not. Although there were no significant interactions for sexual functioning measures, paired-sample \( t \)-tests demonstrate some significant improvements in desire and overall sexual functioning from pre-treatment to follow-up in the ICBT group, and no changes in the PFR group.
Table 7

*Means, Standard Deviations, and Post-Hoc Analyses for the Emotional Functioning Outcomes*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-Treatment</th>
<th>Post-Treatment</th>
<th>Follow-up</th>
<th>Pre → Post</th>
<th>Post → Follow-up</th>
<th>Pre → Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
<td>M (SD)</td>
<td>p (d)</td>
<td>p (d)</td>
<td>p (d)</td>
</tr>
<tr>
<td>PCS Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>21.40 (7.11)</td>
<td>10.40 (7.89)</td>
<td>9.10 (8.27)</td>
<td>.012 (1.41)</td>
<td>.401 (0.15)</td>
<td>.005 (1.60)</td>
</tr>
<tr>
<td>PFR</td>
<td>15.22 (12.17)</td>
<td>7.89 (7.80)</td>
<td>8.33 (10.14)</td>
<td>.004 (0.72)</td>
<td>.765 (0.05)</td>
<td>.004 (0.62)</td>
</tr>
<tr>
<td>PCS Rumination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>9.50 (3.03)</td>
<td>4.90 (3.21)</td>
<td>4.70 (3.13)</td>
<td>.006 (1.47)</td>
<td>.794 (0.06)</td>
<td>.009 (1.56)</td>
</tr>
<tr>
<td>PFR</td>
<td>5.22 (4.79)</td>
<td>3.22 (3.15)</td>
<td>4.00 (4.80)</td>
<td>.034 (0.50)</td>
<td>.313 (0.19)</td>
<td>.093 (0.25)</td>
</tr>
<tr>
<td>PCS Magnification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>2.90 (1.60)</td>
<td>1.90 (2.28)</td>
<td>1.80 (2.25)</td>
<td>.244 (0.50)</td>
<td>.823 (0.04)</td>
<td>.111 (0.56)</td>
</tr>
<tr>
<td>PFR</td>
<td>2.33 (2.35)</td>
<td>1.56 (1.74)</td>
<td>1.67 (2.29)</td>
<td>.088 (0.37)</td>
<td>.760 (0.05)</td>
<td>.282 (0.28)</td>
</tr>
<tr>
<td>PCS Helplessness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>9.10 (4.00)</td>
<td>3.60 (3.83)</td>
<td>2.60 (3.57)</td>
<td>.013 (1.37)</td>
<td>.148 (0.27)</td>
<td>.003 (1.69)</td>
</tr>
<tr>
<td>PFR</td>
<td>7.67 (6.16)</td>
<td>3.11 (3.30)</td>
<td>2.67 (3.74)</td>
<td>.004 (0.92)</td>
<td>.602 (0.12)</td>
<td>.007 (0.98)</td>
</tr>
<tr>
<td>CSQ Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICBT</td>
<td>2.56 (0.88)</td>
<td>4.33 (1.00)</td>
<td>4.33 (1.22)</td>
<td>&lt; .001 (1.88)</td>
<td>1.00 (0.00)</td>
<td>.002 (1.66)</td>
</tr>
<tr>
<td>PFR</td>
<td>2.33 (1.58)</td>
<td>4.22 (1.09)</td>
<td>4.44 (1.33)</td>
<td>.033 (1.39)</td>
<td>.559 (0.18)</td>
<td>.009 (1.44)</td>
</tr>
</tbody>
</table>

*Note.* PCS = Pain Catastrophizing Scale; CSQ = Coping Strategies Questionnaire.
**Emotional functioning.** The following section outlines the results from the mixed-model ANOVAs and paired-samples $t$-tests conducted to determine and compare the effectiveness of ICBT and PFR in treating the emotional functioning aspects of PVD, namely, pain catastrophizing and perception of control over pain. It was expected that both treatment groups would result in improvements, with ICBT leading to greater improvement in these outcomes. Results from the mixed-model ANOVA for pain catastrophizing demonstrated a significant and meaningful time effect $[F(1.41, 23.98) = 19.79, p < .001, η_p^2 = .54]$ with non-significant time by treatment interaction $[F(1.41, 23.98) = 1.28, p = .284, η_p^2 = .07]$ and treatment effects (Figure 18). Paired-sample $t$-tests indicated that participants in both treatment groups had significant and meaningful reductions in catastrophizing from pre- to post-treatment that were maintained from post-treatment to follow-up. From pre-treatment to follow-up, both treatment groups had significant and meaningful improvements in pain catastrophizing.

![Figure 18](image-url)  
*Figure 18.* Results from mixed-model ANOVA assessing changes in pain catastrophizing over time. Error bars represent standard errors.
The subscales of the PCS were examined to determine if there were any underlying differences between the two groups in changes in different areas of catastrophizing. There was a significant and meaningful time by treatment interaction for the Rumination subscale, $F(2, 34) = 3.30, p = .049, \eta^2_p = .16$ (Figure 19). Subsequent mixed-model ANOVAs indicated a non-significant time by treatment interaction from pre- to post-treatment [$F(1, 17) = 2.80, p = .113, \eta^2_p = .14$] and from post-treatment to follow-up [$F(1, 17) = 0.88, p = .360, \eta^2_p = .05$], but a significant and meaningful time by treatment interaction from pre-treatment to follow-up [$F(1, 17) = 4.70, p = .045, \eta^2_p = .22$]. Paired-sample t-tests demonstrated that participants in the ICBT group had significant and meaningful reductions in rumination from pre- to post-treatment and maintained the gains from post-treatment to follow-up. Participants in the PFR group also demonstrated significant and meaningful reductions in rumination from pre- to post-treatment; however, the gains were not maintained to follow-up.

*Figure 19.* Results from mixed-model ANOVA assessing changes in rumination over time. Error bars represent standard errors.
There were non-significant time \([F(2, 34) = 3.28, p = .05, \eta_p^2 = .16]\), time by treatment interaction \([F(2, 34) = 0.15, p = .864, \eta_p^2 = .01]\), and treatment effects for the Magnification subscale (Figure 20). Paired-sample \(t\)-tests indicated no significant changes in magnification in either treatment group.

![Figure 20](image-url) Results from mixed-model ANOVA assessing changes in magnification over time. Error bars represent standard errors.

There was a significant time effect \([F(2, 34) = 23.00, p < .001, \eta_p^2 = .58]\) and non-significant time by treatment interaction \([F(2, 34) = 0.30, p = .75, \eta_p^2 = .02]\) and treatment effects for the Helplessness subscale (Figure 21). Paired-sample \(t\)-tests indicated that participants in both treatment groups had significant and meaningful reductions in helplessness from pre- to post-treatment that were maintained from post-treatment to follow-up. Both treatments, therefore, also had significant and meaningful reductions from pre-treatment to follow-up.
There was a significant and meaningful time effect \( [F(2, 32) = 18.66, p < .001, \eta_p^2 = .54] \) and non-significant time by treatment interaction \( [F(2, 32) = 0.11, p = .894, \eta_p^2 = .01] \) and treatment effects for perception of control over pain (Figure 22). Paired-sample \( t \)-tests demonstrated that participants in both treatment groups had significant and meaningful increases in perception of control over pain from pre- to post-treatment that were maintained from post-treatment to follow-up.
Figure 22. Results from mixed-model ANOVA assessing changes in perception of control over pain over time. Error bars represent standard errors.

In summary, both treatment groups demonstrated improvements in pain catastrophizing and perception of control over pain. Participants in the ICBT demonstrated greater reductions than the PFR group in rumination from pre-treatment to follow-up.

**Participant ratings of global improvement.** The following section outlines the results from independent-sample $t$-tests conducted to compare the effectiveness of ICBT and PFR in participant global ratings of improvement. Independent sample $t$-tests were conducted at post-treatment and follow-up on their perceptions of overall improvement, their treatment satisfaction, and the progress they made with respect to their self-identified goals (Table 8). There were no significant differences between the treatment groups on any of the ratings at either time point.

The participant’s goals can be described as belonging to seven different categories: pain reduction (27%), increase coping and control of pain (23%), increase understanding of pain (20%), improve sex life (13%), increase sexual communication (7%), improve PFM functioning
(7%), and adopt a health view of genitals (3%).

Table 8

*Independent Sample t-tests for the Participant Ratings of Global Improvement at Post-Treatment and Follow-Up*

<table>
<thead>
<tr>
<th>Variable</th>
<th>ICBT M (SD)</th>
<th>PFR M (SD)</th>
<th>t (df)</th>
<th>p</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-Treatment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall improvement %</td>
<td>71.00 (22.83)</td>
<td>79.00 (7.38)</td>
<td>1.05 (10.86)</td>
<td>.315</td>
<td>0.47</td>
</tr>
<tr>
<td>Treatment satisfaction (0-10)</td>
<td>8.80 (1.14)</td>
<td>8.90 (0.99)</td>
<td>0.21 (18)</td>
<td>.836</td>
<td>0.09</td>
</tr>
<tr>
<td>Average goal progress (0-10)</td>
<td>7.47 (1.58)</td>
<td>8.17 (1.52)</td>
<td>1.01 (18)</td>
<td>.326</td>
<td>0.45</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall improvement %</td>
<td>81.30 (15.21)</td>
<td>81.00 (12.65)</td>
<td>-0.05 (18)</td>
<td>.962</td>
<td>0.02</td>
</tr>
<tr>
<td>Treatment satisfaction (0-10)</td>
<td>9.00 (1.15)</td>
<td>9.00 (1.05)</td>
<td>0.00 (18)</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Average goal progress (0-10)</td>
<td>8.32 (1.50)</td>
<td>7.80 (1.21)</td>
<td>-0.85 (18)</td>
<td>.408</td>
<td>0.38</td>
</tr>
</tbody>
</table>

**Symptoms and adverse events.** All participants reported experiencing pain with the use of the vaginal dilators at some point during the course of treatment. Other than expected pain due to treatment modalities, no adverse events were noted in any participant in either treatment group.

**Predicting Treatment Outcome**

The following section outlines the results from multiple regression models conducted to determine predictors of treatment outcome for ICBT and PFR, the third study aim. It was expected that greater improvements in catastrophizing, perception of control over pain, and sexual functioning would be associated with greater improvements in pain in the ICBT group. Alternatively, it was expected that greater improvements in PFM functioning, namely tone and relaxation capacity, would be associated with greater improvements in pain the PFR group.
Treatment outcome was defined as the change in intercourse pain intensity from pre-treatment to follow-up. A change score was calculated by subtracting the pre-treatment score from the follow-up score; thus, negative change scores are indicative of greater improvement in pain. Despite some research warning against the use of change scores (Cronbach & Furby, 1970), more recent research supports their use in a variety of situations (Edwards, 2001; Zumbo, 1999).

To assess whether changes in intercourse pain intensity from pre-treatment to follow-up could be accounted for by changes in PCS scores, CSQ perception of control over pain scores, FSFI scores, PFM tone ratings, and PFM relaxation ability ratings over the course of treatment, change scores for each process variable were calculated by subtracting the pre-treatment score from the post-treatment score. Negative change scores are indicative of improvements in pain catastrophizing, tone, and relaxation ability scores, while positive change scores are indicative of improvements in perception of control over pain and sexual functioning. Moderation analyses, using hierarchical multiple regression analyses, were then performed to assess whether treatment group (moderator variable) moderated the relationship between the change in the process variables (independent variable) and the change in intercourse pain intensity ratings (outcome variable). Separate hierarchical multiple regression models were conducted for each process variable. The independent and moderator variables were centered before being entered into the models, and these centered variables were multiplied to obtain the interaction term. The first step included the treatment group variable and the process variable. The interaction term was added in the second step to test for moderation. Simple slopes analyses were computed to determine the predictive value of the change in each process variable toward change in pain intensity within each treatment group. The results of all moderation analyses are presented in Table 9.
Table 9
Hierarchical Regression Analyses Testing the Moderating Effect of Treatment Group on the Relationship Between Changes in Cognitive, Sexual, and Pelvic Floor Muscle Functioning and Changes in Intercourse Pain Intensity Ratings

<table>
<thead>
<tr>
<th>Variables</th>
<th>Step 1</th>
<th>Step 2</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>$b$</td>
<td>$\beta$</td>
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<tr>
<td><strong>Pain Catastrophizing</strong></td>
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<td></td>
</tr>
<tr>
<td>$\Delta$ PCS</td>
<td>.05</td>
<td>.26</td>
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<tr>
<td>Treatment</td>
<td>-.42</td>
<td>-.13</td>
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<td>Treatment x $\Delta$ PCS</td>
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<tr>
<td><strong>Perception of Control over Pain</strong></td>
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<tr>
<td>$\Delta$ Control</td>
<td>.10</td>
<td>.10</td>
</tr>
<tr>
<td>Treatment</td>
<td>-.60</td>
<td>-.18</td>
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<tr>
<td>Treatment x $\Delta$ Control</td>
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<tr>
<td><strong>Sexual Functioning</strong></td>
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<td>$\Delta$ FSFI</td>
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<tr>
<td>Treatment</td>
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<td>Treatment x $\Delta$ FSFI</td>
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<tr>
<td>Variables</td>
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</tr>
<tr>
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</tr>
<tr>
<td></td>
<td>$b$</td>
<td>$\beta$</td>
</tr>
<tr>
<td>Pelvic Floor Muscle Tone</td>
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<tr>
<td>$\Delta$ PFM Tone</td>
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<td>.29</td>
</tr>
<tr>
<td>Treatment</td>
<td>-.85</td>
<td>-.26</td>
</tr>
<tr>
<td>Treatment x $\Delta$ PFM Tone</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>1.93</td>
<td>.41</td>
</tr>
<tr>
<td>Pelvic Floor Muscle Relaxation Ability</td>
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</tr>
<tr>
<td>$\Delta$ PFM Relax</td>
<td>.52</td>
<td>.36</td>
</tr>
<tr>
<td>Treatment</td>
<td>-1.16</td>
<td>-0.38</td>
</tr>
<tr>
<td>Treatment x $\Delta$ PFM Relax</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>.85</td>
<td>.28</td>
</tr>
</tbody>
</table>

*Note. PCS = Pain Catastrophizing Scale; FSFI = Female Sexual Function Index; PFM = pelvic floor muscle.*

* at least a medium effect size
In the first moderation analysis, neither treatment group nor changes in PCS scores significantly predicted changes in intercourse pain intensity. The interaction between the two variables in the second step was non-significant, adding 13% of explained variance to the prediction of changes in intercourse pain intensity ratings ($p = .135, r = .38$). Simple slope analysis (Figure 23) demonstrated non-significant relationships between changes in pain catastrophizing from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, $b = .08, p = .195, r = .45$ and PFR group, $b = -.10, p = .227, r = -.45$.

![Figure 23](image-url)

**Figure 23.** The relationship between changes in pain catastrophizing from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up. More and less decrease in PCS represent ± 1 SD.

In the second moderation analysis, neither treatment group nor changes in CSQ perception of control over pain scores significantly predicted changes in intercourse pain intensity. A significant and meaningful interaction between the two variables was present in the
second step, adding 28% of explained variance to the prediction of changes in intercourse pain intensity ratings ($p = .027, r = -.54$). Simple slope analysis (Figure 24) demonstrated non-significant relationships between changes in perception of control over pain from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, $b = -1.02, p = .139, r = -.50$ and PFR group, $b = .36, p = .059, r = .65$.

![Figure 24](image)

*Figure 24.* The relationship between changes in perception of control over pain from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up. More and less increase in perception of control represent ± 1 SD.

In the third moderation analysis, neither treatment group nor changes in sexual functioning were found to be significant predictors of changes in intercourse pain intensity ratings. The interaction between the two variables in the second step was non-significant, adding 3% of explained variance to the prediction of changes in intercourse pain intensity ratings ($p = .606, r = -.17$). Simple slope analysis (Figure 25) demonstrated non-significant relationships
between changes in sexual functioning from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, $b = -.12, p = .505, r = -.31$ and PFR group, $b = -.02, p = .787, r = -.12$.

![Graph showing the relationship between changes in sexual functioning from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up. More and less decrease in FSFI-R represent ± 1 SD.](image)

Figure 25. The relationship between changes in sexual functioning from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up. More and less decrease in FSFI-R represent ± 1 SD.

In the fourth moderation analysis, neither treatment group nor changes in PFM tone significantly predicted changes in intercourse pain intensity. The interaction between the two variables in the second step was non-significant, adding 16% of explained variance to the prediction of changes in intercourse pain intensity ratings ($p = .606, r = -.17$). Simple slope analysis (Figure 26) demonstrated non-significant relationships between changes in PFM tone from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, $b = 1.69, p = .095, r = .56$ and PFR group, $b = -.24, p = .680, r = -.15$. 

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In the fifth moderation analysis, neither treatment group nor changes in PFM relaxation capacity significantly predicted changes in intercourse pain intensity. The interaction between the two variables in the second step was non-significant, adding 5% of explained variance to the prediction of changes in intercourse pain intensity ratings ($p = .325$, $r = .25$). Simple slope analysis (Figure 27) demonstrated non-significant relationships between changes in PFM relaxation capacity from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, $b = .71$, $p = .150$, $r = .52$ and PFR group, $b = -.13$, $p = .842$, $r = -.07$. 

Figure 26. The relationship between changes in PFM tone from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up. More and less decrease in PFM tone represent ± 1 SD.
Figure 27. The relationship between changes in PFM relaxation capacity from pre- to post-treatment and changes in intercourse pain intensity ratings from pre-treatment to follow-up. More and less decrease in PFM relaxation capacity represent ± 1 SD.

The study also aimed to determine whether treatment credibility/expectancy and adherence to homework would predict better pain outcomes. It was expected that greater levels of treatment credibility/expectancy and greater adherence to homework would predict more pain improvement in both treatment groups. Ratings of credibility, expectancy, and homework adherence were not significantly related to changes in intercourse pain intensity ratings from pre-treatment to follow-up ($p > .05$, $r < .30$). Moderation analyses, following the steps outlined above, were therefore conducted to determine whether differences between the two treatment groups were masking effects of credibility/expectancy or homework adherence. The results of the moderation analyses are presented in Table 10.
Table 10

Hierarchical Regression Analyses Testing the Moderating Effect of Treatment Group on the Relationship Between Treatment Credibility, Expectations, Homework Adherence and Changes in Intercourse Pain Intensity Ratings

<table>
<thead>
<tr>
<th>Variables</th>
<th>Step 1</th>
<th>Step 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(b)</td>
<td>(\beta)</td>
</tr>
<tr>
<td>Treatment Credibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Credibility</td>
<td>-.01</td>
<td>-.01</td>
</tr>
<tr>
<td>Treatment</td>
<td>-.44</td>
<td>-.14</td>
</tr>
<tr>
<td>Treatment x Credibility</td>
<td></td>
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</tr>
<tr>
<td>Treatment Expectancy</td>
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<td></td>
</tr>
<tr>
<td>Expectancy</td>
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<td>.09</td>
</tr>
<tr>
<td>Treatment</td>
<td>-.52</td>
<td>-.16</td>
</tr>
<tr>
<td>Treatment x Expectancy</td>
<td></td>
<td>-.22</td>
</tr>
<tr>
<td>Homework Adherence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Homework Adherence</td>
<td>-.27</td>
<td>-.16</td>
</tr>
<tr>
<td>Treatment</td>
<td>-.34</td>
<td>-.11</td>
</tr>
<tr>
<td>Treatment x Adherence</td>
<td></td>
<td>1.32</td>
</tr>
</tbody>
</table>

* at least a medium effect size
In the first moderation analysis, neither treatment group nor ratings of treatment credibility significantly predicted changes in intercourse pain intensity. The interaction between the two variables in the second step was non-significant, adding 20% of explained variance to the prediction of changes in intercourse pain intensity ratings ($p = .059, r = -.45$). Simple slope analysis (Figure 28) demonstrated non-significant relationships between credibility ratings and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, $b = -.84, p = .250, r = -.40$ and PFR group, $b = .65, p = .089, r = .57$.

![Figure 28](image)

*Figure 28. The relationship between ratings of treatment credibility and changes in intercourse pain intensity ratings from pre-treatment to follow-up. Lower and higher credibility represent ± 1 SD.*

In the second moderation analysis, neither treatment group nor ratings of treatment expectancy were found to be significant predictors of changes in intercourse pain intensity ratings. The interaction between the two variables in the second step was non-significant, adding less than 1% of explained variance to the prediction of changes in intercourse pain intensity ratings ($p = .803, r = -.06$). Simple slope analysis (Figure 29) demonstrated non-significant
relationships between expectancy ratings and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, \( b = .30, p = .753, r = .12 \) and PFR group, \( b = .08, p = .808, r = .09 \).

![Figure 29](image)

**Figure 29.** The relationship between ratings of treatment expectancy and changes in intercourse pain intensity ratings from pre-treatment to follow-up. Lower and higher expectancy represent ± 1 SD.

In the third moderation analysis, neither treatment group nor ratings of homework adherence significantly predicted changes in intercourse pain intensity. The interaction between the two variables in the second step was non-significant, adding 11% of explained variance to the prediction of changes in intercourse pain intensity ratings (\( p = .168, r = .34 \)). Simple slope analysis (Figure 30) demonstrated non-significant relationships between homework adherence and changes in intercourse pain intensity ratings from pre-treatment to follow-up for participants in the ICBT group, \( b = .70, p = .496, r = .25 \), and PFR group, \( b = -.62, p = .078, r = -.58 \).
Figure 30. The relationship between ratings of homework adherence and changes in intercourse pain intensity ratings from pre-treatment to follow-up. Less and greater adherence represent ± 1 SD.
Chapter 5

Discussion

The current study addressed three main objectives related to treating PVD with non-medical treatment options. Namely, to determine whether ICBT and PFR are effective at reducing the pain of PVD and improving the psychosexual correlates of pain, to examine whether one treatment is more effective than the other at addressing the pain or psychosexual correlates of pain, and to determine modifiable cognitive and behavioural predictors of treatment outcome. Generally, it was expected that both treatments would result in improvements in pain and the psychosexual correlates of pain, but that PFR would result in greater improvements in pain and PFM outcomes while ICBT would results in greater improvements in sexual and emotional outcomes. Furthermore, expectations were that changes in pain cognitions and sexual functioning would predict pain improvement in the ICBT group, that changes in PFM functioning would predict pain improvement in the PFR group, and that greater treatment credibility, expectations and homework adherence would predict pain improvement in both treatment groups. Due to the small sample size, the study was underpowered, and thus it is difficult to make conclusions about between-group differences in changes over the course of treatment. Investigation of the univariate analyses within treatment groups, as well as inspection of the effect sizes, can give us some suggestions as to where future research with larger samples sizes may look to investigate potential treatment differences. The lack of a control group, as is discussed further below, also limits what conclusions can be made regarding the reason for changes over time.

Treatment Impacts on Pain Outcomes

Overall, the study findings support the hypothesis that both treatments may lead to
improvements in pain. With respect to the primary outcome of the study, participants in both
treatment groups demonstrated statistically significant and clinically meaningful reductions in
self-reported average intercourse pain intensity from pre- to post-treatment and pre-treatment to
follow-up, with 80% of participants reporting an average pain rating in the mild range (0-3). The
percentage change in average intercourse pain intensity did not differ between the two treatment
groups at either post-treatment or follow-up. When considering the IMMPACT recommendation
guidelines for clinically important changes in NRS ratings, 90% and 80% of the PFR and ICBT
participants, respectively, demonstrated a moderate clinically important difference (30%
reduction) and 80% and 60% of the PFR and ICBT participants, respectively, demonstrated a
substantial clinically important difference (50%) by the 6-month follow-up. These guidelines
have never before been used within the PVD literature.

When taking into account changes in other pain outcomes from pre-treatment to the 6-
month follow-up, both treatment groups also demonstrated significant and meaningful reductions
in their self-reported intercourse pain unpleasantness ratings and the percentage of intercourse
attempts resulting in pain, with 65% of participants experiencing pain during less than half of
their intercourse attempts. In the current study, participants were also asked about the number of
sexual intercourse attempts they were able to complete (participants could define this as whatever
they considered to be completion) without having to terminate due to pain. This item was
included since previous interactions with women with PVD at the SHRL suggested that this is a
frequent concern among affected women. Numerous other studies investigate the frequency of
sexual intercourse and the impact that treatment has on frequency; however, they do not indicate
whether these are intercourse attempts or whether they were ‘completed’ intercourse occurrences.
Although the current study attempted to assess frequency of intercourse attempts, due to the
changes in sexual partner status, as well as participants who were in relationships that rotated between being long distance and not, the data were too inconsistent to analyze. Participants in both treatment groups had significant and meaningful increases in the percentage of intercourse attempts that they were able to complete without having to stop because of pain, with 75% of participants not having to stop intercourse due to pain by follow-up. Given the fact that a number of these women were still experiencing moderate to severe levels of pain on some intercourse attempts, this is suggestive of increased abilities to cope with pain. Participants reported using various strategies to enable them to bring the pain level down and continue. Some participants, as recommended by the therapists, would continue with sexual activity other than intercourse following more heightened periods of pain, where typically these participants would have entirely discontinued any physical contact prior to treatment.

Additionally, there were significant and meaningful reductions in both the sensory and affective pain ratings as measured by the MPQ in the ICBT group. The majority of published studies on treatment for PVD report only on the intensity of intercourse pain and/or on whether the individual is able to have sexual intercourse. Only a small number of studies have included other pain outcomes, including pain experienced during the cotton-swab test and the MPQ (Bergeron et al., 2001b; Masheb et al., 2009). Neither study, however, distinguished between the sensory and non-sensory qualities of pain using the MPQ, presenting only the total pain rating index or the sensory scale. Based on evidence that pain intensity (i.e., the magnitude of pain) and pain affect (i.e., the distress associated with the experience of pain) reflect distinct components of the pain experience, and that treatment can differentially affect these components, IMMPACT recommendations suggest examination of both of these constructs in clinical trials (Dworkin et al., 2005). In the current study, this was accomplished through the use of intensity and
unpleasantness NRSs and through examining the sensory and affective scales of the MPQ separately. The pattern of changes in these variables in both treatment groups, regardless of significance, suggests that for the current sample, the two constructs held tightly together. Although the MPQ sensory and affective ratings did not demonstrate statistical significance within the PFR group, the significant changes in intensity and unpleasantness NRS ratings indicated that both treatments had positive impacts on the physical and emotional aspects of pain.

Given that the cotton-swab test is the only diagnostic tool for PVD, it is surprising that more treatment studies have not investigated whether treatments impact the presence of pain during this test. In the current study, both treatment groups showed significant and meaningful reductions in the pain they experienced during the examination, with the majority of participants having average cotton-swab ratings in the mild (1-3/10) range by follow-up. Although not apparent in Appendix H since the five vestibular site ratings were averaged, participants who had mild average ratings at the follow-up examination had mild ratings across all five sites. This is suggestive of changes in sensitivity around the entire vestibule over the course of treatment. The positive findings in this study are in line with other studies that also found cotton-swab pain intensity rating reductions following vestibulectomy, GCBT, and biofeedback, but not following supportive psychotherapy (Bergeron et al., 2001b; Masheb et al., 2009).

Given that women with PVD may experience vulvar pain with a variety of different sexual and non-sexual activities (Bergeron et al., 2001a), it is unfortunate that almost no previous treatment studies examined changes in pain during these other activities. Danielsson et al. (2006) did ask participants how frequently they experienced non-coital vestibular pain; however, the study does not indicate whether this referred to provoked or unprovoked pain, or in what situations this pain may have been experienced. The current study, alternatively, examined the
proportion of a set number of sexual and non-sexual activities in which participants were regularly experiencing vulvar pain. The finding that both treatments resulted in less frequent pain outside of the context of intercourse is extremely important, as it suggests that the benefits of treatment may generalize to a broad array of pain triggers and thus likely impact the women in numerous areas of their life. For participants who were not in an ongoing sexual relationship, changes in non-sexual activities (e.g., tampon insertion) or with masturbation would have provided them with feedback about effectiveness of the treatment without having to rely on having regular intercourse with a single partner. Furthermore, as seen by inspection of the data in Appendix H, there were some participants who were still having considerable degrees of pain during intercourse, and pain with every intercourse attempt at follow-up, yet were having significantly less frequent pain with other sexual and non-sexual activities. These other sexual activities may have been the only opportunities for pleasurable sexual experiences with their partner. In addition to the changes in pain during sexual intercourse, changes in other potentially pain triggering activities is an important outcome that may help to better understand changes in sexual and emotional functioning that has been discounted in other treatment studies.

The current study also attempted to assess whether a more objective measure of vestibular pain sensitivity, namely pressure pain threshold as measured through QST, would demonstrate changes following treatment. There were no significant improvements in vestibular pain threshold in either treatment group from pre-treatment to follow-up. Furthermore, the data is suggestive of large amounts of variability in the thresholds at all time points for both treatment groups, as well as variability across the time points within each participant (as seen in Appendix H). This variability may be a result of human error in the use of the vulvalgesiometer, as it is possible that at each time point the device was placed at a slightly different position at the
posterior portion of the vestibule, leading to different levels of sensitivity. Furthermore, participants were not tested during the same phase of their menstrual cycle at each time point. Given that hormonal levels are known to have an impact on pain sensitivity (Helström & Lundberg, 2000; Riley, Robinson, Wise, & Price, 1999), this also may explain the findings that are inconsistent with what was hypothesized.

Overall, there was little evidence to support any differences between the effectiveness of ICBT and PFR on pain outcomes from pre-treatment to 6-month follow-up. Pain experienced during the cotton-swab test was the only variable resulting in a significant interaction effect. Participants in the PFR group demonstrated greater reductions in pain during this examination from pre- to post-treatment than those in the ICBT group; however, the interaction effect was not significant when looking at changes from pre-treatment to follow-up. Greater improvements in the PFR group from pre- to post-treatment may be due to the similarity in the environment of and activity of the cotton-swab test and the rehabilitation provided. Both involved hands-on contact with the vulvar region in the gynecological position, whereas there is no physical contact within the context of CBT. Therefore, familiarity of the activity may have led to reduced anxiety and increased comfort among the PFR participants, thus resulting in lower pain ratings. Alternatively, there may have been greater peripheral nervous system changes in the PFR participants due to the manual nature of the treatment. These changes would then result in decreased pain sensitivity, which is specifically one of the goals outlined by Bergeron and Lord (2003) for PFR, and the reason for hypothesizing that those in the PFR group would have greater improvements in pain outcomes. Beyond this single finding, however, there were no group differences on any of the self-report measures of pain from pre-treatment to follow-up. One possible reason for this is a lack of power to detect between group differences. However, results from the univariate \( t \)-tests
within each treatment group are suggestive of similar levels of improvement in the pain outcomes between the two treatment groups. Thus, it is possible that there is not, as hypothesized, a greater effect of PFR on pain outcomes in PVD. As will be discussed further, one possible explanation for a lack of difference is the cyclical nature of pain.

Despite the possibility that there were no overall differences between the groups from pre-treatment to follow-up, there were a number of interesting differences in the pattern of changes for the two groups upon inspection. For the majority of the pain outcome variables, the greatest improvements were made from pre- to post-treatment and then changes were either maintained, or participants continued to improve, from post-treatment to follow-up for both treatment groups. For the cotton-swab test pain intensity ratings and the proportion of sexual activities resulting in pain, however, whereas the improvements occurred from pre- to post-treatment in the PFR group, the improvements were made from post-treatment to follow-up in the ICBT group. Furthermore, for the vestibular pain threshold, changes in the ICBT group also only occurred from post-treatment to follow-up. These patterns, although not statistically significant between the groups, might suggest that it may take a longer period of time for the impact of CBT to be seen, or that improvements are made following, rather than during, treatment for CBT but not for PFR. Consistent with this pattern, Bergeron et al.’s (2001b) randomized study for PVD also demonstrated that whereas the vestibulectomy and biofeedback groups had significant changes in the cotton-swab pain rating from pre- to post-treatment, improvements were not seen in the GCBT group until the 6-month follow-up. With respect to intercourse pain intensity ratings, whereas vestibulectomy performed better than biofeedback and GCBT at the post-treatment and 6-month follow-up time points, by the 2.5 year follow-up, there was no difference between the vestibulectomy and the GCBT group, indicating that even longer periods of time
following treatment completion may be required to see the full benefit of CBT on pain outcomes (Bergeron et al., 2008). The earlier effect of a treatment such as PFR versus that of CBT may be a result of the nature of the treatment delivery. In addition to the homework exercises conducted during PFR (i.e., stretches, PFM exercises, dilators), the therapist also plays a highly active role throughout the course of treatment via use of biofeedback and numerous hands-on manual techniques. In CBT, alternatively, although the therapist is present to educate, help guide the process of reconceptualization of pain, provide skill instruction, and guide the practicing and consolidation of new skills, there are no therapist-applied manual techniques aimed at impacting the pain of PVD. The participants are thus responsible for integrating the new conceptualization of pain into their lives and regularly practicing these new skills. Without their active participation, little benefit would be expected from the treatment, whereas in the PFR group, if participants did not actively incorporate the exercises into their life, one may still expect some benefit from the techniques being conducted by the therapist in sessions. Thus, it is possible that some changes occurred later for participants in the ICBT group because the participants required more time to practice and effectively integrate the skills, and therefore to gain the full benefit from the treatment components. Participants in the PFR group may have seen earlier benefits during the course of treatment due to the techniques applied by the physiotherapist. Differences in the timing of treatment effects is an important area for future treatment studies to address as it can help in treatment planning and in education prior to the onset of treatment to help set realistic goals and treatment expectations.

Overall, it is challenging to compare the effects on pain found in the current study and previous studies because of the use of different outcome measures and the lack of effect size reporting in previous PVD treatment studies. The randomized study comparing vestibulectomy,
GCBT and biofeedback (Bergeron et al., 2001b), however, did report data that allowed for computation of effect sizes. Although the computed effect sizes cannot be directly compared to those in the current study, an examination of the effect sizes suggests that the reductions in intercourse pain intensity in the current study were higher than those found for GCBT and biofeedback in the previous study, particularly at post-treatment. Although no conclusions can be firmly drawn from an examination of effect sizes, the differences seen may suggest that individualized CBT could lead to better outcomes than the same treatment delivered in group format, and that a comprehensive PFR program could lead to better outcomes than just solely using biofeedback. These comparisons would be important in future research as they can help to determine cost effectiveness of various treatment formats.

Previous meta-analyses document the pain intensity effect size for cognitive-behavioural and behavioural treatments, including biofeedback, for chronic pain conditions as 0.40 (Morley et al., 1999; Morley, 2011). The effect sizes for pain intensity found in the current study for both ICBT and PFR are considerably higher than this. Although methodological aspects of the current study may account for this difference, the effect sizes in the current study are also much higher than the upper limit of the 95% confidence interval for the effect size (0.58) in other chronic pain conditions, suggesting that these non-medical treatment alternatives may be more effective for PVD than for other chronic pain conditions. One possible explanation for this may be that there are better outcomes for recurrent pain conditions rather than chronic pain conditions. However, CBT, behavioural treatment, and physical therapy effect sizes for other recurrent pain conditions, such as recurrent migraines or headaches and endometriosis, are not any higher than for chronic pain conditions (Holroyd, 2002; Petrelluzzi et al., 2012). Thus, it is possible that PVD may be more responsive to non-medical treatment options than other pain conditions because the nature
of the main trigger of PVD pain (i.e., sexual activity) is under a greater degree of control by the individual than for other pain conditions. Comparisons with other chronic and/or recurrent pain conditions will require future PVD treatment studies to utilize measures that are comparable to those included in the general pain literature, such as those recommended by the IMMPACT team, as well as reporting of effect sizes.

**Treatment Impacts on Physical and Emotional Outcomes**

The use of both generic and disease-specific measures of physical functioning is suggested by IMMPACT recommendations for use in chronic pain clinical trials (Dworkin et al. 2005). The current study, unfortunately, did not include a generic measure of physical functioning. As no PVD-specific physical functioning questionnaires exist, physical functioning outcomes were chosen based on the areas of functioning known to be most impacted in PVD, namely, sexual functioning and PFM functioning. Overall, the hypothesis that both treatments would result in improvements in sexual and PFM functioning was not supported. Inconsistent findings among analyses with respect to improvements in these domains make it difficult to make conclusions about between-group differences.

**Sexual functioning.** When measured with the FSFI-R, from pre-treatment to follow-up, ICBT participants had significant and meaningful improvements in sexual desire and in overall sexual functioning while PFR participants did not demonstrate these changes when results were analyzed by paired-sample *t*-tests. Although the time by treatment interactions for both of these variables was not significant, the large effect sizes for the interaction terms, and the differences seen based on *t*-tests, suggest that there was not enough power to detect the differences using ANOVAs. Thus, it is possible that future studies with larger sample sizes may find that ICBT leads to more beneficial outcomes with respect to sexual functioning than PFR. This will be an
important area to explore in future research. Although participants in the ICBT group also demonstrated significant improvements in sexual arousal from pre- to post-treatment, when analyzed from pre-treatment to follow-up, it was no longer significant. Given that CBT directly addresses issues of sexual functioning, it is not surprising that women who completed ICBT reported improvements in this area. All previous PVD treatment studies investigating CBT have similarly found improvements in sexual function (Bergeron et al., 2001b; Desrochers et al., 2010; ter Kuile & Weijenborg, 2006). Interestingly, despite improvements in overall sexual functioning, participants in the ICBT group demonstrated no significant changes in sexual satisfaction. It is possible that despite improvements in functioning, the participants had received considerable education about sexual functioning and may have had higher expectations or wishes for what their sexual life might look like. Alternatively, the lack of improvement may be a consequence of the questionnaire items used to assess sexual satisfaction. Two of the three items refer to aspects of the sexual partnership. Thus, despite participants noticing improvements in their own functioning, there may have been no changes in their partner’s behaviour or their ability to connect to one another. Additionally, participants in the CBT group were encouraged to change aspects of their sexual communication and behaviour with their partners. Since partners were not invited to a therapy session, these changes may not have been well received, thus not allowing for positive changes within the couple. Lastly, it is also possible that more time is required for participants to report improvements in their sexual satisfaction. It was surprising that participants in the PFR group did not demonstrate any significant improvements in any area of sexual functioning despite PFR not directly targeting sexual functioning. Given the cyclical nature of pain, one might expect that with improvements in pain, women would also see improvements in various areas of sexual function. This is supported by findings of improved sexual functioning
following treatments that do not address sexuality at all, such as surgery and lidocaine (Bergeron et al., 2001b; Danielsson et al., 2006). The current study’s findings on lack of sexual functioning changes in PFR is difficult to compare to previous PVD studies since there are inconsistent findings about improvements in these areas in response to treatments targeting the PFMs. Some studies have found overall improvements (e.g., Bergeron et al., 2001b; Goldfinger et al., 2009); however, others that have broken down functioning into its various components have reported mixed results (Danielsson et al., 2006; Goldfinger et al., 2009).

**PFM functioning.** With respect to changes in PFM function, as expected, participants in the PFR group demonstrated better outcomes with respect to PFM tone. Nearly all of the techniques used in PFR are aimed at addressing muscle functioning. Although CBT aims to address this to some extent, with use of at-home PFM exercises and dilators, the therapist is not able to provide feedback to the participants about their correct use of the exercises. Additionally, the use of these techniques is directed more toward the participant’s functional ability to become more aware of their general level of muscle reactivity when provoked by pain and to improve their ability to then change their muscle response. This may explain why participants in the ICBT group did, in fact, have significant and meaningful improvements in their ability to relax their PFMs following a contraction. Given that the PFM assessment was not completed at follow-up, it is not possible to know whether the gains made in each group would be maintained or whether participants in the ICBT group would make gains in PFM tone following treatment after having had more practice with the exercises.

**Emotional functioning.** As already demonstrated by findings of significant and meaningful reductions in affective components of pain in both treatment groups, emotional correlates of pain in PVD are also impacted by non-medical treatment options. Although
IMMPACT recommendations suggest the inclusion of mood questionnaires to measures changes in emotional functioning (Dworkin et al., 2005), in the current study we specifically excluded women who were experiencing substantial mood difficulties and thus, we would not expect to see significant changes in mood due to treatment. This was confirmed by very low baseline BDI-II scores, with only 1 participant scoring above the mildly depressed range. Pain catastrophizing and perceived control over pain were the two negative pain cognitions assessed in the study as they are common among chronic pain conditions (Turk & Monarch, 2002) and are two factors directly addressed in CBT for pain management. Overall, the hypothesis that both treatments would result in improvements in negative pain cognitions was supported. The hypothesis that ICBT would result in greater improvements in emotional outcomes than PFR was only partially supported. Both treatment groups resulted in significant and meaningful improvements in both pain catastrophizing and perceived control over pain from pre-treatment to follow-up, with no between-group differences. Upon further investigation of the PCS subscales, both groups demonstrated significant and meaningful reductions in feelings of helplessness, with no between group differences, while there were no significant changes in magnification in either treatment group. Participants in the ICBT group had a significantly and meaningfully larger reduction in rumination than participants in the PFR group. In fact, from pre-treatment to follow-up whereas participants in the ICBT group had significant and meaningful reductions in rumination, those in the PFR group did not have significant changes. This was despite the PFR group demonstrating a significant and meaningful reduction from pre- to post-treatment, suggesting that this group was not able to maintain the gains made.

Within the context of CBT, all of the pain cognitions assessed in the study were directly targeted. Cognitive restructuring was used to target participants’ negative pain cognitions that
they believed to be problematic, and included thoughts consistent with rumination, magnification, helplessness, and perception of control. Strategies focusing on shifting attention toward pleasurable sensations or other factors in their environment, as well as toward more adaptive thoughts, were also aimed at targeting rumination. The majority of other components of CBT, including reconceptualization of pain, relaxation exercises, use of dilators, and addressing changes that participants can make themselves during sexual activity, are aimed at increasing perceived control over pain. Helplessness is additionally expected to change over the course of CBT as women start to see the impact of the changes they make on pain. Consequently, it is not surprising that all aspects of pain cognitions were improved in the ICBT group, as they have in previous treatment studies for PVD (Bergeron et al., 2001b; Bergeron et al., 2008; Desrochers et al., 2010; ter Kuile & Weijenborg, 2006). PFR also resulted in comparable reductions in helplessness and increases in perceived control over pain. Although negative pain cognitions are not directly targeted in PFR, participants are provided with strategies to use during sexual activity (e.g., changing position, PFM changes, stretches) that we would expect would result in greater perceived control over their pain. Furthermore, as with CBT, when participants are able to see that their actions can have an impact on their pain, a reduced sense of helplessness would likely result. Given that PFR does not address ruminative processes, it is not surprising that participants in the ICBT group demonstrated more significant changes in the area; however, participants in the PFR group did have reductions from pre- to post-treatment that were not maintained at follow-up. Reductions in rumination with PFR were documented in the previous prospective study conducted on PFR (Goldfinger et al., 2009) and may be understood to reflect participants focusing their attention on things other than the pain and their desire for the pain to go away. It is possible that, instead, they were focusing their attention on the strategies that had been provided
to them, or alternatively distracting themselves from the pain. Following treatment, however, half of the participants in the PFR group had an increase in their rumination, whereas participants in the CBT group maintained their gains. This difference between the two groups suggests that treatments containing strategies specifically geared toward reducing rumination may result in more long-term benefits. However, other than this difference in rumination, other areas of pain cognitions improved equally in both groups, suggesting that even when negative thoughts are not directly addressed, they may still be positively affected by treatment.

Overall, despite both treatments resulting in similar levels of improvement in pain, this study suggests that ICBT and PFR may result in very limited and specific differential effects in the PFM and emotional functioning of women with PVD, with CBT resulting in greater improvements in rumination and PFR resulting in greater improvements in PFM tone.

The Cyclical Models of Pain and Mechanisms of Change

Although it is possible that some of the lack of between-group differences found in the current study is a result of low power, for the majority of pain outcomes there were also small effect sizes on the interaction effects and t-tests suggested little differences between the treatment groups. Returning to the vicious cycle of pain (see Figure 1), we can understand why there may be few differences between ICBT and PFR with respect to pain outcomes. Whereas the PFR components put more emphasis on addressing the PFM protective response and tone, CBT components put more emphasis on addressing the psychological and sexual factors. Given that all of these factors are understood within this model to be both consequences of, and contributors to, the pain, when even a single factor is addressed, one can expect to see improvements in pain. Furthermore, one could also expect to see improvements in the other factors, even if they are not directly addressed. As discussed earlier, for instance, we see improvements in emotional
functioning in participants in the PFR group, even though these factors are not directly addressed. The bidirectional relationship between each of the components of the model is also the basic tenet of the cognitive-behavioural model of pain (see Figure 2). This model could, in fact, be used to educate women who are completing either CBT or a behavioural treatment like PFR for PVD. Emotions, thoughts, behaviours, and the body are all understood to influence one another and by targeting one area, the others will be impacted as well. While in CBT, all four quadrants of the model are addressed, PFR focuses on the behaviour and the body.

**Process variables predicting outcome.** Based on the cyclical models of pain, the current study aimed at exploring possible mechanisms of change in both ICBT and PFR by using changes in psychological, sexual, and PFM factors as predictors of change in the primary outcome variable, average intercourse pain intensity ratings. It was hypothesized that greater reductions in pain catastrophizing, and greater increases in perceived control over pain and overall sexual functioning from pre- to post-treatment would predict greater reductions in intercourse pain intensity from pre-treatment to follow-up in the ICBT group. Alternatively, it was hypothesized that greater reductions in PFM tone and greater increases in the ability to relax the PFMs following contraction from pre- to post-treatment would predict greater reduction in intercourse pain intensity from pre-treatment to follow-up in the PFR group. Unfortunately, likely due to the study’s low power, statistically significant relationships between changes in process variables and changes in intercourse pain intensity were not detectable in either treatment group. The pattern of effect sizes, however, along with the direction of the correlations provides some direction for future research with larger samples. For instance, investigation of the relationship between changes in perception of control over pain and changes in pain—the only moderation analysis resulting in statistical significance—revealed large effect sizes for the simple slopes in both
treatment groups. Whereas there was a negative relationship in the ICBT group, representing greater pain reduction among those with more increases in perceptions over control over pain, the relationship was in the opposite direction for those in the PFR group. This interesting pattern may be important for future researchers to investigate as it may be a consequence of the nature of the role of the physiotherapist in the treatment. As discussed earlier, whereas the CBT therapist acted as a guide through treatment to help the participants incorporate a new understanding of their pain and new skills into their lives, the physiotherapist used hands-on techniques that were directly aimed at targeting the pain. This latter process puts the participants into more of a passive role for some of the treatment components. It is possible that participants who see benefits of treatment very early on—and who therefore go on to have greater pain outcomes—come to perceive their physiotherapist as responsible for their pain improvement. This adoption of an external, rather than internal, locus of control could then result in little increase in their own perception of control over pain, since they view their therapist as the one who was making an impact. Several studies have, in fact, found that more of an external locus of control is predictive of greater pain outcomes for physical treatments for various chronic pain conditions (Stanton & Jull, 2003; Veenhof, Van den Ende, Dekker, Köke, Oostendorp, & Bijlsma, 2007). Within CBT, alternatively, having an internal locus of control would be of greater benefit, since it is up to the individual to implement change in their life. Locus of control in behaviourally-focused treatments for PVD is potentially an important area for investigation.

Another interesting pattern present in the simple slopes analyses was the large effect sizes for greater improvements in PFM functioning being associated with greater pain reductions within the ICBT group, while effect sizes were small in the PFR group. Although these correlations did not meet statistical significance, this pattern is inconsistent with the hypothesis
that these factors would be more relevant in the PFR group. The finding of no relationship between changes in tone and changes in pain in the PFR group is counterintuitive given that the theoretical rationale for pelvic floor treatments for PVD is that since tone is believed to exacerbate pain, reductions in tone are believed to result in reductions in pain. Despite this rationale, no previous PVD treatment studies investigating pelvic floor treatments have investigated whether changes in tone, as measured by PFM evaluation, result in changes in pain. Glazer et al.’s (1995) study of EMG biofeedback for vulvodynia did, however, investigate whether changes in EMG amplitude during a contraction and during relaxation, as well as changes in the relaxation standard deviation (a measure of muscle stability at rest) were predictive of changes in pain. The study found that only changes in the stability of muscles were associated with changes in pain, with greater improvements in stability being associated with greater improvements in pain. EMG amplitude measured during relaxation has been used in previous studies to reflect the degree of resting muscle tone (Gentilcore-Saulnier et al., 2010; Jantos, 2008) and thus, Glazer et al.’s (1995) study did not demonstrate that changes in resting muscle tone correlate with changes in pain. Thus, although much of the emphasis on pelvic floor treatments for PVD have focused on the role of muscle tone, it is possible that other aspects of PFM functioning are more important to the improvement of pain. For instance, reducing PFM reactivity may be more important in PFR than the reduction of resting tone. It is the reactivity of the muscles in response to pain that, in fact, is understood to initiate the exacerbating role of PFM functioning in PVD (Reissing et al., 2005).

Modifiable cognitive and behavioural predictors of outcome. The current study also examined modifiable cognitive and behavioural factors associated with treatment as predictors of pain improvement; namely, pre-treatment credibility and expectations, as well as homework
adherence. Although these factors do not fit within the cyclical model of understanding the development and maintenance of PVD, within the CBT model of pain, thoughts and behaviours associated with treatment can have an impact on reversing the negative cycle of pain and represent additional factors that can be directly addressed through the course of treatment to increase success. As with the previous predictors, no statistically significant relationships between these factors and changes in pain were detected, either across groups or within each treatment group. Investigation of the directions of the relationships and the effect sizes suggest some interesting areas for further investigation. For instance, there were different directions of relationships between treatment credibility and homework adherence and reductions in pain between the two treatment groups.

Within the PVD literature, few studies have investigated these variables. In Bergeron et al.’s (2001b) study, whereas participants’ rating of treatment logic was inversely related to intercourse pain at the 6-month follow-up across treatment groups, it was not related to any other outcome variables. Furthermore, ratings of participant’s confidence in the treatment (expectancy) were not related to any outcome variables. Moreover, treatment expectations were not predictive of follow-up outcome measures in ter Kuile and Weijenborg’s (2006) study examining CBT for PVD. Bergeron et al.’s (2001b) study did not find significant correlations between the degree of homework adherence and 6-month follow-up pain measures. The study, however, looked at correlations across the GCBT and biofeedback groups, and thus, it is not possible to know whether there were different relationships within each group. Given the important value that has been placed on these variables within the general pain literature, it would be valuable for subsequent PVD treatment studies to consider the importance of these factors in predicting treatment outcomes. Furthermore, across both treatments, it may be important to look at
adherence to specific treatment components, as it is possible that some treatment components are more helpful than others. It is possible that greater changes are found by targeting specific areas of the model more so than others, and thus, greater adherence to these components will more strongly predict better outcomes.

**Defining Treatment Success**

Because of the cyclical nature of pain and the many facets of biological, psychological, and social/sexual well-being that are affected in PVD, determining how to define treatment success is a challenge. The current study used the guidelines outlined by IMMPACT recommendations and reported the percentage of participants in each group demonstrating a 30% and a 50% reduction in average intercourse pain intensity. A 30% change has been associated with subjective ratings of ‘much better’ or ‘meaningful decreases’ in chronic pain, whereas a 50% change has been associated with ratings of ‘very much improved’ and what patients typically define as ‘treatment success’ or ‘satisfactory improvement’ (Dworkin et al., 2008). Thus, using the 50% reduction criteria, 80% of PFR participants and 60% of ICBT participants could be considered to have a successful treatment outcome at the 6-month follow-up. Within the PVD literature there is no consensus on defining success, making it difficult to compare the present findings to those of other studies in the area. Bergeron’s research team used the same vulvar pain improvement rating used in the current study, and defined ratings of either ‘great improvement’ or ‘complete cure’ as indicative of treatment success. Using this guideline, 80% of participants in both groups demonstrated a successful outcome. These are significantly higher success ratings than those reported in the GCBT and biofeedback groups (e.g., Bergeron et al., 2001b), but similar to that found for PFR in a previous study conducted within the SHRL (Goldfinger et al., 2009). Such global ratings of change have limitations such as the participant having to judge their
baseline level of pain and compare it to the present, and these ratings may be more highly
influenced by biases such as a desire to please the healthcare provider (Farrar et al., 2001). The
fact that both forms of success ratings were equivalent for the PFR group, but that the percentage
of successful ICBT participants was lower when using the percentage change in the pain,
suggests that ICBT participants may have been affected by the presence of their therapist in the
vicinity while completing their global rating of change scale. Thus, it is possible that the
percentage change in pain may be a more accurate reflection of success. Global ratings of change
scores, however, are considered valid and are important because they reflect the participants’
judgment of the clinical importance of the changes in pain (Farrar et al., 2001).

Since pain is a highly subjective experience, many have suggested that decisions about
how to define treatment success should be considered from the patient’s perspective (Robinson et
al., 2005). The IMMPACT recommendations team did conduct research to identify the outcome
domains that chronic pain patients deem relevant to investigate in treatment studies (Turk et al.,
2008b); however, women with PVD present with unique areas of difficulty not relevant to a
general chronic pain population. Thus, the current study asked participants to identify their
treatment goals at the time of their pre-treatment interview and then asked them to rate their
progress on each of the goals following treatment. The most common goal was related to pain
reduction and included factors such as reducing the intensity or the frequency of pain.
Interestingly, five participants did not have any pain reduction goals, indicating that although they
were seeking treatment for their pain, other outcomes were of greater importance to them. Other
goal domains that were consistent with those domains measured in the current study were
increase coping and control over pain (e.g., not worry so much about the pain, learn things to
think about or do to be in control of the pain), improving sexual life (e.g., have desire for sex,
increase pleasure of sex), and improving PFM functioning (e.g., reduce muscle contraction during intercourse, feel more in control of how my body responds to pain). However, there were additional areas mentioned by some participants that were not assessed in the current study, including increasing their understanding of pain (e.g., to understand what the pain is, learn more about the pain), increasing sexual communication (e.g., to be able to communicate when I am in pain, increase sexual assertiveness regarding stopping intercourse), and learning to adopt a healthy view of their genitals (e.g., have a healthy relationship with my genitals). Overall, the participant’s ratings of their progress on their goals were quite high; as was their satisfaction with the treatment they received, suggesting that they viewed the treatment to be successful. The high ratings of goal progress and satisfaction are likely a reflection of the flexibility inherent in both of the treatment options that allowed for the treatment components to focus more on areas that were of greater relevance to the participants. Using a more strict and rigid manual may not have resulted in such high ratings. To gain the best understanding of treatment success from the perspective of the participant, future studies should consider asking participants to rate what level of pain and other outcomes would be necessary to consider treatment to be successful.

**Study Limitations**

Although the current study had numerous strengths over previous PVD treatment studies, including being the first to consider IMMPACT recommendations for domains of outcome measurement, it also had a number of limitations, some that have already been mentioned, that should be acknowledged more fully.

The changes documented in pain and psychosexual correlates of pain in the current study need to be carefully interpreted due to the methodological limitations of the study. The lack of control group makes it difficult to evaluate whether the changes are attributable to the treatments...
themselves or natural history (i.e., other factors that have occurred over the same period of time). The current study attempted to take this into account by contacting 10 women with PVD who had participated in other lab studies to determine whether they experienced changes in their pain over time. The women, on average, were contacted over 9 months following their study participation, though this time period ranged considerably. Overall, 2 of the 10 women sought treatment and only 1 woman reported any improvement in her pain symptoms. On the primary study outcome, change in average intercourse pain intensity rating, this resulted in a significant and meaningful difference between study participants and the no treatment group with respect to the 30% pain reduction cut-off. Although this does provide some information about the stability of pain among women with PVD, there were differences between the no treatment group women and the study participants that may have accounted for the lack of change. Furthermore, the method with which women were asked for pain updates was different than that used to measure changes in pain in the study participants. There is no information in the literature about rates of spontaneous remission or course of pain among women with PVD who have experienced pain for at least 6 months. The participants in the current study had experienced their pain for over 4 years, on average, and some had attempted up to 4 different treatments for their pain. These are both suggestive that the changes found were not due to the mere passage of time. Only the inclusion of a wait-list control group would be able to rule out the changes in outcomes variables being due to the passage of time. Interestingly, a recent study investigating the effectiveness of mindfulness for PVD, demonstrated that a group of women who were waiting for treatment demonstrated significant improvements in pain self-efficacy, feelings of helplessness, and sexual distress (Smith, Brotto, & Basson, 2013). Bergeron et al.’s (2001b) randomized trial, alternatively, found no significant changes in either cotton-swab pain intensity ratings or in MPQ scores over a 6 week baseline
period before treatment. Thus, it is possible that there may be changes in some outcome variables even before treatment commencement due to the knowledge that one will receive treatment.

In order to account for changes due to the mere passage of time, numerous chronic pain clinical trials use benchmarks from previously well-designed studies that allow researchers to determine whether their effect sizes are more in line with the treatment arm or the natural history (wait-list) arm. Although the effect sizes in the current study are well above the effect sizes for the wait-list arms, and even above the treatment arms for non-medical treatment options for chronic pain (Morley, 2011), the benchmarks are not based on PVD pain. There are unfortunately no well-designed PVD treatment studies that have included a wait-list control group that would allow for such an investigation.

In addition to not controlling for the passage of time, the current study does not account for the possibility of a placebo effect. Whereas medical treatment trials have the option of including a placebo control group, credible placebo controls in non-pharmacological studies are difficult, if not impossible, to design. Moreover, given that the treating therapists also conducted the pre-treatment, post-treatment, and follow-up assessments, it is possible that participants adopted the ‘good-participant role’ by reporting greater improvements than they subjectively experienced. Although attempts to minimize this were made (e.g., completion of questionnaires and main outcomes privately), this explanation for the highly positive outcomes cannot be discounted.

One study that allowed women with PVD, who had experienced at least 6 months of pain, to choose surgical, non-surgical, or no treatment at all, found that only 3 of 26 (12%) women who did not receive treatment reported any reduction in pain, with an average reduction of pain being just over 10% (Granot et al., 2004b). This finding is suggestive of the changes in
the current study being due to treatment rather than time, but also brings up the role of motivation and readiness for change in treatment outcome studies. In addition to the 25% of women screened for the current study who reported not participating due to being “too busy”, there were likely numerous other women who were informed of the study who chose not to be screened due to lack of interest in engaging in treatment. Thus, the study sample is composed of highly motivated women who may differ in additional ways from the larger population of women with PVD who seek assessment and/or treatment from health care professionals. For example, previous research has found that women with PVD who do not complete treatment are more likely to have more significant fear of pain (Desrochers et al., 2010). Based on the fear-avoidance model, higher fear of pain is likely to be related to treatment non-compliance and/or avoidance of treatment entirely since treatment may involve experiencing pain and encourage a return to sexual activity. Thus, the current sample may exclude those women with higher levels of fear of pain; this is confirmed by only three women meeting the cut-off for clinically significant levels of catastrophizing on the PCS (see Appendix H). Overall, the results of the study are not necessarily generalizable to women with PVD seen in primary care, specialty clinics, or private psychological or physiotherapy practices.

The majority of the sample was young, Caucasian, and well-educated. These demographic characteristics, as well as baseline pain features, were very similar to those presented in previous PVD treatment studies (e.g., Bergeron et al., 2001b; Danielsson et al., 2006; Desrochers et al., 2010; Goldfinger et al., 2009; ter Kuile & Weijenborg, 2006); however, the mean intercourse pain rating in the current study was somewhat lower than that found in some previous studies using a numerical rating or visual analogue scale. This may be because the current study asked participants to differentiate their worst and average intercourse pain intensity,
with the average rating being used as the primary outcome measure. Previous studies did not report on whether they asked participants to differentiate their worst and average pain. If this is the case, the ratings provided in previous studies would be expected to be higher as participants likely provided ratings closer to their worst pain experienced. Despite the fact that the sample is not generalizable to the general population of women with PVD, the findings are likely comparable to those found in previous PVD studies that have recruited similar samples.

The very small sample size is a considerable limitation in the current study. Effect sizes were calculated throughout the analyses in order to provide additional information about the analyses that are not dependent on sample size. Inspection of effects sizes for non-statistically significant tests revealed a number of areas with quite large effect sizes, suggesting the possibility that lack of statistical significance was due to low power. Furthermore, there was a highly inflated Type I error rate in the current study due to the number of analyses conducted. Given this, the most conservative approach to making conclusions based on the study findings would be to only present on the primary outcome and indicate that both treatments result in significant reductions in pain and that the groups do not differ with respect to changes in this outcome.

Given that both treatments used in this study are comprised of numerous components, some of which have been used independently to treat PVD or other chronic pain conditions, and others which are typically only used in the context of a comprehensive treatment, it is not possible to discern which components of treatment are leading to the improvements in pain and psychosexual correlates of pain. Previous research provides some information about what outcomes may be expected with various components of pain. For instance, one study examined the effectiveness of three sessions of psycho-education for women with PVD and found that although there were no significant changes in pain, the women demonstrated significant
improvements in overall sexual functioning and sexual distress, as well as significant decreases in symptoms of depression and anxiety from pre-treatment to a 6-month follow-up (Brotto, Sadownik, & Thomson, 2010). As already discussed, there is also evidence to support the use of sEMG biofeedback, vaginal dilators, and electrical stimulation as independent treatment modalities for PVD. Research from the general chronic pain literature demonstrates that relaxation training used independently results in similar overall effect sizes to CBT for both migraines and tension-type headaches (Holroyd, 2002). Research on acute and sub-acute low back pain indicates that adding graded exercise to usual care only adds to the effectiveness for individuals with high levels of fear avoidance beliefs (George, Fritz, Bialosky, & Donald, 2003), suggesting that more comprehensive treatments may be more or less beneficial depending on baseline characteristics. No PVD treatment studies have compared any of the independent treatment modalities to one another or to comprehensive CBT or PFR. This kind of comparison would help to determine whether comprehensive treatment is more effective than the single modality treatments, and would aid in carrying out cost-effective treatment plans.

Another factor to take into account with respect to the effectiveness of the two treatments on the pain and psychosexual correlates of pain is that the treatments have a number of overlapping treatment components. Namely, both ICBT and PFR included psycho-education, PFM exercises, vaginal dilators, and recommendations regarding making changes to sexual activity. This high level of overlap may, in fact, be one explanation for why differences between the two treatment groups, particularly with respect to pain outcomes, were only on isolated outcomes. Given the comprehensiveness of the PFR program and its use of graded exposure (dilators), it would be considered to fit within the context of behavioural therapy. Cognitive-behavioural and behavioural therapy are both used for other chronic pain conditions and are often
collapsed together in systematic reviews and meta-analyses. Both treatments, in fact, are based on the same model of pain for PVD (the vicious cycle of pain) and thus aim to reduce the pain and improve the functioning of women with PVD by targeting different components of the model.

A further limitation of the study is that treatment integrity was not measured. Thus, it is not possible to know how closely the therapists were adhering to the treatment manual and how much flexibility was incorporated into the treatments. Although there was flexibility in the use of the manuals to ensure relevancy of the material to each participant, the manualized approach still means that the treatments provided in the current study are not entirely reflective of how CBT or PFR might be delivered in clinics. The number of sessions, duration of time in treatment, and treatment components would likely vary from patient to patient and thus, the effectiveness of the treatments found in the current study do not necessarily reflect the effectiveness of CBT and PFR delivery in the ‘real world’.

An additional limitation of the study is that the gynecological examination conducted to determine eligibility for the study did not include a full examination (e.g., ultrasound, bacterial swabs) to rule out other factors that could have accounted for the participants’ pain. Thus, it is possible that some participants’ pain could have been due to other medical conditions. Fifteen of the participants, however, had seen their family physician and/or a gynecologist with respect to their pain where standard practice is to rule out other causes of pain such as STIs, yeast or bacterial infections, or dermatologic conditions. The participants who did not specifically see a physician for their pain, however, were still required to have had a gynecological examination at some point in the past to participate in the study. Had their most recent exam been since their pain started, even a standard physical examination would have ruled out bacteria or yeast as a cause for pain, and visual and pelvic examination could have furthermore ruled out dermatologic or
other conditions (e.g., endometriosis) that may have resulted in vulvar pain. Thus, although possible, it is unlikely that other medical conditions accounted for the presence of the pain in the current sample.

Lastly, whereas participants completing PFR were invited to bring their partner to one session for education and instruction for performing stretches, this option was not presented to participants in the ICBT group. The involvement of a partner in treatment may have contributed to some success in those who followed through with this option. Furthermore, while some participants were in committed relationships over the course of treatment, other participants were single or did not have a consistent partner, making the ratings of pain with sexual activity across the three time points not necessarily related to one another.

**Clinical and Research Implications**

Given the small sample size and methodological limitations of the study, firm conclusions about the effectiveness of ICBT and PFR cannot be made based on the results of this single study. However, the findings do point toward a number of clinically relevant points that can be considered in future research and in treatment planning. First, the findings suggest that both ICBT and PFR result in significant reductions in pain that are maintained following treatment. Furthermore, there is evidence that both treatments also lead to improvements in other areas, including some areas of emotional well-being and PFM functioning. ICBT also appears to result in improvements in some areas of sexual functioning. Thus, many of the hypotheses regarding changes within each treatment group were supported. Overall, the magnitude of improvements in both pain and psychosexual outcomes seen in the current study suggests that non-medical treatment options should be given more consideration by medical professionals when developing a treatment plan. The study was unfortunately unable to clearly answer the
question of whether one treatment results in more significant improvements than another. Most of the hypotheses set forth were not supported. However, there were significant between-group differences for changes in PFM tone and for rumination. There are also some suggestions that ICBT may result in greater improvements in sexual functioning than PFR; however, more research needs to be conducted to replicate these results. These initial findings may provide some support for decisions about treatment suitability being based on the patient’s goals for treatment or on what the patient’s baseline presentation suggests is most problematic. For instance, women with PVD who are presenting with PFM tone may be better suited to PFR whereas women demonstrating high levels of ruminative pain cognitions or significant problems in their sexual functioning may be better suited to CBT. Although a physical examination by a family physician or a gynecologist might reveal some evidence of PFM dysfunction, a full assessment including PFM and psychosexual functioning is not typically done in these settings, making appropriate referrals difficult to make. Multidisciplinary pain centres that include various medical specialties, as well as psychological and physiotherapy services are thus best suited to appropriately assess women with PVD and determine the best treatment plan. However, perhaps a brief screening tool for physicians’ offices could be developed to allow physicians to obtain the minimum necessary information to determine the optimal treatment plan for each patient.

Future studies should be large-scale, well-controlled clinical trials that include both long-term follow-ups and a wait-list control group. Given the difficulties with recruitment of women with PVD, researchers from various sites and cities should consider collaborating on future treatment trials and conduct multi-site studies to enhance sample sizes. This would not only allow for increased power to detect between group differences, but also enable recruitment of a more diverse sample of women suffering from PVD. There is still a need to compare ICBT and PFR to
medical and other non-medical treatment options. Specifically, determining whether group or individual format CBT result in differential treatment outcomes will help psychological treatment providers deliver their services in the most beneficial and cost-effective manner. Similarly, determining whether a comprehensive PFR program adds benefit over and above that found with single modality physical treatments such as biofeedback or vaginal dilators will aid in treatment planning as well. Furthermore, treatment studies comparing consecutive versus concurrent methods of multimodal treatments would help to better elucidate the best approach.

The current study was the first PVD treatment study to consider the recommendations put forth by the IMMPACT team. Despite the limited conclusions regarding effectiveness that can be drawn from the study due to the methodological limitations, this study highlights a novel approach to PVD treatment study design. Not only does the study fully encompass a biopsychosocial perspective, but it attempts to align itself with the general pain treatment literature. Given that the IMMPACT recommendations are based on a combination of strong empirical support, as well as expert opinion, other PVD researchers should consider adopting these guidelines when planning future treatment studies. Using a standard set of outcome measures across PVD trials will permit more meaningful comparisons between studies and will enable the pooling of data from different studies for the purpose of systematic reviews and meta-analyses. The current study demonstrated a first example of how the IMMPACT recommendations can be adapted to the PVD population. However, collaborative discussions among PVD researchers and clinicians could result in more firm guidelines about how best to measure the treatment outcomes within this population.

Limited conclusions can be made with respect to the study’s aim of determining modifiable predictors of treatment outcome. This area, however, should continue to be considered
in future studies. Much of the previous research focused on baseline variable predictors that cannot be modified. Researchers should consider investigating cognitive and behavioural factors that may be addressed within treatment itself. Findings in the current study highlight the possibility that areas of PFM functioning other than tone are just as relevant. Further research should be conducted to determine these additional areas as treatment techniques could be developed to address these features. Additional data was collected by the study physiotherapist and will be analyzed to determine whether there were other features of PFM functioning that could account for treatment improvements. For instance, 4D ultrasound imaging was performed before and after treatment to determine whether morphological changes occur in the muscles that could account for improvements.

There is still a considerable amount of research that needs to be conducted into being able to better predict treatment outcomes. Previous studies have often collapsed across treatment groups, and the findings of the current study suggest that predictors of outcome should be investigated within, rather than across, treatment groups. Eventually, studies that match participants to treatment based on their baseline characteristics will help in better assessment and treatment planning for women with PVD.
Chapter 6

Conclusions

Keeping the limitations of this study in mind, the main conclusions that can be drawn from the results are: 1) there are potentially effective non-medical treatment options for highly treatment-motivated women with PVD, 2) PFR and ICBT lead to equivalent improvements in pain outcomes among women with PVD that are maintained or continue to improve up to 6 months following treatment, 3) ICBT may result in improvements in some areas of sexual functioning among women with PVD, while PFR does not appear to result in improvements in these areas, 4) both ICBT and PFR may result in improvements in PFM relaxation capacity, while only PFR leads to reductions in PFM tone, and 5) both ICBT and PFR may result in improvements in some areas of negative pain cognitions, while only ICBT appears to lead to reductions in ruminative thinking. This research contributes to our understanding of the effectiveness of two commonly used non-medical treatment options for pain. Specifically it suggests that both ICBT and PFR have high success and satisfaction rates. Furthermore, there is little evidence from the study findings to suggest choosing one treatment over the other, particularly if the patients’ treatment goal is pain reduction. Lastly, the most unique aspect of this study was that it demonstrates how important clinical trial guidelines set out by general chronic pain researchers and clinicians can be adapted for a population of women with PVD. The use of such guidelines will enable better comparisons of treatments for PVD and hopefully provide more credibility to PVD among general pain researchers and clinicians.
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Appendix A

Study Advertisement

Do You Have **Pain** During Sexual Intercourse?
Are You Looking For a **Treatment** Option For This Pain?

We are looking for women to participate in a study on the effectiveness of two non-medical treatment options for painful intercourse.

**Study Procedures:**
gynaecological examination, interview, physical testing and assessment, 8 sessions of treatment (cognitive-behavioural therapy or pelvic floor physical therapy) over 12 weeks, and follow-up sessions.

**Treatment provided free of charge**
(compensation also provided)

Interested?
For more information, please contact the Sexual Health Research Lab
(613) 533-3276
SHRL@queensu.ca

Investigators:
Caroline Pukall PhD, Linda McLean BScPT, PhD, Susan Chamberlain MD
Corrie Goldfinger, MSc, PhD Student, Stephanie Thibault-Gagnon BScPT, MSc Student
Appendix B
Telephone Script

Telephone Information Sheet: ICBT or PFPT for PVD

Start here if it is a new potential participant:
Thank you for your interest in the study. First of all, can I ask you where you found out about the study? [fill this in on the screening form] continue below→

Start here if we recruited them through previous lab studies:
Can I ask in what city you currently live? Will you be living in this same city for the next few months? [fill this in on the screening form] First I am going to tell you about the purpose of this study, as well as the details of what your participation would entail if you are eligible and choose to participate. If you are still interested after the description of the study, then I will ask you a number of questions to determine your eligibility for the study. If you are not eligible for this study but would like your name to be added to our lab recruitment database for future studies for which you may be eligible, then this can be done at that time. This description and screening questionnaire could take about 20 to 30 minutes, and some of the questions are personal in nature. Is now an appropriate time to complete the interview, or would you like us to give you a call back? [If to call back, get their name and contact information and the best time to reach them] Please interrupt me at any time if you have questions.

**Read this if they live in Kingston and will be in Kingston for the next few months or if they live outside of Kingston but are interested in carrying out treatment in Kingston**
The purpose of this study is to determine the effectiveness of two different non-medical treatment options for women with a form of vulvar or genital pain called provoked vestibulodynia, or PVD. PVD affects approximately 12% of women. More specifically, it refers to pain experienced near the opening of the vagina that usually occurs at times of vaginal penetration; however, it may also be experienced at other times when pressure is applied to the area. We are only including women in this study who have PVD. However, if you think you may have PVD but have not been given a
diagnosis, that is fine; we go through a formal process of determining whether or not you have PVD.

The two treatment options we are studying are individual cognitive-behavioural therapy, or ICBT, and pelvic floor physical therapy, or PFPT. It has been shown that how women think about and respond to their pain can contribute to the worsening of the pain, and cognitive-behavioural therapy can thus help reduce pain by changing negative thought and behavioural patterns. The pelvic floor muscles are the muscles responsible for vaginal, urinary, and anal functioning. For example, these muscles are the ones you would tense up to prevent urination. It is believed that a tightening of the muscles in the pelvic floor contributes to the maintenance and worsening of vulvar pain, and that physical therapy can thus help reduce this muscle tension, therefore decreasing pain. Both of these treatment options have shown success in previous studies, however their effectiveness have not been compared against one another.

Do you have any questions so far before I go on to tell you about what participation includes?

Your participation in the study would include several steps. First, you would have a gynaecological exam carried out at the Kingston General Hospital with a gynaecologist, and a research assistant would be present in the room to take down notes. A graduate student would obtain a brief medical and mental health history before the examination. As Kingston General Hospital is a teaching hospital, it is also possible that a medical student will attend the gynecological exam. This would be a 15-minute appointment in which the doctor will determine the presence or absence of PVD. If a diagnosis is not made, or cannot be made due to an inability to complete the examination, then participation in the study cannot continue. If a diagnosis of PVD is made then you would come into the Sexual Health Research Lab at the Psychology Department at Queen’s University for one 2 hour session on a different day. This session would be run by a female graduate student and would include an interview and questionnaire session covering information about sociodemographics, medical, sexual and general pain history, vulvar pain history, general health and emotional well-being, and sexual functioning. It also entails sensory testing during which the graduate student will be applying different amounts of pressure to the vestibule, or the area around the opening to the vagina. She will be asking you when you
feel pain, and will ask you to rate the intensity and unpleasantness of the sensations. The pressures increase slowly and continuously and stop increasing when you indicate that you can no longer tolerate the pain. Pressure does not increase to any standard amount for all participants, so the amount of increase will depend entirely on your tolerance levels. Although pain will be experienced during this examination, no health risks are posed and the painful sensations should not last for a long period of time. A female research assistant will be in the room at the time of the sensory testing to record information.

You will also complete a 1.5 hour physical assessment at the School of Rehabilitation Therapy with a physiotherapist who is currently a graduate student as well. She is a registered physiotherapist by the College of Physiotherapists of Ontario who has training and experience using pelvic floor physiotherapy with women with PVD. The assessment will consist of a brief review of your medical history and information gathered during your prior interview so as to not re-pose the same questions, questions regarding physical activity and diet, body size measurements such as weight and height, an intra-vaginal manual pelvic floor assessment using a maximum of two fingers, as well as an ultrasound imaging evaluation of your pelvic floor muscles where a head is placed over your genital area and images are captured during tasks such as voluntarily contracting and relaxing your muscles. During the pelvic floor assessment, the physiotherapist will visually and manually evaluate your pelvic floor muscles both externally and internally. This will be done in order to evaluate its functioning. Much like the sensory testing session, no health risks are posed by the physiotherapy assessment techniques and any discomfort you feel should be lower in intensity than the pain you experience with intercourse.

After you have finished all of the testing you will be randomly selected to complete either the CBT treatment or the PFPT treatment. Both treatments consist of eight 1-1.5 hour treatment sessions over 12 weeks on Queen’s campus. The CBT sessions will be conducted by the same psychology graduate student who does the interview and sensory testing. The components of the CBT treatment are: education about PVD and pain in general, education about the effects of pain on sexual functioning, techniques to improve sexual functioning, relaxation exercises, pelvic floor muscle exercises, the use of vaginal dilators which are phallic-shaped silicone instruments, changing thinking patterns, education about sexual communication, and coping techniques. You
will be asked to complete homework between sessions. The PFPT sessions will be conducted by 
the physiotherapist who does the physical assessment. The components of the treatment include: 
education, active pelvic floor exercises similar to Kegel exercises, manual intra-vaginal 
techniques such as pelvic floor massage and stretches, pelvic floor muscle exercises using 
biofeedback, electrical stimulation, insertion of vaginal dilators, at-home exercises, stretches for 
leg muscles, deep breathing, and recommendations regarding sexual activity. The biofeedback 
and electrical stimulation involve the insertion of a small probe in your vagina which is hooked 
up to a computer system. During biofeedback a graphic on a computer screen shows your pelvic 
floor muscle work, and during electrical stimulation, the system delivers non-harmful electric 
currents which help you increase your awareness of your muscles.

All participants in each treatment group will receive the same treatment approach, but treatment 
is flexible enough so that each participant will progress according to her own pace. There might 
be some pain or discomfort associated with the vaginal dilators and some of the techniques used 
by the physiotherapist, but efforts are made to progress treatment while minimizing pain. Both 
treatment options require participants to do homework and keep logs when not in session, and 
therefore, require motivation and work; these aspects of the treatment are important to maximize 
progress.

The treatments and the vaginal dilators will be provided to you free of charge. We ask that you 
avoid any other form of treatment for the PVD pain during the course of the study and until you 
have returned for your follow-up sessions. Within one month after you have completed the eight 
sessions of treatment you will return for follow-up testing. This will include a gynaecological 
exam at the Kingston General Hospital, an interview and questionnaires and sensory testing 
session, and a physical assessment. You will complete this same set of testing again at 
approximately six months after completing your treatment. After completion of the post-treatment 
sessions you will be compensated $35, and you will be compensated another $65 after the 
completion of the six-month follow-up sessions. [If they live outside of Kingston: You will also 
be reimbursed up to a certain amount for the expenses of coming into Kingston for testing at the 
three times points, but you will not receive reimbursement for costs associated with coming into 
Kingston for your treatment sessions.]
Are you interested in seeing if you are eligible for participating in the study? *(Note this on the screening form)*

If no, thank them for their time, and ask them to feel free to call back if they change their mind. If yes, *get their full name*. Go through the questions on the screening form. If you come to a *(ineligible)* explain why they are ineligible and thank them for their time. Ask them if they would like their name and contact information to be put into our recruitment database so we can contact them about future studies for which they may be eligible. Fill this out.

If they are eligible for the study: At this point you are eligible for the study. Are you still interested in participating? *(fill this in on form)* If yes, we can now book you for the gynaecological exam to ensure that you are eligible to participate in the entirety of the study.

Obtain the participants contact information including at least one telephone number, the best time to call, and whether we can leave a message (we will only say that we are calling from Queen’s University). Get two email addresses (if possible) that they check regularly. Mark on the form that they are eligible to participate. Book the gynaecological exam and note this date on the screening form. If schedules are such that the woman will be menstruating during the gynecological exam and she does not mind, that is fine. Let them know that the gynecological exam should not take more than 15 minutes however there may be a bit of waiting time before and they will need to fill out forms, so they should prepare to be there for at least 30 minutes. Let them know that someone will contact them a few days before the gynecological exam to let them know the details of where to go.

We can also book you in for the interview and sensory session and the physical assessment now, however remember that your participation is dependent on a positive diagnosis of PVD at the time of the gynaecological examination. After the exam we will inform you about the gynaecologist’s diagnosis and will let you know whether or not you are able to participate.
Telephone Screening Form: ICBT or PFPT for PVD

ICBT / PFPT

Date and Method of Initial Contact: ______________ Date of Screening: ______________

Contacted Previous Participant [1] OR Participant Contacted Us [2]

Participant Name: _____________________________________________________________

[1] [0]

Home #: (      ) - (best time to call: ) leave a message? Y N

Cell #: (      ) - (best time to call: ) leave a message? Y N

Work #: (      ) - (best time to call: ) leave a message? Y N

City: __________________

Email addresses: _______________________________________________________________

Recruitment Source: ___________________________________________________________

Interested in finding out if they are eligible? Y [1] N [0] If no, reason___________________

Eligible for study after screening? Y[1] N [0] Not sure (______________________________)

If no, why? _____________________________________ __________________

Interested in participating? Y [1] N [0] If no, reason_________________________________

Eligible for study after gynaecological exam? Y [1] N [0]

Availability ___________________________________________________________________

Pre-Treatment Testing: Date and Time

Gynaecological Exam: __________________

Interview/Questionnaire/Sensory Testing: __________________

Pelvic Floor Muscle Assessment: __________________

Post-Treatment Testing: Date and Time

Gynaecological Exam: __________________

Interview/Questionnaire/Sensory Testing: __________________

Pelvic Floor Muscle Assessment: __________________

Follow-up Testing: Date and Time

Gynaecological Exam: __________________

Interview/Questionnaire/Sensory Testing: __________________

Pelvic Floor Muscle Assessment: __________________
1. Are you fluent in English?  Y [1]  N* [0]

2. To determine if you are eligible to participate in the study we will need to ask you some questions about your medical history. Is that okay?  Y [1] (→3)  N [0]

   If no, say “In order to determine whether you are eligible to participate we need to ask these questions. If you would like to think about it please take your time and call us back if you change your mind.”

3. How old are you? _________________ (* not eligible if under 18)

4. Is there any possibility that you might currently be pregnant?  Y* [1]  N [0]

5. Are you currently in a romantic or sexual relationship?  Y [1]  N [0]
   If yes, is this relationship heterosexual [1] or same-sex [0]? ________________________

6. Are you currently suffering from any medical or psychiatric conditions?  Y* (if c is endorsed or condition is very serious) [1]  N [0] (→6) (ask about incontinence)
   If yes:
   a) With what condition(s) have you been diagnosed? (If unsure of eligibility ask questions about how long they’ve had this diagnosis, severity of condition) __________________________

   b) Are you taking medication/receiving treatment for this/these conditions?  Y [1]  N [0]
   If yes, which one(s)? __________________________

   c) Does this condition interfere significantly with you daily and sexual functioning?  Y* [1]  N [0]

7. Do you have a pace maker?  Y* [1]  N [0]

8. Have you ever suffered, or are you currently suffering, from a pain condition other than genital pain?  Y* (if d is endorsed or condition is very serious) [1]  N [0] (→7)

   If yes:
   a) With what condition(s) have you been diagnosed? (same probes as above)___________
b) When did/do this episode/these episodes occur and how long do they last?

___________________________________________________________________________

c) Are you currently taking painkillers/other treatment for this conditions? Y [1] N [0]
If yes, which one(s)? _____________________________

d) Does this condition interfere significantly with your daily and sexual functioning?
Y* [1] N [0]

9. Do you currently experience pain in your genital region?  Y [1] N* [0]

a) For how long have you had this pain/when did the pain start?
(*not eligible if < 6 months—tell them to call back if the pain persists for 6 months)

b) I am going to ask you some questions about when you experience genital pain.
1. Is your genital pain always or almost always present even in situations where pressure is not being applied to the genitals  Y* [1] N [0]
2. Do you experience the genital pain during intercourse or other sexual activities which involve vaginal penetration? (penis, fingers, sex toys) Y [1] N [0]
   If yes, what percentage of intercourse attempts results in pain? ______________
   On a scale from 0 to 10 where 0 equals no pain at all and 10 equals worst pain ever felt, how would you rate the worst pain that you experience during sexual intercourse? ______________
   Using the same scale, how would you rate the average pain that you experience during sexual intercourse? ______________
3. Do you experience the genital pain during tampon insertion Y [1] N [0] Don’t use tampons [N/A]
   If yes, what percentage of these instances results in pain? ______________
   Does your pain prevent tampon use? Y [1] N [0]
4. Do you experience the genital pain during gynaecological exams?  Y [1] N [0]
   Does your pain prevent you from having gynaecological exams? Y [1] N [0]
5. Is your genital pain always or almost always present and worsens during intercourse or other activities involving vaginal penetration  Y* [1] N [0]
6. Other _____________________________
c) Have you had pain since your first sexual intercourse experience? (versus having had pain free intercourse before the onset of pain)  Y [1]  N [0]

If no, was there anything in particular that happened just before the pain started that you attribute to the pain starting? (e.g., new partner, injury, yeast infection, etc)

________________________________________________________________________

d) Thinking of instances when you have vaginal penetration, when does the pain start during these situations?

1. Is it before the penis/object touches the vagina; it is always there  Y* [1]  N [0]
2. Is it when the penis/object starts to enter the vagina  Y [1]  N [0]
3. Is it when the penis/object is entered and thrusting  Y* (only if 2. not endorsed) [1]  N [0]
4. Is it only after penetration  Y* (only if 2. not endorsed) [1]  N [0]
   If yes, how long does it last? ____________________________________________

ep) I’m going to list some genital areas and please let me know if you experience pain in each area by responding yes or no.

1. At the vaginal opening  Y [1]  N [0]
2. Everywhere on the vulva (on the labia)  Y* [1]  N [0]
3. Inside the vagina  Y [1]  N [0]
4. In the pelvic or abdominal region (deep pain)  Y* [1]  N [0]
5. Another area  Y [1]  N [0] ________________________________

e) What adjectives would you use to describe the pain? __________________________

__________________________________________________________________________

g) Have you received a diagnosis for this pain?  Y [1]  N [0]

If yes, what diagnosis/diagnoses did you receive? ________________________________

By whom? ______________________________________________________________

When? _______________________________________________________________

h) Are you currently undergoing any treatment for the pain?  Y [1]  N [0]

If yes, which one(s)? ______________________________________________________

Have you noticed any changes with the use of this treatment?  Y [1]  N [0]
If yes, what changes? _____________________________________________________

Would you be willing to stop this treatment for the length of the study?  Y [1] N* [0]

i) Have you undergone any treatment for the pain in the past?   Y [1] N [0]
If yes, which one(s)? ______________________________________________________
Did you noticed any changes with the use of this treatment?   Y [1] N [0]
If yes, what changes? _____________________________________________________

10. Do you have any difficulty with vaginal penetration other than the pain?   Y* (if spasms or
avoidant behaviour that doesn’t allow penetration at all) [1] N [0]
If yes, what? ______________________________________________________________

11. When was your last gynaecological examination including a speculum examination?
______________________________________ (* not eligible if they have never had a gynaecological exam)


13. Do you have a regular menstrual cycle (approximately once a month)?  Y [1] N [0]

If yes, was this in the last six months?  Y* [1] N [0]
How many vaginal deliveries _______ and caesarean-sections _______ have you had?
Are you currently breastfeeding?  Y* [1] N [0]
Appendix C
Letter of Information and Consent Form

Letter of Information and Consent Form

A randomized comparison of individual cognitive behavioural therapy and pelvic floor physical therapy in the treatment of provoked vestibulodynia

Investigators:
Caroline Pukall, Ph.D., Associate Professor, Department of Psychology, Queen's University
Corrie Goldfinger, M.Sc., Ph.D. Student, Department of Psychology, Queen's University
Linda McLean, P.T., Ph.D., Associate Professor, School of Rehabilitation Therapy, Queen's University
Stephanie Thibault-Gagnon, B.Sc.P.T., M.Sc. Candidate, School of Rehabilitation Therapy, Queen's University
Susan Chamberlain, M.D., Assistant Professor, Department of Obstetrics and Gynecology, Queen's University

Background Information: You are being invited to participate in a research study directed by a multidisciplinary treatment team consisting of psychologists, physical therapists, and a gynaecologist. This study is evaluating the effectiveness of two different non-medical treatment options for women with provoked vestibulodynia (PVD), a common cause of painful intercourse. These two treatments are individual cognitive-behavioural therapy, or ICBT, and pelvic floor physical therapy, or PFPT. A graduate student from the Sexual Health Research Laboratory (SHRL) will read through this consent form with you, describe the procedures in detail, and answer any questions you may have. This study has been reviewed for ethical compliance by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board.

There is currently no single treatment that has been shown to be effective for all women with PVD. Research has indicated that increased pelvic floor muscle (PFM) tension plays a role in
maintaining and worsening the pain in women with PVD. Research has also shown the role that negative thinking and behaviour patterns can play in maintaining and worsening the pain of PVD. Research has shown improvements in pain and sexual functioning (e.g., arousal) after using CBT, PFPT and vaginal dilator therapy (VDT; one component of PFPT); however, no studies have compared the relative effectiveness of such non-medical treatment options. Furthermore, there has been minimal research done on the effectiveness of CBT done with individuals (ICBT) rather than in a group format.

**Purposes of the Study:** The purpose of the study is to conduct a randomized study (i.e., individuals are randomly assigned to either treatment group) to determine the relative effectiveness of ICBT and PFPT in reducing pain and improving psychological and sexual functioning in women with PVD. The effectiveness of these treatments will be compared against the effectiveness of at-home VDT. A secondary purpose of the study is to examine the usefulness of ultrasound imaging for investigating PFM functioning in women with PVD.

**Inclusion and Exclusion Criteria:** You will be considered for this study if you meet the following criteria: (1) are 18 years of age or older, (2) are fluent in English, (3) meet the diagnostic criteria for PVD during the study gynaecological examination, and (4) have experienced vulvar pain for a minimum of six months. You will not be considered for this study if you meet any of the following criteria: (1) have any serious medical, psychiatric, or other pain conditions that significantly interfere with daily or sexual functioning, (2) have generalized vulvodynia (i.e., more widespread vulvar pain that occurs without provocation) and/or significant vaginismus (i.e., are not able to have at least one finger inserted vaginally), (3) are pregnant, breastfeeding, or have given birth within the last six months, (4) have menopausal onset vulvar pain, (5) have a pacemaker, or (6) are unwilling to abstain from other treatments for PVD during the course of the study. If your status with respect to any of these has changed since your initial telephone screening and you believe that you may no longer be eligible to participate, please let the graduate student know.

**Procedures of the Study:** Your participation in the study involves undergoing the following procedures: 1) a gynaecological examination; 2) a structured interview and questionnaires and
sensory testing session; 3) a physical assessment, 4) eight sessions of either ICBT or PFPT over 12 weeks, 5) a repetition of procedures 1-3 within one month after completing the treatment, and 6) a repetition of procedures 1-3 six months after completing the treatment.

**Gynaecological examination:** Before the examination, the graduate student will obtain a brief medical and mental health history. During the gynaecological examination (approximately 15 minutes), the gynaecologist will visually and manually examine the internal and external genitalia and reproductive organs, and palpate the labia majora, labia minora, vulvar vestibule, perineum (i.e., area between the vaginal and anal openings), and midline area of the vulva with a cotton-swab. After each palpation, you will be asked to indicate the intensity of your pain on a scale from 0 to 10. You will be in control of the procedure and may ask to stop or slow down at any time. A graduate student will be present during the examination to record information. If your diagnosis is not consistent with PVD, or if you cannot complete all aspects of the gynaecological examination, you will not be eligible to participate in the remainder of the study. In this case, the graduate student will explain to you why you are not eligible and can provide you with some information about vulvar health if you wish. If there is an unclear diagnosis, consultation will be made with the primary investigator of the study and you will be contacted by phone within one week to inform you of your eligibility. Please note that although the gynaecologist will be seeing you for the examination, a file will not be created for you at Kingston General Hospital and no ongoing gynaecologic care will be provided. The gynaecologist’s role is strictly that of diagnosis for the purpose of inclusion into the research study.

**Interview, questionnaires, and sensory testing:** The structured interview and questionnaires will take place at the SHRL at the Department of Psychology, Queen's University with a psychology graduate student (approximately 1.5 hours). The interview and questionnaires will cover demographic information, sexual and relationship history, medical and gynaecological history, a comprehensive history of vulvar pain, pain intensity ratings, thoughts and behaviours related to pain, sexual functioning, and current mental health status. Following the completion of these, you will complete a brief (approximately 15 minutes) sensory testing session in which the psychology graduate student will measure your pressure pain threshold (i.e., the point at which you first detect the sensation of pain). You will be explained the details of the testing, shown the
measurement tool to be used, instructed on the use of rating scales, and given the opportunity to ask any questions. A female member of the SHRL will also be present in the room to record information and run the computer program. A cotton-swab tip attached to a spring device will be applied to three areas around the vestibule (i.e., the entrance of the vagina) and pressed slowly in a continuous manner until you report a level of pain consistent with what you experience during intercourse. You will press a button twice, first when you first feel pain and then when you reach your intercourse level of pain. You will be asked to rate the intensity and unpleasantness of the pain sensations on scales from 0 to 10. The cotton-swab applicator will be applied three times at each position of the vestibule with breaks in between each pressure application. We do not increase pressure to any standard amount for all participants, so the amount of increase will depend entirely on your ratings. Although some of the stimuli may be uncomfortable and painful, they will not damage your skin. You will be in control of the procedure and may ask to stop or slow down at any time. You can withdraw from and/or terminate any stimulus that is too uncomfortable at any time.

*Physical assessment:* The physical assessment (approximately 1.5 hours) will take place in a private setting at the Pelvic Floor Laboratory at the School of Rehabilitation Therapy, Queen's University. The assessment will be conducted by a rehabilitation science graduate student who is a registered physical therapist with the College of Physiotherapists of Ontario, has received training in PFPT and has been evaluating and treating women with vulvar pain disorders for close to two years. A female research assistant may be present in the room to record information. Prior to the evaluation, the procedures will be reviewed with you and any questions or concerns will be addressed. For most of the evaluation, you will be in the gynaecological position with pillows behind your back for comfort, feet rested in heel rests, a strap placed around your knees for support, and a towel or gown will be provided. The assessment will include: 1) a brief review of your medical history and the interview already conducted with the psychology graduate student, 2) questions regarding fitness, diet, and bowel and bladder function (since all these aspects of health can affect your pelvic floor muscles), 3) measurement of body weight and height and the dimensions of your pelvis and hips, 4) visual inspection of the genital region, 5) visual observation of your ability to contract and relax your pelvic floor muscles (PFMs), 6) assessment of sensation to touch and reflexes in the genital region, 7) assessment of PFM tension in the
external genital region, 8) manual assessment of the PFMs to evaluate strength, resistance to stretch, and relaxation after contraction of PFMs and degree of vaginal opening, and 9) ultrasound imaging of your PFMs at rest, as well as while you perform activities including voluntary PFM contractions, coughing, and bearing down. For the internal assessment component (step 8), one or two gloved and lubricated fingers will be inserted into the vagina depending on your level of comfort. Clean non-latex gloves will be used and disposed of after each assessment. The ultrasound imaging (step 9) involves placing an ultrasound transducer over your perineum/labia; the ultrasound transducer will be cleaned and sterilized before and after each use and a clean non-latex glove will be placed over it to avoid direct contact and prevent the transmission of any infection.

After you have finished all of the testing you will be randomly selected to complete either the ICBT treatment or the PFPT treatment. You will not be able to choose the treatment which you will complete. Both treatments consist of eight 1.5 hour treatment sessions over 12 weeks.

Treatments:

ICBT
The ICBT sessions will be conducted by Corrie Goldfinger, the same graduate student who did the interview and sensory testing, under the supervision of Dr. Caroline Pukall, a registered psychologist in the province of Ontario. The ICBT sessions will be conducted at the SHRL. The goals of CBT are to aid you in: (1) understanding your pain as a multifactorial pain problem influenced by various factors including thoughts, emotions, behaviours, and couple interactions; (2) modifying the factors associated with pain during intercourse and increasing adaptive coping skills and decreasing pain intensity; (3) improving the quality of sexual functioning, and (4) consolidating skills. The program includes: education about PVD (e.g., diagnosis, causes, effects), education about a multifactorial view of pain, education about the effects of pain on sexual functioning (i.e., desire and arousal) and techniques to improve these factors, relaxation exercises including abdominal breathing, PFM exercises, using graduated vaginal dilators at home, changing negative thinking patterns about pain, teaching useful sexual communication skills, coping self-statements and distraction techniques, and the role and experience of the
partner. You will be asked to complete homework between sessions (e.g., readings, pain diaries, relaxation exercises, vaginal insertions, sensate focus) as well as keep a log of the pain you experience and any homework exercises you complete.

**PFPT**

The PFPT sessions will be conducted by Stéphanie Thibault-Gagnon, PT, the same graduate student who did the physical assessment, under the supervision of Drs. McLean and Pukall. The PFPT sessions will be conducted at the Pelvic Floor Laboratory in the School of Rehabilitation Therapy. The goals of PFPT are to: (1) increase awareness PFMs, (2) improve PFM control, (3) normalize muscle tone in the PFMs, (4) increase the compliance of the vaginal opening, (5) desensitize the vulvar vestibule (i.e., reduce pain) and other painful areas, (6) decrease fear of pain and fear of vaginal penetration, (7) increase control of PFM upon vaginal penetration, and (8) deepen understanding of the role of PFMs in PVD, the role of PFPT, and other treatment options. The initial session will consist of mainly education and further PFM evaluation, very similar to the physical assessment, in order to set appropriate treatment goals. The remaining PFPT treatment sessions will consist of: continuous education, anti-pain techniques such as the application of cold compresses, a home exercise program which will be modified according to your progress, general lower extremity stretches, breathing exercises, active pelvic floor exercises, manual intra-vaginal techniques, insertion techniques and self-PFM stretches using graduated vaginal dilators in-session and at-home, biofeedback, and electrical stimulation. The biofeedback involves the insertion of a small probe into your vagina which shows how your muscles are working on a computer screen (i.e., when you contract, the graphic line will go up, and when you relax, the graphic line will go down), and helps in the improvement of PFM control. The electrical stimulation uses the same probe and delivers non-harmful electric currents to the PFMs, which helps you increase your awareness of your PFMs. If you have a partner, they will be invited to attend the last PFPT session (8th session) to promote partner involvement and provide an opportunity for them to ask questions and learn about PVD and PFPT. Furthermore, if there is interest, the physical therapist will teach your partner manual PFM techniques which can replace the self-PFM stretches at home. Education regarding sexual activity will also be provided. Positive outcomes in women with PVD have been found with similar PFPT treatment techniques,
and this is why all of the above components are included in this PFPT protocol.

Both treatments will be progressed based on your own symptoms, which means that the treatment is flexible and allows each participant to progress according to their own pace. You and your therapist will discuss each step of the treatment, and you will be in control of your treatment progression. Both treatment options require that you do homework and keep logs when not in session, and therefore, require motivation and work. These aspects of the treatment are important in terms of seeing progress. All participants are expected to adhere to the treatment plan.

Post-treatment and follow-up sessions: Within one month after the completion of the 12 weeks of treatment, the gynaecological examination, interview and questionnaires, sensory testing, and physical assessment will be repeated to assess the short-term effects of the treatments on pain and other symptoms. To assess the long-term effect of the treatments, these same appointments will be repeated approximately six months after you finish the treatment. If you are no longer living in Kingston at the time of the six-month follow-up, your ground travel expenses (e.g., train, bus, gas) and meals will be covered for you to travel to Kingston for one day. You will be reimbursed for your travel expenses up to $200 and your meals for that one day will be covered (maximum of $10 for breakfast, $13 for lunch, and $27 for dinner). You will be required to submit receipts to obtain your reimbursement.

Compensation: All treatment will be provided free of charge and you will be provided with a set of four dilators that are yours to keep after the completion of the study. You will be given $35 at the completion of the post-treatment sessions and $65 at the completion of the six-month follow-up sessions to compensate you for the time and inconvenience related to the multiple appointments required by this study. If you live outside of KFL&A (Kingston, Frontenac and Lennox & Addington), you will also be reimbursed for your ground travel expenses (e.g., train, bus, gas) up to $200 for each of the three testing visits and your meals will be covered (maximum of $10 for breakfast, $13 for lunch, and $27 for dinner) for those three days that you are required to come to Kingston for testing. You will be required to submit receipts to obtain your
reimbursement. Costs incurred for carrying out the treatment sessions in Kingston (e.g., travel, parking, food) will not be reimbursed.

**Alternative Therapies:** As there is currently no agreed-upon standard of care for the treatment of PVD, there are other methods of treatments that you could seek out for your pain rather than entering this study. These options include: medical interventions such as topical, injectable, or oral medications; surgical interventions; other forms of psychotherapy; other pelvic floor muscle treatment options such as biofeedback, and alternative interventions such as acupuncture or hypnotherapy.

**Risks and Benefits:** It is possible that you may experience some discomfort or pain due to some of the procedures (i.e., gynaecological examination, sensory testing, physical assessment, PFPT techniques, and vaginal dilator insertions). Some of the issues discussed in the interview and with either of the therapists may be considered sensitive (e.g., sexuality, depression) and therefore may cause some distress. PFPT can also cause a temporary increase in PFM soreness as a result of the treatment techniques, but this soreness should subside within 30 minutes of the treatment session.

The direct potential benefits include: access to a multidisciplinary treatment team comprised of psychologists and physical therapists; education about PVD, pelvic floor muscle function, pain, and sexual functioning; and a greater understanding of the cycle of pain. You may also experience a reduction in vulvar pain and/or improvements in psychological and sexual variables related to pain reduction (e.g., improved sexual functioning, improved quality of life) after the treatment. The indirect benefit of your participation is that clinicians will have a better understanding of the usefulness of and relative benefits of ICBT and PFPT as treatment options for women with PVD; this information may benefit other women in the future.

**Confidentiality:** All information obtained during the course of this study is strictly confidential and your anonymity will be protected at all times. A hard copy of your interview, questionnaires, gynaecological examination, physical assessment, and therapy notes will be kept in a filing cabinet in locked offices (i.e., SHRL and Pelvic Floor Laboratory). Electronic copies of some of your questionnaires will be kept in a password-protected file in the same locked offices. All of these forms and files identify you **only** by a participant ID number rather than your name, and the
electronic file which matches up participant names and ID numbers will be password-protected. The information related to your pre-treatment, post-treatment, and follow-up testing will only be connected to your participant ID number and will be available only to the investigators directly involved in this study, as well as research assistants and other members (e.g. graduate students, volunteers) of the SHRL who are required to sign a confidentiality form. Your name and contact information, along with some information about your health and pain, were obtained during the telephone screening that already took place. These forms will be kept in a locked filing cabinet, and your name and contact information will remain accessible only to members of the SHRL for the purposes of scheduling appointments. Information related to your treatment will only be available to the two graduate students conducting the therapy, as well as their supervisors who are outlined on the front page of this information letter. Neither your name nor any other identifying information will be mentioned in any publications or reports.

**Participant Rights and Liability:** Your participation in this study is voluntary. You may withdraw from this study at any time and your withdrawal will not affect your future access to services. You are also free to refuse to answer any questions posed, or refuse to undergo any assessment or treatment component at any time during the course of the study, without explanation. The study investigators may decide to withdraw you from this study for scientific reasons at any time during the study. In this case, you will be informed of the reason for withdrawal and compensation will be adjusted accordingly. In the event that you are injured as a result of the study procedures, medical care will be provided to you until resolution of the medical problem. You have the right to obtain copies of the study forms with your information if you request. By signing this consent form, you do not waive your legal rights nor release the investigators from their legal and professional responsibilities.

**Participant's Signature:** I have read and understood the consent form for this study, I have had the purposes and procedures of this study explained to me. I have been given sufficient time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form. I will receive a copy of this consent form for my information.
If at any time I have further questions, problems, or adverse events, I can contact:

Study Investigators:

Faculty Supervisors:
Caroline Pukall, Ph.D. at (613) 553-3200 or caroline.pukall@queensu.ca
Linda McLean, BSc(PT), Ph.D. at (613) 533-6101 or mcleanl@queensu.ca

Graduate Students:
Corrie Goldfinger at (613) 533-3276 or 5cg24@queensu.ca
Stephanie Thibault-Gagnon at (613) 533-6000 extension 79009 or pelvicfloorstudy@gmail.com

Department of Psychology, Head:
Dr. Rick Beninger at (613) 533-2492 or psychead@queensu.ca

School of Rehabilitation Therapy, Director:
Dr. Elsie Culham at (613) 533-6727 or elsie.culham@queensu.ca

If I have questions regarding my rights as a research subject I can contact:
Dr. Albert Clark, Chair, Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board at (613) 533-6081
By signing this consent form, I am indicating that I agree to participate in this study.

Signature of Participant  Print Name   Date

Statement of Investigator: I have carefully explained to the participant the nature of the above research study. I certify that, to the best of my knowledge, the participant understands clearly the nature of the study and demands, benefits, and risks involved to participants in this study.

Signature of Investigator  Print Name   Date
Appendix D
Pre-Treatment Interview

Structured Interview

CBT vs. PFPT vs. VDT Treatment Study

Pre-Treatment Interview

Participant ID Number ________________

Treatment ______________________

Date of Interview ____/____/_____ (MM/DD/YYYY)

Notes:
PART A: Socio-Demographic Information

First I am going to ask you some general questions about yourself.

1) What is your date of birth_____/_____/_____(MM/DD/YYYY)  Age__________

2) What is your place of birth? _________________________________

3) How do you define your ethnocultural heritage, not your nationality? _________________________
   ________________________________________________________________________________

4) What is your first spoken language? _________________________________

5) Do you identify with any religious community?
   Yes □1 Which one? _________________________________
   No □2

6) Does your religious or spiritual identity play an important role in your life?
   Yes □1
   No □2

7) What is the highest level of formal education you have received?
   Some high school □1
   High school graduate □2
   Some trade school □3
   Trade school graduate □4
   Some college or undergraduate degree □5
   College or undergraduate graduate □6
   Some graduate school or professional training □7
   Graduate or professional school degree □8
   Other □9 _________________________

8) How many years of schooling has that included? ________________________
9) What is your current employment status?
   Employed full-time □1
   Employed part-time □2
   Student □3
   Retired □4
   Unemployed □5
   On disability □6
   Full-time parenting □7
   Other □8 _________________________________________________

10) What is your approximate total annual income? If you are living with a partner please include their income in this value.
   $0 - $9,999 □1
   $10,000 - $19,999 □2
   $20,000 - $29,000 □3
   $30,000 - $39,999 □4
   $40,000 - $49,000 □5
   $50,000 - $59,000 □6
   $60,000 and over □7

Notes:

PART B: Relationship and Sexuality History

Now I am going to ask you some questions about your sexuality and about your relationship history. Please note that if you are currently involved in a relationship or are dating, you will be asked questions about your partner. If you are in an open or non-monogamous relationship, the questions referring to 'your partner' refer to your main partner.

1) How do you define your sexual orientation?
2) Are you currently in a relationship?
   Yes □1
   No □2
   a. If yes, what is the sex of your current partner?
      Male □1
      Female □2
      Other □3 ________________________________

3) At what age did you first have consensual penetrative intercourse? (heterosexual experience: refers to penis-in-vagina intercourse; same-sex experience: refers to the first time a partner penetrated you with fingers or a sex toy) ________________

4) Some women report experiencing pain during their first experience of penetrative intercourse. Please rate the intensity of the pain you felt on a scale from 0-10. __________

5) Please rate the unpleasantness of the pain during your first experience of penetrative intercourse (that is, how much the experience bothered you) on a scale from 0 to 10. ______

6) Have you experienced vulvar pain since your first penetrative intercourse experience?
   Yes □1
   No □2
   Other □3 Explain if pattern of pain and no pain. ________________________________

7) With how many partners have you had penetrative intercourse? ________________
   a. Of these, how many were with long-term partners (i.e., 3 months or longer)? ___
8) **If secondary PVD,** With how many partners have you had penetrative intercourse since your vulvar pain started? ____________
   a. Of these, how many were with long-term partners (i.e., 3 months or longer)? ___

9) Which of the following best describes your current relationship situation?
   - Single, not dating □ 1
   - Not dating any one person regularly □ 2
   - Dating one partner regularly □ 3
   - Dating one partner regularly—long distance □ 4
   - Living with a partner □ 5
   - Married □ 6
   - Common-law □ 7
   - Separated □ 8
   - Divorced □ 9
   - Widowed □ 10
   - Other □ 11 _____________________________

10) How long have you been in this situation? ____________ years ____________ months

11) **If currently in a relationship,** For how long have you been with your current partner?
    ____________ years ____________ months

12) **If you are currently single or dating and do not consider yourself involved in a committed relationship,** when did your most recent committed relationship end? ________

13) I am going to read a list of sexual activities that individuals may engage in.

   **If primary PVD:** I would like you to indicate which activities you have engaged in since the onset of your vulvar pain. When answering this question please keep in mind all of your partners, not just your current or most recent relationship.

   **If secondary PVD:** I would like you to indicate which activities you have engaged in prior to and after the onset of your vulvar pain. When I list them the first time let me know if you engaged in this activity before your pain started by responding yes or no. When I list them
again, let me know if you engaged in this activity after you started having pain. When answering this question please keep in mind all of your partners, not just your current or most recent relationship.

<table>
<thead>
<tr>
<th>Prior to Vulvar Pain</th>
<th>After onset of pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>_____</td>
<td>a. Manual stimulation of partner’s genitals _____</td>
</tr>
<tr>
<td>_____</td>
<td>b. Partner’s manual stimulation of your genitals _____</td>
</tr>
<tr>
<td>_____</td>
<td>c. Oral stimulation of partner’s genitals _____</td>
</tr>
<tr>
<td>_____</td>
<td>d. Partner’s oral stimulation of your genitals _____</td>
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<tr>
<td>_____</td>
<td>e. Penetrative vaginal intercourse on you _____</td>
</tr>
<tr>
<td>_____</td>
<td>f. Penetrative vaginal intercourse on partner _____</td>
</tr>
<tr>
<td>_____</td>
<td>g. Manual stimulation of partner’s anus _____</td>
</tr>
<tr>
<td>_____</td>
<td>h. Partner’s manual stimulation of your anus _____</td>
</tr>
<tr>
<td>_____</td>
<td>i. Oral stimulation of partner’s anus _____</td>
</tr>
<tr>
<td>_____</td>
<td>j. Partner’s oral stimulation of your anus _____</td>
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<tr>
<td>_____</td>
<td>k. Penetrative anal intercourse on you _____</td>
</tr>
<tr>
<td>_____</td>
<td>l. Penetrative anal intercourse on partner _____</td>
</tr>
<tr>
<td>_____</td>
<td>m. Penetrative sex-toy play on partner _____</td>
</tr>
<tr>
<td>_____</td>
<td>n. Penetrative sex-toy play on you _____</td>
</tr>
<tr>
<td>_____</td>
<td>o. Masturbation (clitoral stimulation) _____</td>
</tr>
<tr>
<td>_____</td>
<td>p. Masturbation (internal stimulation) _____</td>
</tr>
</tbody>
</table>

14) To what extent has your vulvar pain impacted your ability to initiate dating relationships? Please rate on a scale from 0 (no impact) to 10 (greatest impact imaginable). __________

15) Do you feel that your vulvar/genital pain has negatively affected:
   a. Your current relationship?
      Yes □1
      No □2
      N/A □99

   b. Past relationships?
Yes □1
No □2
N/A □99

i. **If yes**, please rate how much the pain has negatively impacted your relationships on a scale from 0 (no impact) to 10 (greatest impact imaginable). __________

ii. **If yes**, in what ways has the pain negatively impacted your relationships? Please describe:

___________________________________________________________________________
___________________________________________________________________________

16) Do you feel that your vulvar/genital pain has positively impacted
a. Your current relationship?
   Yes □1
   No □2
   N/A □99

b. Past relationships?
   Yes □1
   No □2
   N/A □99

i. **If yes**, please rate how much the pain has positively impacted your relationships on a scale from 0 (no impact) to 10 (greatest impact imaginable). __________

ii. **If yes**, in what ways has it positively impacted your relationship? Please describe:

___________________________________________________________________________
___________________________________________________________________________

17) It can be common for women with vulvar pain to notice changes in their desire, mental and physical arousal, and orgasmic ability due to their pain, whether related to sexual activity with a partner or masturbation. Do you feel that your vulvar/genital pain has impacted your sexual functioning in any way?
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Yes  □1
No    □2

i. If yes, in what ways has it impacted your sexual functioning? (probe for each area)
___________________________________________________________________________
___________________________________________________________________________

18) If has a current partner, does your partner have any problems related to his/her sexual functioning?
   Yes      □1
   No       □2
   N/A      □99

i. If yes, please explain
___________________________________________________________________________
___________________________________________________________________________

Notes:

PART C: Gynaecological and Medical History

1) Do you menstruate regularly (approximately once a month)?
   Yes□1
   No       □2 Why not? ____________________________________________________________

2) If has current partner: Do you and/or your partner use any method(s) of contraception?
   Yes□1
   No       □2

If no current partner: Did you and/or your past partners use any method(s) of contraception?
   Yes        □1
   No         □2

  a. If yes to either question, which one(s)? ________________________________

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b. If using hormonal contraceptive, which brand? ______________________________

c. How long have you been using the hormonal contraceptives? ____________

3) Have you ever had a yeast infection?
   Yes □ 1 How many? ______________________ (i)
   No □ 2

   a. If yes, have you suffered from repeated yeast infections?
      Yes □ 1 Since what age? _______________________ (i)
      No □ 2
      DK □ 3
      N/A □ 99

   b. If yes, how were the yeast infections diagnosed?
      Clinical plus positive culture □ 1 Number of times ______
      Clinical only □ 2 Number of times ______
      Self-diagnosed □ 3 Number of times ______

4) I am going to list a number of gynecological problems, please let me know which ones you have had.
   Chlamydia □ 1 Trichomoniasis □ 8
   Gardnerella vaginalis □ 2 Bladder/urinary infections □ 9
   Genital Warts or HPV □ 3 Interstitial cystitis □ 10
   Gonorrhea □ 4 PID □ 11
   Genital herpes □ 5 Endometriosis □ 12
   HIV □ 6 Hemorrhoids/anal fissures □ 13
   Syphilis □ 7 Other ________________ □ 14

5) Now I am going to list a number of gynecological interventions, please let me know which ones you have had.
   Hysterectomy □ 1 Curettage □ 5
   Laparoscopy □ 2 Abortion □ 6
6) Do you have any current or past medical conditions?
   Yes □ 1 What condition(s)? ____________________________
   No □ 2

   If yes, please explain condition and if it is current or past. ____________________________

7) Do you have any current or past psychiatric/mental health conditions such as depression or anxiety?
   Yes □ 1
   No □ 2

   If yes, please explain condition and if it is current or past. ____________________________

8) Have you ever been diagnosed with any chronic pain conditions?
   Yes □ 1
   No □ 2

   If yes, please explain condition and if it is current or past. ____________________________

9) Are you currently taking any medication or analgesics (i.e., pain medication) whether they are prescribed or over the counter?
   Yes □ 1
   No □ 2

   a. If yes, why? __________________________________________
   b. For how long? _________________________________________
10) How much bodily pain (other than genital pain) have you had during the past 4 weeks?

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<tbody>
<tr>
<td>None</td>
<td>□ 1</td>
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<tr>
<td>Very Mild</td>
<td>□ 2</td>
</tr>
<tr>
<td>Mild</td>
<td>□ 3</td>
</tr>
<tr>
<td>Moderate</td>
<td>□ 4</td>
</tr>
<tr>
<td>Severe</td>
<td>□ 5</td>
</tr>
<tr>
<td>Very Severe</td>
<td>□ 6</td>
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</table>

11) Some people have problems that cause pain or discomfort, or they may experience regular pain or discomfort in different parts of their body. Can you please tell me if you have any conditions that cause pain or if you regularly experience pain anywhere in your body? (probe specifically for any low back, pelvis, or hip problems or pain)

For each response, ask:

a. How serious of a problem is this for you?

(0 = not at all serious, 5 = moderately serious, 10 = extremely serious)

b. How would you rate the intensity of the pain?

c. What is the cause of the pain (e.g., condition, injury, unknown, surgery, etc.)?

<table>
<thead>
<tr>
<th>Condition/Body Part</th>
<th>Seriousness</th>
<th>Intensity</th>
<th>Cause</th>
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12) Did you ever fall on your tailbone, pelvis, hip, or low back?

Yes  □ 1
No   □ 2

a. If yes, when/how long ago? _________ Year _________ Month

b. Did you have pain resulting from your fall?

Yes  □ 1
No   □ 2

i) If yes, how intense was the pain from 0 to 10? ___________

ii) If yes, how long did the pain last (in days, weeks, months or years)?

___________

Notes:

PART D: Pain with Intercourse History and Treatment History
1) When did you first start experiencing pain with intercourse? _______month ______year

2) When did it start; that is, where there any particular events that occurred just before or at the onset of the pain?
   - With first experience □1 After repeated bladder infections □5
   - After repeated yeast infections □2 After gynecological surgery ______ □6
   - After childbirth □3 After abortion □7
   - For no apparent reason □4 Change of partner □8
   - Life stress (marital conflict, $ problems, etc) (specify: ________________________) □9
   - Other (specify: __________________________________________________________) □10

3) What do you believe to be the cause of your pain?
  ___________________________________________________________________________
  ___________________________________________________________________________

4) How many health professionals have you consulted for the pain?  __________

5) I would like to get a history of the professionals you have consulted for your pain, any diagnoses, any treatments you have tried, whether by recommendation of a health professional or on your own accord, and any effects of these treatments. Can you tell me about this? (Probe questions: What kind of health professional have you consulted for the pain? Did they provide you with any diagnosis and/or treatment recommendations? Of these treatments, which, if any, did you try and for how long? Did you see any changes following the treatment?)

<table>
<thead>
<tr>
<th>Professional</th>
<th>Diagnosis, if any (when)</th>
<th>Treatment, if any (When, how long)</th>
<th>Attempted? Y/N</th>
<th>Any changes? (better/worse %)</th>
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6) I just want to clarify then the general kinds of treatments that you have tried. Changing aspects of sex life (e.g., position, speed, enhancing arousal) □1
Creams (e.g., K-Y, Crisco, moisturizers, corticosteroids, hormonal, anesthetics) □2
Alternative medicine (e.g., vitamins, diets, homeopathic remedies) □3
Pelvic floor treatments (e.g., physiotherapy, biofeedback, dilators, Kegels) □4
Psychological treatments (e.g., psychotherapy, hypnosis) □5
Surgery (e.g., vestibulectomy, laser) □6
Other medical treatments (e.g., hormones, interferon, antibiotics) □7
Small changes (e.g., cotton underwear, mild soaps, changing mattresses) □8
Other (please specify:_______________________________________________) □9
None □10

Notes:

**PART E: Vulvar Pain Characteristics**

1) Have you had sexual intercourse in the past 6 months?
   Yes □1
   No □2 If no, answer questions about intercourse related to past experiences

   a. If no, how long has it been since you last had intercourse? _____months _____years

   b. What are the reasons that you have not had intercourse in the past 6 months?
      I have no partner at the moment □1
      It hurts too much □2
      I have no desire □3
      I fear pain □4
      I am too anxious □5
      I don’t want penetration □6
      My partner has erection problems □7
      My partner has no desire □8
      My partner is concerned about hurting me □9
      Other (please specify:_______________________________________________) □10
2) I’m going to list a number of activities and I’d like for you to let me know whether you regularly experience(d) pain in your genital region during these activities by responding yes or no. If you do not engage in an activity at all then please let me know, however, if you engaged in the activity previously but stopped because it caused pain please let me know. For those activities with which you do have regular pain, I’d like to know the last time you attempted that activity and the last time that activity was painful.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes</th>
<th>No</th>
<th>Stopped due to pain</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Sexual intercourse</td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>□1</td>
<td></td>
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<tr>
<td>No</td>
<td>□2</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Stopped due to pain</td>
<td>□3</td>
<td></td>
<td></td>
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<tr>
<td>N/A</td>
<td>□99</td>
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<tr>
<td>b. Finger insertion (own or partner’s)</td>
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<tr>
<td>i. 1 finger:</td>
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<td>Yes</td>
<td>□1</td>
<td></td>
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<tr>
<td>No</td>
<td>□2</td>
<td></td>
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<td>ii. 2 fingers:</td>
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<tr>
<td>Yes</td>
<td>□1</td>
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<td>No</td>
<td>□2</td>
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<tr>
<td>Stopped due to pain</td>
<td>□3</td>
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<td>N/A</td>
<td>□99</td>
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<tr>
<td>c. Inserting a tampon/feminine hygiene product</td>
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<tr>
<td>Yes</td>
<td>□1</td>
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<tr>
<td>No</td>
<td>□2</td>
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<tr>
<td>Stopped due to pain</td>
<td>□3</td>
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<td>N/A</td>
<td>□99</td>
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<td>d. Removing a tampon/feminine hygiene product</td>
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<td>Yes</td>
<td>□1</td>
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<tr>
<td>No</td>
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<tr>
<td>Stopped due to pain</td>
<td>□3</td>
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<tr>
<td>N/A</td>
<td>□99</td>
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<tr>
<td>e. Partner stimulating you manually</td>
<td></td>
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</tbody>
</table>
f. Partner stimulating you orally
   Yes □ 1
   No □ 2
   Stopped due to pain □ 3
   N/A □ 99

   g. Masturbating (ask to specify if alone or with partner and if any toy used, which one?)
      i. Clitoral stimulation
         Yes □ 1 please specify___________________________
         No □ 2
         Stopped due to pain □ 3
         N/A □ 99
      
      ii. Internal stimulation
         Yes □ 1 please specify___________________________
         No □ 2
         Stopped due to pain □ 3
         N/A □ 99

   h. Friction with clothing (e.g., jeans, tight pants)
      Yes □ 1 please specify___________________________
      No □ 2
      N/A □ 99

   i. Urinating in general
      Yes □ 1
      No □ 2

   j. Urinating after intercourse
      Yes □ 1
      No □ 2
      Stopped due to pain □ 3
      N/A □ 99

k. Athletic activity (e.g., biking)
Yes □1 please specify ___________________________ __________
No □2 _______________ _______________
Stopped due to pain □3
N/A □99

l. Pain not related to any specific activity/non-provoked pain
Yes □1 _______________ _______________
No □2
N/A □99

m. In the sitting position (e.g., legs crossed or other)
Yes □1 please specify ___________________________ __________
No □2 _______________ _______________

n. Other
Yes □1 please specify ___________________________ __________
No □2 _______________ _______________
Stopped due to pain □3
N/A □99

o. If they do not report any pain with penetrative activities, so in the past 6 months you have not had any regular vulvar pain due to any kind of penetrative activity?
  Correct □1 (omit questions 7-11)
  Incorrect □2 Please explain ______________________ ____________________________

Indicate report of past behaviour (P) or current behaviour (C)

3) Approximately how many times per month do you attempted to
   a) have intercourse? ______
   b) have non-intercourse sexual penetration? ______

4) Approximately what percentage of these attempts resulted in successful entry
   a) and some penetration during intercourse? ______
   b) during non-intercourse sexual penetration? ______
5) During what percentage of attempts have you been able to
a) have intercourse to whatever you consider to be completion, without having to terminate
due to pain? _______
b) complete the activity without having to terminate due to pain? _______

6) What percentage of
a) sexual intercourse attempts was painful? _______
b) non-intercourse sexual penetration was painful? _______

(Can show them this outline if they need help with identifying a %)
   a) 10% or less of the time (equal to or less than 1 out of ten times) – rarely
   b) about 25% of the time (1 out of 4 times) – sometimes
   c) about 50% of the time (1 out of 2 times) – half of the time
   d) about 75% of the time (3 out of 4 times) – most of the time
   e) 90% of the time (9 out of 10 times) – almost always

7) I am going to ask you some questions about the pain during these penetrative activities
   including when the pain starts, how long it lasts, where you feel the pain, and what the pain
   feels like.

   a. Would you say that all of these different activities result in pain that has all of these same
      qualities?
      Yes □1 (ask questions 8-11 for all of the penetrative activities combined)
      No □2

   b. If no, can you tell me which ones result in the same kind of pain? (ask questions 8-11 for
      each cluster of activities)
      Activity/Cluster 1: ______________________________________
      Activity/Cluster 2: ______________________________________
      Activity/Cluster 3: ______________________________________
      Activity/Cluster 4: ______________________________________
8) When does the pain typically start?
   Before the penis/object touches the vaginal opening; it is always there □1 □1 □1 □1
   When the penis/object starts to enter the vagina □2 □2 □2 □2
   When the penis/object has fully entered and is thrusting □3 □3 □3 □3
   After penetration (how long does it last? ________________) □4 □4 □4 □4
   Other (please specify: ________________________________) □5 □5 □5 □5

9) How long does the pain typically last?
   Only during penile/object entry □1 □1 □1 □1
   Only during penile/object thrusting □2 □2 □2 □2
   Only for a period after penile/object exit □3 □3 □3 □3
   During penile/object entry and after penile/object exit □4 □4 □4 □4
   During penile/object entry and during penile/object thrusting □5 □5 □5 □5
   During penile/object thrusting and for some time after penile/object exit □6 □6 □6 □6
   During entry, during thrusting, and after exit □7 □7 □7 □7
   It is never the same: there is no typical pattern □8 □8 □8 □8

   a. If it lasts after penile/object exit, please state for how long after the pain is felt.
      Time: ______________ minutes ______________ hours ______________ days

10) **Show MPQ diagrams.** Where do you typically feel the pain during penetration? Is there a specific spot you can show me?
   At the vaginal opening (diagram 1) □1 □1 □1 □1 specify ______________
   Everywhere on the vulva (diagram 1) □2 □2 □2 □2
   Clitoris (diagram 1) □3 □3 □3 □3
   Inside the vagina (diagram 2) □4 □4 □4 □4
   In the pelvic or abdominal region (diagram 3) □5 □5 □5 □5

   **Administer the MPQ for intercourse pain or other sexual penetration pain if not having intercourse**
I’m going to ask you now to use these rating scales to rate the intensity and unpleasantness of penetrative activities.

11) On a scale of 0 to 10, please rate the:
   a. Worst intensity of pain you experience during intercourse. _____
   b. Average intensity of pain you experience during intercourse. _____
   c. Worst unpleasantness you experience during intercourse. _____
   d. Average unpleasantness you experience during intercourse. _____
   e. Worst intensity of pain you experience during non-intercourse penetration. _____
   f. Average intensity of pain you experience during non-intercourse penetration. _____
   g. Worst unpleasantness you experience during non-intercourse penetration. _____
   h. Average unpleasantness you experience during non-intercourse penetration. _____

12) Do you experience sexual pleasure during the sexual activities in which you engage?
   Yes □ 1 specify activities __________________________

   No □ 2 specify activities ____________________________

13) Many women find that their vulvar pain varies based on various contextual factors. For instance, they may find that they experience more intense pain if they are stressed or less intense pain if they are more mentally aroused. I will list a number of contextual variables and please indicate, by responding yes or no, if you feel that each factor contributes to your experience of pain. If applicable, also indicate the direction of impact; that is, if the factor makes the pain more or less intense.

<table>
<thead>
<tr>
<th>Contextual Factor</th>
<th>Yes</th>
<th>No</th>
<th>Direction of Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental arousal</td>
<td>□</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td>Physical arousal</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Lubrication</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Penis/object size</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Amount of foreplay</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Emotional closeness with partner</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Amount of life stress</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Amount of anxiety in the moment</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Alcohol/drug use</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Who the partner is</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Relationship conflict</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Time of menstrual cycle</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Pain medication use (oral/topical)</td>
<td>□</td>
<td>□</td>
<td></td>
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<tr>
<td>Other</td>
<td>□</td>
<td>□</td>
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</tbody>
</table>
14) **If have a current partner**, How does your partner react to the pain?

___________________________________________________________________________

___________________________________________________________________________

15) What is a typical sexual scenario for the two of you when you have to stop sexual activity? And then what is it like when you continue? And what are the reactions afterward?

___________________________________________________________________________

___________________________________________________________________________

We have come to the end of the interview, however, before we end I’d like to ask you about your goals for treatment.

16) Name three goals you have for your treatment and objectively define what improvement and success would look like. (e.g., I would be able to have pain free sex any time I wanted to). Also, what would help or hinder achieving your goals?

1) _______________________________________________________________________

2) _______________________________________________________________________

3) _______________________________________________________________________

___________________________________________________________________________

___________________________________________________________________________

Discontinue Interview
Appendix E

Consent to Treat

Consent Form for Psychological Services

Psychological Services

Although the treatment being used in this study is standardized across participants, psychotherapy will always vary depending on the personality of the participant, and the particular problems they bring forward. There are many different methods I will use to deal with the problems that you hope to address. Psychotherapy is not like a medical doctor visit. Instead, it calls for a very active effort on your part. In order for therapy to be most successful, you will have to work on things that we talk about in therapy both during our sessions and outside of sessions.

Psychotherapy can have benefits and risks. Since therapy often involves discussing unpleasant aspects of your life, you may experience uncomfortable feelings like sadness, guilt, anger, frustration, loneliness, or helplessness. Additionally, due to the nature of your concerns, you may experience some physical pain in your genital region with some of the exercises that are used in this treatment. On the other hand, psychotherapy has also been shown to have benefits for people who go through it and this particular form of therapy has shown benefits in women with vulvar pain. There are no guarantees for what you will experience, however.

I am a student in the Clinical Psychology Program at Queen's University. For this study, I am being supervised by a registered clinical psychologist (Dr. Caroline Pukall, Department of Psychology, Queen's University) who practices in sex therapy. I will meet with Dr. Pukall to discuss the contents of the therapy session with her.

You should evaluate the general information about what the sessions entail, which have been explained to you verbally and in the initial consent form, along with your own opinions of whether you feel comfortable working with me. If you have questions about my procedures, we should discuss them when they arise.
Professional Fees
There is no fee for the services being provided in the context of this research study.

Contacting Me
You can call the Sexual Health Research Lab at (613) 533-3276 to reach me. I am often not immediately available by telephone; you can leave a message for me at the lab with one of the research assistants or graduate students. If you are difficult to reach, please leave some times when you will be available. Sometimes it may be easier to reach me by email at 5cg24@queensu.ca; this is also a good option if you do not feel comfortable leaving your name with a lab member.

Confidentiality
In general, the privacy of all communications between a participant and a therapist is protected by law, and I can only release information about our work to others outside of the treatment team with your written permission. However, there are a few exceptions. Please see the “Information about Confidentiality” form for an explicit discussion of the limits of confidentiality.

Please let me know if you have any questions about this consent form. This copy is for you to keep.
Consent for Psychological Treatment

I ____________________________

(Name of client, please print)

agree to let ____________________________________________ provide

(Name of psychology service provider, please print)

psychological intervention for myself.

I understand the following:

✓ The reason for the recommended treatment
✓ Goals for the treatment
✓ How the treatment will be done
✓ What things might happen because of this treatment
✓ That this consent may be withdrawn at any point in the process

Name of client (please print): _______________________________________

Signature: _______________________________ ________

Date: ____________________________________ _______

Name of psychology service provider: ________________________________

Signature: _______________________________ ________

Date: ____________________________________ _______

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Information about the Limits of Confidentiality

All information disclosed within sessions is confidential and will not be disclosed to anyone outside of your treatment team without your written and informed consent except where reporting is required by law, that is –

1. where there is suspicion that a child or children (that is, an individual who is PRESENTLY under the age of 16) has been or is being abused,
2. where the client is likely to harm herself or himself unless protective measures are taken,
3. where the client presents a serious danger of violence to others,
4. if the client reveals that he or she has been sexually abused by a health care provider (for example, a psychologist or physician) covered by the Regulated Health Professionals Act, it is necessary by law to report the name of the perpetrator to his/her governing body, and
5. if the therapy records (e.g., session notes) are subpoenaed by the court.

IF YOU HAVE ANY CONCERNS ABOUT THESE MATTERS, OR ABOUT THIS FORM, PLEASE DISCUSS THESE WITH ME.

__________________________________________________________________________________________

PLEASE SIGN THE ACKNOWLEDGEMENT BELOW TO INDICATE THAT YOU HAVE READ THIS INFORMATION ABOUT CONFIDENTIALITY

__________________________________________________________________________________________

I acknowledge the circumstances that limit confidentiality and I accept them.

__________________________________________________________________________________________

Client’s name  Client’s signature  Date

__________________________________________________________________________________________

Witness’ name  Witness’ signature  Date
Consent Form for Pelvic Floor Physiotherapy Services

Pelvic Floor Physiotherapy Services

The pelvic floor physiotherapy evaluations and treatments that will be performed over the course of this study are based on current practice standards. You will receive the same type of services if you were to consult a physiotherapist in a clinical setting, who has specific training in the evaluation and treatment of provoked vestibulodynia and other pelvic pain disorders.

Pelvic floor physiotherapy can have benefits and risks. Due to the nature of your concerns, you may experience some physical pain in your genital region with some of the evaluation and treatment techniques that are used in physiotherapy, but this pain should be brief in nature and should dissipate within one half hour of the treatment session. On the other hand, physiotherapy has been shown to have benefits in women with vulvar pain. There are however, no guarantees that you will see improvements.

The physiotherapist you will be seeing over the course of this study is a graduate student at the School of Rehabilitation Therapy at Queen’s University. She has received post-graduate training in pelvic floor physiotherapy and has been evaluating and treating women with vulvar pain for two years.

You should evaluate the general information about what the pelvic floor physiotherapy evaluations and treatments which have been explained to you verbally and in the initial consent form. You should form your own opinions of whether you feel comfortable working with the physiotherapist, and should not participate in any aspect of the assessment or treatment sessions if you are uncomfortable with them. If you have any questions or concerns regarding the pelvic floor physiotherapy evaluation and treatment procedures, feel free to let the physiotherapist know so that she can provide clarification and discuss other options with you.

Professional Fees
There is no fee for the services being provided in the context of this research study.
Contacting Me
You can call the Pelvic Floor Laboratory at (613) 533-6000 ext. 79009 to reach the physiotherapist. She is often not immediately available by telephone; but you can leave a message and she will contact you as soon as possible. If you are difficult to reach, please leave some times when you will be available. You may find it easier to reach the physiotherapist by email at pelvicfloorstudy@gmail.com.

Confidentiality
The privacy of all communications between a client and a physiotherapist are protected by law, and the physiotherapist can only release information about our work to others outside of the treatment team with your written permission. In the context of this research study, your case may be discussed with other members of the research team, however if this is the case, you will not be identified by name during these discussions or in any publications or presentations that arise from this work.

Participant Rights and Liability: You are free to withdraw from the treatment and the study at any time. You are also free to refuse to undergo any evaluation or treatment component at anytime during the course of the study.

Please let the physiotherapist know if you have any questions about this consent form. This copy is for you to keep.

Standard pelvic floor physiotherapy evaluations and/or treatments entail the following:

- Insertion of up to 2 fingers inside the vagina to evaluate the strength and flexibility of the pelvic floor muscles to provide feedback on the quality of contraction to help you gain control of these muscles, and stretching of these muscles to improve flexibility
- Insertion of 1 finger inside the anus (only during initial evaluation) to evaluate the strength and flexibility of the pelvic floor muscles
- Insertion of a vaginal probe for treatment using Biofeedback & Electrical stimulation
Consent for Pelvic Floor Physiotherapy Evaluation and Treatment

I _______________________________________________ (Name of client, please print)

agree to allow ___________________________________________________________ provide

(Stephanie Thibault-Gagnon, PT)

pelvic floor physiotherapy evaluations and interventions for the purposes of treatment of my
pelvic pain condition.

I understand the following:

✓ The reason for the recommended treatment
✓ The Goals for the treatment
✓ How the treatment will be done
✓ What things might happen because of this treatment
✓ That this consent may be withdrawn at any point in the process

Name of client (please print): ______________________________________________________________________

Signature: _______________________________ ________

Date: ____________________________________ _______

Name of physiotherapy service provider: ________________________________________________

Signature: _______________________________ ________

Date: ____________________________________ _______

_____ ____________________________
Witness’ name    Witness’ signature  Date

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Appendix F
Post-Treatment/Follow-up Interview

Structured Interview

CBT vs. PFPT vs. VDT Treatment Study

Post-Treatment/Follow-up Interview

Participant ID Number ________________

Treatment ________________________

Date of Interview ____/_____/______ (MM/DD/YYYY)

Notes:

204
PART A: Relationship and Sexuality Update

1) Is your relationship status the same as when we last met?
   Yes □1 (go to Question 4)
   No □2

2) Which of the following best describes your current relationship situation?
   Single, not dating □1
   Not dating any one person regularly □2
   Dating one partner regularly □3
   Dating one partner regularly—long distance □4
   Living with a partner □5
   Married □6
   Common-law □7
   Separated □8
   Divorced □9
   Widowed □10
   Other □11
   ______________________________________

3) How long have you been in this situation? ______ years ______ months

4) I am going to read a list of sexual activities and I would like you to indicate which activities you have engaged in since we last met.
   a. Manual stimulation of partner’s genitals
   b. Partner’s manual stimulation of your genitals
   c. Oral stimulation of partner’s genitals
   d. Partner’s oral stimulation of your genitals
   e. Penetrative vaginal intercourse on you
   f. Penetrative vaginal intercourse on partner
   g. Manual stimulation of partner’s anus
   h. Partner’s manual stimulation of your anus
   i. Oral stimulation of partner’s anus
   j. Partner’s oral stimulation of your anus
   k. Penetrative anal intercourse on you
   l. Penetrative anal intercourse on partner
   m. Penetrative sex-toy play on partner
n. Penetrative sex-toy play on you _____
o. Masturbation (clitoral stimulation) _____
p. Masturbation (internal stimulation) _____

Notes:

**PART B: Gynaecological and Medical Update**

1) Has there been any change in your menstrual cycle pattern since we last met?
   Yes □1
   No □2
   a. **If yes,** From ____________________________ to ___________________________
   b. Why? __________________________________________________________________

2) Have you changed your method(s) of contraception or brand of oral contraceptive since we last met?
   Yes □1
   No □2
   a. **If yes,** From _________________________ to ___________________________

3) How many yeast infections have you had since we last met? ________ (If 0 → 4)
   a. What treatments did you use? ________________________________
   b. How were they diagnosed?
      Clinical plus positive culture □1 Number of times ______
      Clinical only □2 Number of times ______
      Self-diagnosed □3 Number of times ______
   c. Is this an increase, a decrease, or no change since we last met?
No change □1
Increase □2
Decrease □3

4) Have you been diagnosed with any gynecological conditions since we last met?
Yes □1
No □2

a. If yes, which one(s)?
Chlamydia □1
Gardnerella vaginalis □2
Genital Warts or HPV □3
Gonorrhea □4
Genital herpes □5
HIV □6
Syphilis □7
Trichomoniasis □8
Bladder/urinary infections □9
Interstitial cystitis □10
PID □11
Endometriosis □12
Hemorrhoids/anal fissures □13
Other ________________ □14

5) Have you undergone any gynecological surgeries/interventions since we last met?
Yes □1
No □2

a. If yes, which one(s)?
Hysterectomy □1
Laparoscopy □2
Ovariectomy □3
Tubal Ligation □4
Curettage □5
Abortion □6
Other ________________ □7
None □8

6) Are you currently pregnant?
Yes □1
No □2

7) Have you experienced any changes in terms of your general medical health (e.g., diagnosis of
pain disorder) since we last met?
Yes □1
No □2

a. If yes, what? ______________________________________________________________
   _________________________________________________________________________

b. Have you been taking medications because of this/these problems?
   Yes □1 i. Which ones?
   ______________________________________________
   No □2

8) Have you been diagnosed with any psychiatric disorders since we last met?
   Yes □1
   No □2

a. If yes, which one(s)? _______________________________________________________
   _________________________________________________________________________

b. Have you been taking medications because of this/these problems?
   Yes □1 i. Which ones?
   ______________________________________________
   No □2

9) Have you changed any medication-supplements since we last met?
   Yes □1
   No □2

a. If yes, which change(s)? ___________________________________________________
   _________________________________________________________________________

10) How much bodily pain (other than genital pain) have you had during the past 4 weeks?
Some people have problems that cause pain or discomfort, or they may experience regular pain or discomfort in different parts of their body. Can you please tell me if, since we last met, you had any conditions that caused pain or if you regularly experienced pain anywhere in your body?

For each response, ask:

d. How serious of a problem is this for you?  
(0 = not at all serious, 5 = moderately serious, 10 = extremely serious)
e. How would you rate the intensity of the pain?

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<thead>
<tr>
<th>Condition/Body Part</th>
<th>Intensity</th>
<th>Seriousness</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

Notes:

**PART C: Vulvar Pain Update and Treatment Success and Satisfaction**

1) Have you had or attempted sexual intercourse since our last interview?
   Yes □1
   No  □2

   a. If no, how long has it been since you last had intercourse? ______________

   b. If no, what are the reasons that you have not had intercourse since our last interview?
      I have no partner at the moment □1
      It hurts too much □2
      I have no desire □3
      I fear pain □4
I am too anxious □5
I don’t want penetration □6
My partner has erection problems □7
My partner has no desire □8
My partner is concerned about hurting me □9
The therapist suggested that I do not attempt intercourse □10
Other (please specify: ____________________________________________________) □11

2) I’m going to list a number of activities and I’d like for you to let me know whether you regularly experienced pain in your genital region during these activities since our last interview by responding yes or no. If you did not engage in an activity at all then please let me know, however, if you engaged in the activity previously but no longer engage in the activity because it causes pain please let me know. Also, I would like you to indicate if the frequency with which you have pain with each activity is the same as since our last interview, if it is less frequent (i.e., improvement), or if it is more frequent (i.e., worsened).

<table>
<thead>
<tr>
<th></th>
<th>Sexual intercourse</th>
<th>Sexual intercourse</th>
<th>Finger insertion (own or partner’s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Yes □1</td>
<td>No □2</td>
<td>i. 1 finger:</td>
</tr>
<tr>
<td></td>
<td>Stopped due to pain □3</td>
<td>N/A □99</td>
<td>Yes □1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No □2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Stopped due to pain □3</td>
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<td></td>
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<td></td>
<td>N/A □99</td>
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<tr>
<td>b.</td>
<td>Finger insertion (own or partner’s)</td>
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<tr>
<td></td>
<td>i. 1 finger:</td>
<td></td>
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<tr>
<td></td>
<td>Yes □1</td>
<td>Similar frequency □1</td>
<td></td>
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<tr>
<td></td>
<td>No □2</td>
<td>Less frequent □2</td>
<td></td>
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<tr>
<td></td>
<td>Stopped due to pain □3</td>
<td>More frequent □3</td>
<td></td>
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<td>N/A □99</td>
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<td>ii. 2 fingers:</td>
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<td></td>
<td>Yes □1</td>
<td>Similar frequency □1</td>
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<td></td>
<td>No □2</td>
<td>Less frequent □2</td>
<td></td>
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<td></td>
<td>Stopped due to pain □3</td>
<td>More frequent □3</td>
<td></td>
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<td></td>
<td>N/A □99</td>
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<td>Options</td>
<td>Frequency Options</td>
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<td>c.</td>
<td>Inserting a tampon/feminine hygiene product</td>
<td>Yes  □1</td>
<td>Same frequency □1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No    □2</td>
<td>Less frequent □2</td>
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<tr>
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<td></td>
<td>Stopped due to pain □3</td>
<td>More frequent □3</td>
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<td></td>
<td></td>
<td>N/A   □99</td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td>Removing a tampon/feminine hygiene product</td>
<td>Yes  □1</td>
<td>Same frequency □1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No    □2</td>
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Yes   □1  
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Stopped due to pain □3  
N/A   □99  
Same frequency □1  
Less frequent □2  
More frequent □3  

Sporting activity  
Yes □1 please specify  
_________________________________  
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3) Since our last interview, approximately how many times per month have you attempted to
   a) have intercourse? ______
   b) have non-intercourse sexual penetration? _____

   If this has changed significantly over the course of this time period:
   - if you have regular contact with a partner please think about the most recent month
   - if you do not have regular contact with a partner please think about the last period of time you had regular contact with one

4) Approximately what percentage of your attempts resulted in successful entry
   a) and some penetration during intercourse? ______% 
   b) during non-intercourse sexual penetration? ______% 

   You can use this scale to help you come up with a % value; however you can choose any number between 0 and 100.
   a) 10% or less of the time (equal to or less than 1 out of ten times) – rarely
   b) about 25% of the time (1 out of 4 times) – sometimes
c) about 50% of the time (1 out of 2 times) – half of the time
d) about 75% of the time (3 out of 4 times) – most of the time
e) 90% of the time (9 out of 10 times) – almost always

5) During what percentage of attempts have you been able to
   a) have intercourse to whatever you consider to be completion, without having to terminate
doing to pain? ______%
   b) complete the activity without having to terminate due to pain? ______%

6) What percentage of
   a) sexual intercourse attempts was painful? ______
   b) non-intercourse sexual penetration was painful? ______

7) I’m going to ask you some questions about the pain during these penetrative activities
   including when the pain starts, how long it lasts, where you feel the pain, and what the pain
   feels like.
   a) Would you say that all of these different activities result in pain that has all of these same
      qualities?
      Yes □1
      No □2
   b. If no, can you tell me which ones result in the same kind of pain? (ask questions 8-11 for
      each cluster of activities)
      Activity/Cluster 1: ______________________________________
      Activity/Cluster 2: ______________________________________

8) When does the pain typically start?
   Before the penis/object touches the vaginal opening; it is always there □1 □1
   When the penis/object starts to enter the vagina □2 □2
   When the penis/object has fully entered and is thrusting □3 □3
   After penetration (how long does it last? ____________________________) □4 □4
   Other (please specify:__________________________________________) □5 □5

9) How long does the pain typically last?
Only during penile/object entry □1 □1
Only during penile/object thrusting □2 □2
Only for a period after penile/object exit □3 □3
During penile/object entry and after penile/object exit □4 □4
During penile/object entry and during penile/object thrusting □5 □5
During penile/object thrusting and for some time after penile/object exit □6 □6
During entry, during thrusting, and after exit □7 □7
It is never the same: there is no typical pattern □8 □8

10) Where do you typically feel the pain during penetration?
At the vaginal opening □1 □1
Everywhere on the vulva □2 □2
Inside the vagina □3 □3
In the pelvic or abdominal region □4 □4

Administer the MPQ for intercourse pain or other sexual penetration pain if not having intercourse.

I’m going to ask you now to use these rating scales to rate the intensity and unpleasantness of penetrative activities.

11) On a scale of 0 to 10, please rate the:
   a. Worst intensity of pain you experienced during intercourse. _____
   b. Average intensity of pain you experienced during intercourse. _____
   c. Worst unpleasantness you experienced during intercourse. _____
   d. Average unpleasantness you experienced during intercourse. _____
   e. Worst intensity of pain you experienced during non-intercourse penetration. _____
   f. Average intensity of pain you experienced during non-intercourse penetration. _____
   g. Worst unpleasantness you experienced during non-intercourse penetration. _____
   h. Average unpleasantness you experienced during non-intercourse penetration. _____

Ask participant to complete questions 12-20 on the Vulvar Pain Update-Participant Form

Discontinue questionnaire
Notes:
The following questions ask about the treatment that you received during this study. Please be as honest as possible when responding. Your responses are important in determining how effective the treatment you received was for you and to help inform future practice in the field.

12) Since our last interview, have you attempted to treat or alleviate the vulvar pain in any other way than the treatment you received in this study?
   Yes □1 a. What treatments? ____________________________________________
   No □2

13) Up to what point do you feel your vulvar/genital pain has improved following the treatment you received in this study?
   Complete cure (no more pain) □1
   Great improvement □2
   Some improvement □3
   Little improvement □4
   No improvement □5
   The pain is worse □6

14) Thinking just about your vulvar/genital pain, estimate how much better you are on a scale from 0 (no better) to 100 (completely better): ___%

15) Overall (including pain, emotional, sexual and relationship functioning, etc), estimate how much better you are on a scale from 0 (no better) to 100 (completely better): ___%

16) The following are the goals that you set before you began treatment. Please indicate to what degree you feel you made progress on each goal.
   a) ________________________________________________________________
      0 1 2 3 4 5 6 7 8 9 10
      No progress toward goal Moderate progress toward goal Goal was attained

   b) ________________________________________________________________
17) Can you think of anything else—aside from the treatment you received in this study—that may have contributed to improve your vulvar pain (e.g., partner change, life circumstances)?

______________________________________________________________________________

______________________________________________________________________________

18) How, if at all, do you think the treatment and/or the effects of the treatment in general have impacted your relationship to this point? (Note. You can choose both positive and negative if you feel it has had both of these impacts)

Positive Impact □1 Explain: _______________________________________________________

______________________________________________________________________________

Negative Impact □2 Explain: _______________________ _________________________

______________________________________________________________________________

Ha no impact □3

N/A, I am not in a relationship □4

19) Do you feel the treatment was beneficial to you in aspects other than vulvar pain reduction (e.g., other pain reduction, stress reduction, relationship factors)?

Yes □1

No □2

a. If yes, in what ways? __________________________________________________________
20) On a scale of 0 to 10, please rate your overall satisfaction with the treatment you received.

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21) On a scale of 0 to 10, please rate your overall satisfaction with the progress you made over the course of the treatment.

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Appendix G

Research Ethics Board Approval

QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD

September 21, 2009

Dr. C. Pulkall
Department of Psychology
Humphrey Hall
Queen’s University

Dear Dr. Pulkall,

Study Title: A randomized comparison of individual cognitive behavioural therapy and pelvic floor physical therapy in the treatment of provoked vestibulodynia

Co-Investigators: Ms. C. Goldfinger, Dr. L. McLean and Dr. S. Chamberlain

The members of the Queen’s University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board have examined the protocol (July 2009), Telephone Information Sheet, Recruitment Posters and the revised consent forms (Version 2: September 17, 2009) for your project (as stated above) and consider it to be ethically acceptable. This approval is valid for one year from the date of the Chair’s signature below. Please attend carefully to the following list of ethics requirements you must fulfill over the course of your study:

➢ Reporting of Amendments: If there are any changes to your study (e.g., consent, protocol, study procedures, etc.), you must submit an amendment to the Research Ethics Board for approval. (see http://www.queensu.ca/vpr/reb.htm).

➢ Reporting of Serious Adverse Events: Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information.

➢ Reporting of Complaints: Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of becoming aware of the complaint. Note: All documents supplied to participants must have the contact information for the Research Ethics Board.

➢ Annual Renewal: Prior to the expiration of your approval (which is one year from the date of the Chair’s signature below), you will be reminded to submit your renewal form along with any new changes or amendments you wish to make to your study. If there have been no major changes to your protocol, your approval may be renewed for another year.

Yours sincerely,

Chair, Research Ethics Board

Date

Study Code: PSYC-096-09

➢ Investigators please note that if your trial is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete.
QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD

The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards as defined by the Tri-Council Policy Statement; Part C Division 5 of the Food and Drug Regulations, OHRP, and U.S DHHS Code of Federal Regulations Title 45, Part 46 and carries out its functions in a manner consistent with Good Clinical Practices.

Federalwide Assurance Number : #FWA00004184
#IRB00001173

Current 2009 membership of the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board

Dr. A.F. Clark
Emeritus Professor, Department of Biochemistry, Faculty of Health Sciences, Queen's University (Chair)

Dr. H. Abdollah
Professor, Department of Medicine, Queen's University

Rev. T. Deline
Community Member

Dr. M. Evans
Community Member

Dr. S. Irving
Psychologist, Providence Care, St. Mary's of the Lake Hospital Site

Prof. L. Keeping-Burke
Assistant Professor, School of Nursing, Queen's University

Mrs. J. Kotecha
Research & Programs Manager, Centre for Studies in Primary Care, Department of Family Medicine, Queen's University

Dr. J. Low
Emeritus Professor, Department of Obstetrics and Gynaecology, Queen's University and Kingston General Hospital

Dr. W. Racz
Emeritus Professor, Department of Pharmacology & Toxicology, Queen's

Dr. B. Simchison
Assistant Professor, Department of Anesthesiology, Queen's University

Dr. A.N. Singh
WHO Professor in Psychosomatic Medicine and Psychopharmacology Professor of Psychiatry and Pharmacology Chair and Head, Division of Psychopharmacology, Queen's University Director & Chief of Psychiatry, Academic Unit, Quinte Health Care, Belleville General Hospital

Dr. E. Tsai
Associate Professor, Department of Paediatrics and Office of Bioethics, Queen's University

Rev. J. Warren
Community Member

Ms. K. Weisbaun
LL.B. and Adjunct Instructor, Department of Family Medicine (Bioethics)

Dr. S. Wood
Director, Office of Research Services (Ex-Officio)
### Appendix H

#### Participant Raw Scores on Outcome Measures

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