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Effectiveness of Cognitive-Behavioral Therapy and Physical Therapy for Provoked Vestibulodynia: A Randomized Pilot Study

Corrie Goldfinger, PhD,[1] Caroline F. Pukall, PhD,[1] Stephanie Thibault-Gagnon, BSc, PT,[2] Linda McLean, PhD,[3] and Susan Chamberlain, MD[4]

ABSTRACT

Introduction: Non-medical and non-surgical treatments for provoked vestibulodynia target psychological, sexual, and pelvic floor muscle factors that maintain the condition.

Aim: The goal of the study was to compare the effects of cognitive-behavioral therapy (CBT) and physical therapy (PT) on pain and psychosexual outcomes in women with provoked vestibulodynia.

Methods: In a clinical trial, 20 women with provoked vestibulodynia were randomly assigned to receive CBT or comprehensive PT. Participants were assessed before treatment, after treatment, and at 6-month follow-up by gynecologic examination, structured interviews, and standardized questionnaires measuring pain, psychological, and sexual variables.

Main Outcome Measures: Outcome measurements were based on an adaptation of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendations. The primary outcome was change in intercourse pain intensity. Secondary outcomes included pain during the cotton swab test, pain with various sexual and non-sexual activities, and sexual functioning and negative pain cognitions.

Results: The two treatment groups demonstrated significant decreases in vulvar pain during sexual intercourse, with 70% and 80% of participants in the CBT and PT groups demonstrating a moderate clinically important decrease in pain ($\geq$30%) after treatment. Participants in the two groups also had significant improvements in pain during the gynecologic examination, the percentage of painful intercourse attempts, the percentage of activities resulting in pain, and the ability to continue intercourse without stopping because of pain. Psychological outcomes, including pain catastrophizing and perceived control over pain, also showed improvement in the two groups. Significant improvements in sexual functioning were observed only in participants who completed CBT. Few between-group differences were identified other than the PT group showing earlier improvements in some outcomes. Nearly all improvements were maintained at the 6-month follow-up.

Conclusion: The results of the study suggest that CBT and PT can lead to clinically meaningful improvements in pain and areas of psychosexual functioning.

Key Words: Cognitive Behavioral Therapy; Pain; Physical Therapy; Provoked Vestibulodynia; Treatment; Vulvodynia

INTRODUCTION

Provoked vestibulodynia (PVD) is the most common subtype of vulvodynia, affecting approximately 12% of women.[1] Medical treatments for PVD have varying success rates,[2] and although vestibulectomy has the highest success rates for PVD,[2] surgery is typically recommended after the failure of less invasive treatments.[3] Based on findings that psychosexual and pelvic floor muscle (PFM) factors play a role in maintaining PVD,[4–6] studies have investigated the effects of cognitive-behavioral therapy (CBT) and physical therapy (PT) interventions for PVD. However, there is limited research investigating the effects of a

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[1]Department of Psychology, Queen's University, Kingston, Ontario, Canada;
[2]School of Rehabilitation Therapy, Queen's University, Kingston, Ontario, Canada;
[3]School of Rehabilitation Sciences, University of Ottawa, Ottawa, Ontario, Canada;
[4]Department of Obstetrics and Gynecology, Queen's University, Kingston, Ontario, Canada

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comprehensive PT program and CBT delivered on an individual basis. Furthermore, no studies have compared the effects of CBT and PT, despite these options being the most commonly provided non-medical and non-surgical treatments for PVD.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations outline six outcome domains for clinical trials of chronic pain: pain, physical functioning, emotional functioning, participant ratings of global improvement, symptoms and adverse events, and participant disposition.[7] Conducting PVD treatment studies that are more in line with the general chronic pain literature could help in making more direct comparisons between treatments for PVD and other pain conditions. We present the results obtained from a pilot study in which we randomly assigned women with PVD to receive individual CBT or PT. This study is the first to apply the IMMPACT recommendations for pain measurement to a PVD trial.

AIMS

This study aimed to determine the effects of each treatment in addressing the bio-psychosexual components of PVD and compare the effects of CBT and PT.

METHODS

Participants

The study was conducted from September 2009 to April 2012. The study was approved by the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board. Eligible women were at least 18 years old and met the criteria for PVD (ie, vulvar pain at attempted vaginal penetration for $\geq$6 months, pain limited to the vulvar vestibule during the study gynecologic examination, and no identifiable reason for the pain). Exclusion criteria included other serious medical, psychiatric, or other pain conditions that significantly affected daily or sexual functioning; generalized vulvodynia and/or significant vaginismus; current pregnancy, breastfeeding, or being less than 6 months' postpartum; and unwillingness to abstain from other PVD treatments. Interested women were screened for preliminary eligibility and those who were deemed potentially eligible underwent a gynecologic examination to confirm eligibility. Figure 1 presents the flow chart of participants and reasons for study discontinuation.

Procedures

The gynecologic examination included palpation of the labia majora, labia minora, midline area of the vulva, perineum, and vulvar vestibule with a cotton swab. The vulvar vestibule was randomly palpated at five different sites (1, 4, 6, 8, and 11 o'clock) and women rated the intensity of their pain on an 11-point numerical rating scale from 0 (no pain at all) to 10 (worst pain ever felt). Participants completed a structured interview and validated questionnaires and then were randomized to CBT or PT.

The two treatments consisted of eight 1.5-hour one-on-one sessions with the respective therapist and homework activities. The time to complete all treatment sessions ranged from 8 to 24 weeks (mean = 14.19, SD = 3.90). The PT protocol included education, PFM exercises, manual techniques, surface electromyographic biofeedback, progressive vaginal penetration exercises through the use of four silicone vaginal dilators of varied diameter, stretches of the hip muscles, deep breathing and global body relaxation exercises, and pain management techniques. The CBT program included education, collaborative reconceptualization of PVD as a multifactorial pain condition, desensitization exercises including instructions on how to perform a genital self-exploration at home, diaphragmatic breathing and other relaxation techniques, techniques for increasing sexual desire and arousal, sexual communication skills training, cognitive restructuring, and instructions on carrying out PFM exercises and on using the four silicone vaginal dilators to perform progressive vaginal penetration exercises at home (same dilators as used in PT).

After treatment and 6 months after treatment completion, participants underwent another gynecologic examination, interview, and questionnaires. Participants who did not complete all treatment sessions still underwent the post-treatment and follow-up assessments.

MAIN OUTCOME MEASURES

Table 1 lists the pain, physical functioning, emotional functioning, and participant ratings of global improvement outcome measurements. The primary outcome was change in intercourse pain intensity; all other outcomes were secondary. There were no symptoms or adverse events and thus no outcome measurements in this domain. Participant disposition is presented in Figure 1.

Analysis

To investigate the effects of each treatment, paired-sample t-tests or χ^2 tests were conducted to determine changes from before to after treatment and from before treatment to 6-month follow-up within each treatment group. To compare the effects of treatments, interaction effects from mixed-model analyses of variance (ANOVAs) were investigated. Where there were significant interaction effects, subsequent ANOVAs were conducted to determine the time points at which the differences occurred.

RESULTS

In total, 20 women were randomized to treatment and completed pretreatment, post-treatment, and 6-month follow-up assessments. Demographic, health, and pain characteristics of participants in the two treatment groups are presented in Table 2. There were no statistically significant differences between groups for any of the variables investigated.

As presented in Table 3, there were significant improvements in average intercourse pain intensity, percentage of painful