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Mediators of Change in Cognitive-Behavioral Couple Therapy for Genito-Pelvic Pain:

Results of a Randomized Clinical Trial

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Abstract

Objective: A novel cognitive-behavioral couple therapy (CBCT) has shown efficacy for treating provoked vestibulodynia (PVD), the most common type of genito-pelvic pain, in comparison to topical lidocaine. However, mechanisms of therapeutic change have not been determined. We examined women's and partners' pain self-efficacy and pain catastrophizing as mediators of change in CBCT, using topical lidocaine as a control group. **Method:** 108 couples coping with PVD were randomized to 12-week CBCT or topical lidocaine and assessed at pre-treatment, post-treatment, and six-month follow-up. Dyadic mediation analyses were conducted. **Results:** CBCT was not more effective in increasing pain self-efficacy than topical lidocaine, so this mediator was discarded. In women, decreases in pain catastrophizing at post-treatment mediated improvement in pain intensity, sexual distress and sexual function. In partners, decreases in pain catastrophizing at post-treatment mediated improvement in sexual function. Partners' decreases in pain catastrophizing also mediated reductions in women's sexual distress. **Conclusions:** Pain catastrophizing may be a mediator specific to CBCT for PVD, explaining improvements in pain and sexuality. **Keywords:** couple therapy, chronic pain, cognitive behavioral therapy, catastrophizing, self-efficacy

Introduction

Genito-pelvic pain/penetration disorder, classified as a female sexual dysfunction in the *Diagnostic and Statistical Manual of Mental Disorders*, is a common and distressing condition characterized by pain upon vaginal penetration (American Psychiatric Association, 2013). Its population prevalence is 8% in pre-menopausal women. The most common form of genito-pelvic pain/penetration disorder is provoked vestibulodynia (PVD; Harlow et al., 2014), characterized by a burning pain at the vulvar vestibule (i.e., the entrance of the vagina) when pressure is applied. Afflicted women report poorer sexual function and satisfaction, and more sexual and psychological distress than women without PVD (Khandker et al., 2011; Pazmany et al., 2014). Controlled studies

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indicate that their partners also report lower sexual satisfaction and greater erectile difficulties (Pazmany et al., 2014).

In line with a biopsychosocial model of chronic pain, interpersonal factors may modulate the experience of, and ability to cope with, chronic pain (Cano & Goubert, 2017). In the context of PVD, dyadic cross-sectional, prospective and daily diary studies have shown robust associations between relationship factors and women's pain intensity as well as both partners' psychological and sexual outcomes (Rosen & Bergeron, 2019). Targeting these key outcomes, cognitive-behavioral therapy (CBT) is the most studied and empirically validated psychological treatment for PVD (Goldstein et al., 2016). Three RCTs of group or individual CBT showed that it significantly reduced women's pain intensity and improved their psychological and sexual adjustment, in comparison to other psychological or medical treatments (Bergeron et al., 2016; Bergeron et al., 2008; Masheb et al., 2009). In order to address the important role of relationship factors in PVD, a third wave cognitive-behavioral couple therapy (CBCT) was developed by Corsini-Munt et al. (2014). This treatment shares pain management strategies with other CBTs for chronic pain, but also focuses on improving couples' intimacy and sexuality. In the RCT examining the efficacy of this novel intervention, as compared to an anesthetic ointment, CBCT yielded significant improvements in women's pain and catastrophizing, and both partners' sexuality at post-treatment and six-month follow-up (Bergeron et al., 2021). Yet the mechanisms underlying its efficacy are not well understood. Changes in pain-related cognitions, including self-efficacy and catastrophizing, are key hypothesized mechanisms in CBT (Turner et al., 2007). However, the few RCTs examining their role as mediators of change in second and third wave CBT for chronic pain yielded mixed results (Kemani et al., 2016; Turner et al., 2007) and have not taken into account the interpersonal context of pain. To address these gaps, the present study aimed to examine pain self-efficacy and pain catastrophizing as mediators of the efficacy of CBCT.

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One of the ways that CBT is believed to improve chronic pain problems is by increasing pain self-efficacy and decreasing pain catastrophizing (Turner et al., 2007) – the cognitive variables having received the most empirical support among individuals with chronic pain, including women and couples coping with PVD (Desrochers et al., 2009; Lemieux et al., 2013; Rosen et al., 2013). Pain catastrophizing is included in the Fear-Avoidance Model of chronic pain, suggesting that maladaptive pain cognitions are associated with emotional and behavioral responses (e.g., fear and avoidance) that contribute to maintain pain and associated disability and distress (Vlaeyen & Linton, 2012), and pain self-efficacy has been included in more recent iterations of this model (Slepian et al., 2020). Pain catastrophizing is characterized by magnification of the threat of pain, rumination about pain and hopelessness, and has been found in cross-sectional and prospective studies to be associated with greater pain and disability in various chronic pain populations (Edwards et al., 2016). Interestingly, the Communal Coping Model proposes that pain catastrophizing may serve to elicit support and empathy from one's social environment, pointing to the relevance of studying this variable in a relational context (Sullivan et al., 2006). Pain self-efficacy refers to an individual's beliefs regarding their pain management abilities, and has been added to the Fear-Avoidance Model; it promotes adaptive pain coping and decreases avoidance of pain-related behaviors (Slepian et al., 2020). Among women with PVD, greater pain catastrophizing was associated with greater pain during sexual activity, and greater pain self-efficacy, with lower pain and better sexual function (Desrochers et al., 2009). In another study, when partners reported greater pain self-efficacy and lower pain catastrophizing, women reported lower pain (Lemieux et al., 2013).

In a RCT comparing the efficacy of group CBT and a topical steroid treatment for women with PVD, pain self-efficacy and catastrophizing predicted lower pain intensity at six-months follow-up in the CBT group, but not better sexual function (Desrochers et al., 2010). In a recent treatment study among women with PVD comparing group CBT to mindfulness-based CBT, pain

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catastrophizing was identified as a mediator of improvements in pain and sexual distress in both groups (Brotto et al., 2020). However, most participants were not randomized. In the only RCT examining the mediating effect of pain catastrophizing – but not pain self-efficacy – in acceptance and commitment therapy (ACT) among adults with chronic pain (Kemani et al., 2016), compared to applied relaxation, changes in pain catastrophizing did not mediate improvements in pain interference during ACT. In summary, although CBT interventions are commonly recommended for chronic pain, we still know little about their mediators of change, especially in third wave CBTs (Brotto et al., 2020; Kemani et al., 2016). Importantly, although relationship factors modulate pain intensity, pain adjustment and treatment responsiveness in PVD (Rosen & Bergeron, 2019), the few studies examining such mediators have not considered the experience of the partner.

The goal of the current analysis was to examine the mediating effect of changes in pain self-efficacy and catastrophizing in CBCT for PVD, as compared to overnight topical lidocaine, in a RCT using an intent-to-treat strategy. We controlled for the effects of topical lidocaine on the mediators, to test whether CBCT would be significantly better than lidocaine in improving pain self-efficacy and catastrophizing, and thus whether those mediators would be specific to CBCT. We examined whether changes in pain self-efficacy and catastrophizing during CBCT in both women with PVD and their partners mediated the effects of CBCT, as compared to lidocaine, on women's pain intensity during vaginal penetration as well as both partners' sexual function and sexual distress. Because both members of the couple were included in the analyses, we examined how changes in pain self-efficacy and catastrophizing in each partner mediated the efficacy of CBCT on their own and their partner's outcomes. We hypothesized that women's increase in pain self-efficacy and decrease in pain catastrophizing would mediate the effects of CBCT on their own pain, sexual function and sexual distress, and that partners' increase in pain self-efficacy and decrease in pain

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catastrophizing would mediate the effects of the CBCT on women's pain, but not women's sexual function and distress. No hypotheses were formulated concerning partners' outcomes.

Method

The present study was part of a randomized clinical trial comparing the efficacy of CBCT to topical lidocaine for the treatment of PVD in two North American cities (blinded for review). The research protocol was the same across the two sites. All procedures were approved by the institutional review boards of health centres and universities where the research took place.

Participants

Couples were recruited between May 2014 and March 2018. In the final sample of 108 couples, 45 (41.67%) were recruited through advertisements in newspapers, websites, universities, hospitals and medical clinics, 37 (34.26%) through their participation in a previous study conducted by the authors, 25 (23.15 %) were referred by a physician and 1 (0.92%) by a friend. Research Site A recruited 61 couples and Research Site B recruited 47 couples. Inclusion criteria for couples were: 1) being at least 18 years of age; 2) women experiencing pain during sexual penetration that occurred on at least 80% of vaginal penetration attempts in the last six months; 3) women's pain limited to penetration or other activities involving pressure to the vulvar vestibule; 4) women having a diagnosis of PVD confirmed by a collaborating physician; 5) penetration or attempted penetration at least once a month during the last three months, given our main outcome was pain during penetration ; 6) being in a couple relationship for at least six months 7) cohabiting and/or having at least four in-person contacts per week in the last six months.

Exclusion criteria for couples were: 1) women with pain being over 45 years of age and/or having started menopause, because of the genital changes associated with menopause; 2) actively receiving treatment for PVD and not wanting or being able to discontinue for the study; 3) women with pain having an active infection or dermatological condition, as diagnosed by a physician; 4)

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severe untreated self-reported medical or psychiatric condition in either partner (e.g., untreated psychotic disorder) warranting professional attention; 5) being pregnant or planning to become pregnant in the coming months (duration of the clinical trial); 6) currently being in couple therapy, or being in an individual therapy focusing on pain and/or sexuality.; 7) clinical levels of relational distress, as indicated by the cut-off score of the well-validated Couple Satisfaction Index (Funk & Rogge, 2007); 8) self-reported intimate partner violence. Fifty-three couples were randomized to CBCT and 55 to lidocaine.

Procedure

Data were gathered at the pre-treatment, post-treatment and six-month follow-up assessments of the randomized clinical trial (blind for review). To assess couples' eligibility, a brief telephone screening interview was conducted by a research assistant with the woman having pain. Eligible couples were invited to a laboratory-based appointment conducted by a research assistant or a PhD student in psychology. This pre-treatment evaluation allowed further assessment of the eligibility of the couple. During this appointment, free and informed consent was obtained. A structured interview was conducted with both partners together, after which they both completed self-report questionnaires on separate tablet computers using Qualtrics Research Suite online software. Eligibility was then determined by reviewing their interview and questionnaire responses. All women still eligible after the pre-treatment evaluation took part in a gynecological examination including the standardized cotton-swab test to confirm their PVD diagnosis. Eligible couples were randomized to CBCT or lidocaine, according to the independent stratified randomization method provided by Dacima Software (Dacima Software Inc., Montreal, QC, Canada). Only each site's research coordinator and the CBCT therapists were aware of treatment randomization. All other research personnel and investigators were kept blind for the entire duration of the study. The post-

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treatment and six-month follow-up assessments included a structured interview and self-report questionnaires. Couples received \$30 for each assessment.

Measures

Pain catastrophizing. Pain catastrophizing was measured using the *Pain Catastrophizing Scale* (Sullivan et al., 1995). This scale has twelve items, to which participants respond on a 5-point Likert scale from 0 (not at all) to 4 (all the time), and assesses women's experience of rumination, magnification, and helplessness in relation to their pain. It has good psychometric properties and the factor structure has been demonstrated to be stable across both clinical and non-clinical populations (Osman et al., 2000). Total scores range from 0 to 52, with higher scores indicating higher catastrophizing. Partners completed an adapted version of this questionnaire measuring their own level of catastrophizing about the woman's pain. This adapted version is also validated (Cano et al., 2005). In the present sample, Cronbach's alphas were .88 for women and .91 for partners at pre-treatment, and .93 for women and .93 for partners at post-treatment.

Pain self-efficacy. Both partners completed the *Painful Intercourse Self-Efficacy Scale*, a 20-item self-report measure divided in three subscales regarding self-efficacy for controlling: 1) pain during penetration, 2) impact of pain on sexual function, 3) other symptoms such as frustration due to the pain (Desrochers et al., 2009). It is a scale adapted from the Arthritis Self-Efficacy Scale (Lorig et al., 1989). Women indicated how they perceived their ability to carry out sexual activities or to achieve particular outcomes in pain management, responding on a scale from 10 (very uncertain) to 100 (very certain). This measure has demonstrated good validity and reliability in previous studies (Desrochers et al., 2009). Partners completed an adapted version of this scale that assessed their perception of the woman's pain self-efficacy. Scores range from 10 to 100. Higher scores indicate greater self-efficacy. In the present sample, Cronbach's alphas were .86 for women and .91 for partners at pre-treatment, and .94 for women and .94 for partners at post-treatment.

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Pain. Women's pain intensity during vaginal penetration was assessed using a numerical rating scale (NRS) ranging from 0 (no pain at all) to 10 (worst pain ever). This measure of pain is positively correlated with other measures of pain intensity (Turk & Melzack, 2011).

Sexual function. The *Female Sexual Function Index* (FSFI) was used to measure women's sexual function (Rosen et al., 2000). This 19-item measure assesses sexual desire, arousal, orgasm, sexual satisfaction and pain/discomfort experienced during sexual activity and penetration. It demonstrated high internal consistency and validity across several samples of women with sexual difficulties (Wiegel et al., 2005). To avoid overlap with the pain outcome, the three items on pain were removed from the total FSFI score for women diagnosed with PVD, thus their total score included 16 items. Scores obtained in these sexual domains were summed and multiplied by a respective factor that homogenizes the influence of each dimension. Total scores ranged from 2 to 30. Higher scores indicate greater sexual function. Men's sexual function was measured using the *International Index of Erectile Function* (IIEF) (Rosen et al., 1997). This 15-item self-report questionnaire assesses erectile function, orgasm, sexual desire, intercourse satisfaction and overall sexual satisfaction. It is well validated and widely used. Items were summed to provide a total score ranging from 5 to 75. Higher scores indicate greater sexual function. Given that the FSFI and IIEF have different score ranges, a transformation was performed to allow for analyses with same-sex partners. The total FSFI scores of same-sex partners were scaled to match the total IIEF scores of the male partners through an algebraic multiplication $[(x-2)*(75/34)]$. For both the FSFI and the IIEF, items for which participants reported no sexual activity (which included caressing, foreplay and masturbation) or did not attempt penetration in the last four weeks were coded as missing values instead of zero to avoid biasing the score towards dysfunction (Meyer-Bahlburg & Dolezal, 2007). Cronbach's alphas were .92 for women and .78 for partners at pre-treatment, .94 for women and .76 for partners at post-treatment, and .93 for women and .81 for partners at six-month follow-up.

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Sexual distress. The *Female Sexual Distress Scale* (Derogatis et al., 2008) was used to assess sexuality-related personal distress of both partners. On this 13-item measure, participants answered on a 5-point Likert-type scale ranging from 0 (never) to 4 (always). This scale demonstrated good psychometric properties (Derogatis et al., 2008). This measure was initially designed for women, but uses a gender neutral language and has been validated with men (Santos-Iglesias et al., 2018). Total scores range from 0 to 52. At pre-treatment, Cronbach's alpha was .91 for women and .91 for partners, .96 for women and .94 for partners at post-treatment, and .97 for women and .93 for partners at six-month follow-up.

Treatment Conditions

Cognitive-behavioral couple therapy (CBCT). CBCT consisted of 12 weekly face-to-face sessions. The first session was 90-minutes long and subsequent sessions were all 75-minutes long. A treatment manual detailing the outline of each session, indicating material to cover, homework to be assigned at each session and points to emphasize, was followed by all the therapists. This manual can be obtained by writing to the last author. Adherence to the treatment manual was ensured by video recording all sessions of therapy. The therapists were clinical psychology PhD-level students (N = 8) or junior clinicians (PsyD or PhD, N = 2; MA in clinical sexology, N = 1) and all of them received training on delivering the CBCT manual interventions, literature on PVD and principles of sex and couple therapy. All therapists had weekly supervision with a registered clinical psychologist specialized in sex and couple therapy. Couples attended, on average, 10.64 out of 12 (SD = 3.53; 88.7%) therapy sessions. Participant treatment adherence was assessed via frequency ratings of weekly home practice of exercises, completed by each partner. Homework completion rates were determined based on homework completed during the week it was assigned. Women completed 67.7% of their homework exercises, and partners 58.6%. The goals of the CBCT were as follows: a) provide psychoeducation about PVD and re-conceptualization as a multidimensional pain

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condition; b) develop a couple perspective on PVD, seeing pain as affecting and being affected by both partners; c) increase adaptive coping strategies by addressing pain-related thoughts, feelings, behaviors and couple interactions, namely by increasing self-efficacy and decreasing catastrophizing; d) improve couples' adaptive communication regarding pain and sexuality; and e) facilitate shared pleasurable sexual experiences. Interventions were rooted in third-generation CBT, including ACT. More information regarding the CBCT is detailed elsewhere (blind for review).

Topical lidocaine. Participants assigned to the medical treatment performed nightly applications of a lidocaine ointment (50mg/g, Lidocaine ointment 5% USP Lidodan, Odan, 35g) during 12 weeks, as described by Zolnoun et al. (2003). In this RCT, we compared CBCT to lidocaine because most women will first see a physician for their pain and will be prescribed a topical treatment – lidocaine being one of the most prescribed (Updike et al., 2005). The ointment was applied directly at the vulvar vestibule and on a cotton gauze maintained at the vulvar vestibule by the participant's underwear overnight, in order to keep the ointment in contact with the vulvar vestibule for about 8 hours. To monitor potential adverse events and facilitate compliance, a research assistant conducted standardized phone calls once a week, and participants were instructed to inform this assistant if they experienced any bothersome symptoms. Participants also completed a daily log to monitor treatment application. They applied the ointment 79.4% of the time during the 12 weeks.

Statistical Analyses

The associations between outcomes (pain intensity, sexual function and sexual distress) and socio-demographic variables (pain duration, relationship duration, age, income and, education level and the site where the treatment occurred) were examined to assess the need to include covariates in the mediation models. Correlation analyses between pain self-efficacy, pain catastrophizing, and outcome variables were also conducted. We performed linear regressions to test for differences between the two treatment conditions with respect to the potential mediating variables, pain self-

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efficacy and pain catastrophizing. Only the mediators showing statistically significant treatment effects were included as a mediating variable in the models. As there is a growing consensus that a significant total effect of X on Y should not be required for searching for evidence of indirect effects (Zhao et al., 2010), all outcomes were examined regardless of the significance of the direct effect of treatment condition. Descriptive and preliminary statistics were computed using SPSS 25.

Mediation analyses were conducted using *Mplus*, version 8.3 (Muthén & Muthén, 1998-2017) to examine the effects of the treatment condition on the outcome variables at post-treatment and six-month follow-up through the putative treatment mediator at post-treatment. Analyses with the outcomes at post-treatment are of concurrent associations between mediators and outcomes (concurrent models), whereas analyses at follow-up allow an examination of temporal associations (temporal models). All analyses used an analysis of covariance approach that controlled for study entry values of each mediator and outcome variables. The actor-partner interdependence framework for mediation data was adopted because it accounts for the interdependence of the partners' data (Kenny et al., 2006). With this statistical framework, the interdependence of the data is taken into account because data of both partners are modelled concurrently. Women's pain, as well as women's and partners' sexual function and sexual distress (post-treatment levels for the concurrent models and six-month follow-up levels for the temporal model) were entered as dependent variables in distinct models. Women's and partners' significant mediator variables (post-treatment levels) were entered in each model. As potential confounders of the mediator-outcome relationship, the baseline values of the mediator and outcomes were included as covariates in all mediation models. The effects of treatment condition on women's and partners' outcomes were the direct effects. The direct effects quantified the estimated difference in outcomes between participants in the CBCT and lidocaine conditions at post-treatment (concurrent model) or six-month follow-up (temporal model) independent of the mediating variables. The effects of treatment condition on outcome variables

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through the mediators are the indirect effects. The indirect effect quantified how much participants in the CBCT and lidocaine conditions differed on the outcome variables at post-treatment (concurrent model) or six-month follow-up (temporal model) as a result of the influence of the treatment conditions on the mediator, which in turn influenced the outcome variables. The sum of the direct and the indirect effects is the total effect. In our dyadic mediation model, there are four possible indirect effects; two *actor* indirect effects and two *partner* indirect effects.

In accordance with the intent-to-treat design, all randomized couples were included in the analyses (Gupta, 2011). Missing data were accounted for using the full information maximum likelihood method (FIML) (Enders & Bandalos, 2001). The chi-square statistic, the comparative fit index (CFI), the root mean square error of approximation (RMSEA) and the standardized root mean square residual (SRMR) were used to evaluate the fit of each model (Hooper et al., 2008). A non-statistically significant chi-square value, a SRMR value of .08 or less, a CFI value of .90 or higher, and a RMSEA value below .06 indicate a good fit to the data (Hooper et al., 2008). The indirect effects were tested using a nonparametric bootstrap approach with 10,000 data sets that are created by resampling subjects from the original data set. The indirect effects were considered statistically significant when 0 was excluded from the confidence intervals (95% CI).

Results

Sample Characteristics

Table 1 displays sample demographics by treatment received for the total sample of 108 couples. On average, women had their pain condition for six years, reflecting the chronicity of PVD.

Preliminary Analyses

Table 2 displays means and standard deviations for the mediators and outcomes. Pearson's product-moment correlations were computed to examine zero-order associations among the study variables. Those associations are displayed in Table 3.

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A set of preliminary analyses was conducted to examine correlations between the study variables and women's and partners' age and education level, couples' annual income, relationship duration and pain duration as well as site. Relationship duration, pain duration, research site, and women's and partners' age were significantly related to at least one of the mediators or outcomes. Because partner's age and relationship duration were strongly correlated ($r = .59, p < .001$), and women's age and relationship duration were strongly correlated ($r = .66, p < .001$), only relationship duration was included as a covariate in subsequent models. Thus, research site, pain duration and relationship duration were included as covariates in the mediation models.

Linear regression showed that, controlling for site, pain duration and relationship duration, women in the CBCT condition had significantly lower levels of pain catastrophizing at post-treatment than those in the lidocaine condition, $b = -7.37$ ($SE = 1.78$), $p < .001$, $\beta = -.31$. Partners in the CBCT condition also had significantly lower levels of pain catastrophizing at post-treatment than participants in the lidocaine condition, $b = -4.37$ ($SE=1.79$), $p = .015$, $\beta = -.19$. Women's pain self-efficacy did not show a statistically significant treatment condition effect, $b = 3.28$ ($SE = 3.20$), $p = .305$, $\beta = .09$. Further, partners' pain self-efficacy did not show a statistically significant treatment effect, $b = 6.22$ ($SE = 3.31$), $p = .060$, $\beta = .15$. Therefore, only pain catastrophizing was included in the mediation analyses.

Mediation Models

Results of the dyadic mediation models, concurrent and temporal, are provided in Tables 4 and 5, respectively. A figure also illustrates the results of the temporal models (Figure 1).

Indirect effects on pain. The concurrent dyadic mediation model with women's pain intensity during penetration at post-treatment as the outcome showed a satisfactory fit to the data, $\chi^2(12) = 12.44$, $p = .411$; CFI = 1.00; RMSEA = .02, 90%CI [.00 to .10]; SRMR = .05. This model revealed a statistically significant indirect actor effect of CBCT, relative to the control active-

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treatment condition of topical lidocaine, on women's pain via women's pain catastrophizing (Table 4). This result indicated that a proportion of the effect of CBCT on pain intensity was explained by a reduction in women's pain catastrophizing at post-treatment. The percentage of variance in women's pain at post-treatment explained by the model was 34.2%. The temporal mediation model showed a satisfactory fit to the data, $\chi^2(12) = 12.48$, $p = .408$; CFI = 1.00; RMSEA = .02, 90%CI [.00 to .10]; SRMR = .05. This model revealed a statistically significant indirect actor effect of CBCT on women's pain reduction at follow-up via women's pain catastrophizing (Table 5). The indirect partner effects of CBCT on women's pain were not significant. The percentage of variance in women's pain at follow-up explained by the model was 33.2%.

Indirect effects on sexual function. The concurrent dyadic mediation model with women and partners' sexual function at post-treatment as outcomes showed a satisfactory fit to the data, $\chi^2(17) = 15.84$, $p = .536$; CFI = 1.00; RMSEA = .00, 90%CI [.00 to .08]; SRMR = .06. This model revealed a statistically significant indirect actor effect of CBCT, relative to the control active-treatment condition of topical lidocaine, on women's sexual function via their own pain catastrophizing (Table 4). This model revealed another significant indirect actor effect of CBCT on partners' sexual function through their own pain catastrophizing (Table 4). Both indirect partner effects of CBCT on women's and partners' sexual function were not significant. The percentage of variance explained by the model was 51.8% for women's sexual function at post-treatment and 71.1% for partners' sexual function at post-treatment. The temporal dyadic mediation model showed a satisfactory fit to the data, $\chi^2(17) = 15.29$, $p = .574$; CFI = 1.00; RMSEA = .00, 90%CI [.00 to .08]; SRMR = .05. This model revealed a statistically significant indirect actor effect of CBCT, relative to the control active-treatment condition of topical lidocaine, on women's sexual function via their own pain catastrophizing (Table 5). No other significant indirect effects were found for this

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model (i.e., no partner effects). The percentage of variance explained by the model was 38.3 % for women's sexual function at follow-up and 44.2% for partners' sexual function at follow-up.

Indirect effects on sexual distress. The concurrent dyadic mediation model showed a satisfactory fit to the data, $\chi^2(17) = 23.09, p = .147$; CFI = 0.98; RMSEA = .06, 90%CI [.00 to .11]; SRMR = .05. This model revealed a statistically significant indirect actor effect of CBCT, relative to the control active-treatment condition of topical lidocaine, on women's sexual distress via their own pain catastrophizing (Table 4). This model revealed another significant indirect actor effect of CBCT on partners' sexual distress through their own pain catastrophizing (Table 4). A significant indirect partner effect of CBCT on women's sexual distress through partners' pain catastrophizing was also found. The percentage of variance explained by the model was 58.0% for women's sexual distress at post-treatment and 64.4% for partners' sexual distress at post-treatment. The temporal dyadic mediation model showed a satisfactory fit to the data, $\chi^2(17) = 23.87, p = .123$; CFI = 0.97; RMSEA = .06, 90%CI [.00 to .11]; SRMR = .05. This model revealed a statistically significant indirect actor effect of CBCT, relative to the control active-treatment condition of topical lidocaine, on women's sexual distress via their own pain catastrophizing (Table 5). This model revealed another significant indirect actor effect of CBCT on partners' sexual distress through their own pain catastrophizing (Table 5). The percentage of variance explained by the model was 34.2% for women's sexual distress at follow-up and 47.5% for partners' sexual distress at follow-up.

Discussion

This study aimed to examine the roles of pain self-efficacy and pain catastrophizing as therapeutic mediators of CBCT for PVD relative to topical lidocaine, using pre-treatment, post-treatment and six-month follow-up assessments from a randomized clinical trial. Hypotheses were partially confirmed. First, women in the CBCT condition reported a steeper decrease in their pain intensity at post-treatment through a steeper reduction in their pain catastrophizing, compared with

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women in the lidocaine condition, and this reduction in pain catastrophizing predicted sustained improvement in their pain at six-month follow-up. Second, women and partners in the CBCT condition reported a steeper increase in their sexual function at post-treatment, each through a steeper reduction in their pain catastrophizing, as compared with women and partners in the lidocaine condition, and women's pain catastrophizing reduction predicted sustained improvements in their sexual function at six-month follow-up. Third, women in the CBCT condition reported a steeper decrease in their sexual distress at post-treatment through a steeper reduction in their own and their partners' pain catastrophizing, as compared with the lidocaine condition, and this reduction in women's pain catastrophizing predicted sustained improvements in their sexual distress at six-month follow-up. Partners in the CBCT condition reported a steeper decrease in their sexual distress at post-treatment through a steeper reduction in their pain catastrophizing, compared with partners in the lidocaine condition, and this reduction in pain catastrophizing predicted sustained improvements in their sexual distress at six-month follow-up. CBCT did not improve pain self-efficacy at post-treatment significantly more than the lidocaine. This study contributes to the literature examining the role of pain self-efficacy and pain catastrophizing as mediators of change in CBT for chronic pain, and results suggest that both partners' pain catastrophizing reductions may be a specific mechanism underlying their improvements following CBCT for PVD.

Consistent with our expectations, findings showed that CBCT improved women's pain, sexual function and sexual distress through a steeper reduction in their own levels of pain catastrophizing, as compared to the topical lidocaine treatment. These results build on previous evidence supporting a prospective link between pain catastrophizing and PVD in predicting treatment outcome (Desrochers et al., 2010), and provides further support for the Fear-Avoidance Model and its relevance for PVD. This model suggests that ruminating, amplifying and feeling helpless about the pain are important psychological factors maintaining chronic pain because they

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contribute to maladaptive avoidance patterns (Vlaeyen & Linton, 2012). It is possible that reductions in pain catastrophizing promote more adaptive behaviors, which in the context of PVD could be a reduced avoidance of sexual intimacy and an increased engagement in sexual activities other than penetration. This result is also in line with that of Brotto et al. (2020), whereby pain catastrophizing was a significant mediator of change in both group mindfulness-based CBT and group CBT, suggesting that pain catastrophizing is an important target in 2nd and 3rd wave CBT.

In addition, results showed that CBCT had a positive indirect effect on partners' sexual function and distress at post-treatment and sexual distress at six-month follow-up, through decreases in their own pain catastrophizing. This is an important finding, as controlled studies have shown that partners' sexuality is also significantly impaired in couples coping with PVD (Pazmany et al., 2014). Targeting pain catastrophizing in CBCT may be beneficial not only for women's sexuality, but also for their partners'. Partners are not actively involved in the lidocaine treatment, relative to CBCT, which could explain the latter's greater impact on their pain catastrophizing. The impact of CBCT on partners' pain catastrophizing is consistent with results of a pilot study testing CBCT for couples coping with PVD, in which exploratory analyses showed a decrease in pain catastrophizing at post-treatment for both members of the couple (Corsini-Munt et al., 2014). Thus, findings provide further evidence that CBCT can significantly change partners' view of the pain, from more threatening to more manageable.

Decreases in partners' pain catastrophizing were a significant indirect path by which CBCT had a positive effect on women's sexual distress at post-treatment, but not their levels of pain intensity or sexual function. The only study examining the cross-sectional associations between partners' pain catastrophizing and women's pain and sexual adjustment found that lower levels of partners' pain catastrophizing were associated with lower levels of women's pain, but the associations with sexual outcomes were not significant (Lemieux et al., 2013). Also, in a large study

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with women with genito-pelvic pain and their partners, partner catastrophizing was associated with more negative and greater solicitous partner responses, which were in turn associated with women's higher pain (Davis et al., 2015). In our study, the non-significant association between partners' pain catastrophizing and women's pain and sexual function could be explained by the fact that we examined changes in partners' pain catastrophizing following therapy, as compared to lidocaine, and we were predicting the changes in women's pain and sexual function following therapy. This is an important distinction with past findings. Moreover, our mediation models included simultaneously changes in women and partners' pain catastrophizing, suggesting that changes in women's catastrophizing play a more important role in their changes in pain and sexual function than changes in partner's catastrophizing. Because the affective and relational dimensions of sexual difficulties are integral parts of sexual distress, more variance in this outcome may be explained by changes in the partner, beyond the effects of the therapy on women's pain catastrophizing.

Surprisingly, CBCT did not increase pain self-efficacy significantly more than the lidocaine. This result is consistent with that of a previous RCT comparing group CBT to a topical steroid in the treatment of PVD, whereby participants in the group CBT demonstrated significantly better improvement in pain catastrophizing from pre-treatment to post-treatment than the topical steroid participants, but both treatments were as effective in reducing pain self-efficacy (Bergeron et al., 2016). It is also possible that including the partner in CBCT impacted pain catastrophizing. According to the Communal Coping Model of pain (Sullivan et al., 2006), pain catastrophizing may serve to elicit support and empathy from the social environment. Thus, a couple intervention may help women find more adaptive ways of communicating their support needs to their partner, which can decrease their use of pain catastrophizing. Nevertheless, several interventions targeted pain self-efficacy in our CBCT, such as pain journals, which aimed to increase awareness of factors associated with pain variations in order to develop better coping strategies and increase pain self-efficacy.

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Results should be interpreted in light of the study limitations. First, even though variables were assessed at pre- and post-treatment and six-month follow-up, which allowed for testing of the temporal precedence of the mediators, this design is not optimal to examine mechanisms of change (Kazdin, 2009). Frequent assessments during treatment allow for the examination of more fine-grained patterns of change of mediator during treatment and outcomes after treatment (Laurenceau et al., 2007). Second, all outcomes were assessed using retrospective self-report questionnaires.

The present study boasts several strengths. The sample size was adequate and included all randomized couples, as per an intent-to-treat strategy, which increased the external validity of the findings, as compared to other similar studies (Turner et al., 2007). This is the first RCT examining pain catastrophizing and pain self-efficacy as mediators of change embedded in the social context of pain. Thus, the use of a dyadic design and analytic approach is a strength of the present study. Additionally, all women received a clinical diagnosis of PVD, leading to a homogeneous sample. Moreover, results of the present study have substantial clinical applications. They support the relevance of targeting not only women's pain catastrophizing in CBT, but also partners' catastrophizing in order to decrease both partners' sexual impairment. Findings may be of use for developing clinical interventions focused on both partners' pain-related cognitions. In a context where research on mediators of change in CBT is equally sparse in chronic pain and sex and couple therapy, this study adds to the body of literature by suggesting that pain catastrophizing may be a specific mechanism by which CBCT improves women's pain and both partners' sexual health.

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Table 1

Sample Demographics for Women with PVD and their Partners

	Total N = 108 couples		CBCT Condition N = 53 couples		Lidocaine Condition N = 55 couples	
	Women	Partners	Women	Partners	Women	Partners
Sex of the partners						
Men		105 (97.22%)		52 (98.11%)		53 (96.36%)
Women		3 (2.78%)		1 (1.89%)		2 (3.64%)
Age (years)	27.06 (6.26)	29.04 (7.76)	26.51 (5.51)	28.40 (7.20)	27.60 (6.91)	29.65 (8.29)
Pain duration (months)	78.22 (62.44)		67.21 (52.30)		88.83 (69.70)	
Cultural background						
English Canadian	39 (36.10%)	46 (42.60%)	19 (35.8%)	25 (47.17%)	20 (36.36%)	21 (38.18%)
French Canadian	43 (40.20%)	34 (31.50%)	18 (33.96%)	12 (22.64%)	25 (45.45%)	22 (40.00%)
Other	25 (23.15%)	28 (25.93%)	15 (28.30%)	16 (30.19%)	10 (18.18%)	12 (21.81%)
Missing	1 (0.93%)	0	1 (1.89%)	0	0	0
Education level (years)	17.06 (2.24)	16.14 (2.93)	16.84 (2.27)	15.78 (2.37)	17.27 (2.31)	16.48 (2.71)
Marital status						
Not living together	22 (20.40%)		13 (24.53%)		9 (16.36%)	
Cohabiting	56 (51.90%)		27 (50.94%)		29 (52.73%)	
Married	30 (27.80%)		13 (24.53%)		17 (30.91%)	
Relationship length (months)	65.20 (49.67)		61.13 (47.46)		69.14 (51.84)	
Couple's annual income						
\$0-\$19,999	20 (18.52%)		9 (16.98%)		11 (20.00%)	
\$20,000-\$39,999	22 (20.38%)		15 (28.30%)		7 (12.73%)	
\$40,000-\$59,999	15 (13.89%)		5 (9.43%)		10 (18.18%)	
\$60,000-\$79,999	16 (14.81%)		7 (13.21%)		9 (16.36%)	
\$79,999 and over	34 (31.48%)		16 (30.19%)		18 (32.73%)	
Does not wish to disclose	1 (0.93%)		1 (1.89%)		0	
Treatment site (1=Blinded for review)	47 (43.5%)		23 (43.4%)		24 (43.6%)	

Note. Values are *n* (%) or mean (SD).

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Table 2

Descriptive Statistics of Key Variables for Women with PVD and their Partners

Variables	Total N = 108 couples		CBCT Condition N = 53 couples		Lidocaine Condition N = 55 couples	
	Women	Partners	Women	Partners	Women	Partners
Mediators						
Pain catastrophizing (PCS)–Pre-treatment	26.79 (10.30)	24.42 (11.39)	28.04 (9.96)	22.99 (9.96)	25.58 (10.57)	25.80 (12.55)
Pain catastrophizing (PCS)–Post-treatment	15.84 (11.42)	18.40 (11.50)	13.15 (8.42)	15.16 (9.66)	18.25 (13.19)	21.19 (12.29)
Pain self-efficacy (PISES)–Pre-treatment	58.11 (14.92)	59.59 (16.02)	57.99 (15.57)	60.46 (16.60)	58.23 (14.40)	58.76 (15.56)
Pain self-efficacy (PISES)–Post-treatment	72.66 (17.98)	68.09 (20.27)	74.28 (17.28)	71.37 (19.31)	71.20 (18.65)	65.25 (20.83)
Outcomes						
Pain intensity (VAS)–Pre-treatment	6.66 (1.80)		6.81 (1.77)		6.51 (1.82)	
Pain intensity (VAS)–Post-treatment	4.69 (2.24)		4.70 (2.21)		4.67 (2.29)	
Pain intensity (VAS)–Follow-up	4.58 (2.54)		4.45 (2.51)		4.70 (2.58)	
Sexual function (FSFI, IIEF)–Pre-treatment	17.12 (4.75)	58.38 (7.70)	17.30 (5.02)	57.29 (8.08)	16.96 (4.53)	59.43 (7.24)
Sexual function (FSFI, IIEF)–Post-treatment	19.09 (5.35)	61.41 (6.72)	19.37 (5.27)	60.54(6.21)	18.84 (5.47)	62.13 (7.10)
Sexual function (FSFI, IIEF)–Follow-up	19.37 (5.28)	60.32 (7.73)	19.09 (5.16)	59.08 (7.69)	19.61 (5.42)	61.30 (7.71)
Sexual distress (SDS)–Pre-treatment	34.09 (9.76)	16.85 (9.83)	34.64 (9.40)	16.25 (8.33)	33.56 (10.15)	17.44 (11.13)
Sexual distress (SDS)–Post-treatment	25.18 (14.14)	15.08 (10.91)	21.63 (12.90)	14.41 (9.02)	28.37 (14.56)	15.65 (12.35)
Sexual distress (SDS)–Follow-up	24.02 (14.58)	15.19 (10.61)	23.69 (14.47)	16.25 (9.93)	24.32 (14.82)	14.29 (11.18)

Note. PCS = Pain Catastrophizing Scale; PISES = Painful Intercourse Self-Efficacy Scale; VAS = Visual Analog Scale; FSFI = Female Sexual Function Index; IIEF = International Index of Erectile Function; SDS = Sexual Distress Scale.

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Table 3

Correlations Between Pain Catastrophizing, Pain Self-efficacy and Outcome Variables for Women with PVD and their Partners at Post-treatment and Follow-up

	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.
1. Pain catastrophizing–Post (W)	.30**	-.73**	-.40**	.43**	.36**	-.41**	-.35**	-.14	-.08	.63**	.44**	.03	.02
2. Pain catastrophizing–Post (P)	-	-.24*	-.44**	.20	.20*	-.19	-.15	-.18	-.11	.40**	.34**	.64**	.46**
3. Pain Self-efficacy–Post (W)		-	.60**	-.48*	-.47**	.61**	.45**	.46**	.34**	-.73**	-.62**	-.11	-.15
4. Pain Self-efficacy–Post (P)			-	-.35**	-.52**	.44**	.33**	.54**	.37**	-.52**	-.51**	-.34**	-.34**
5. Pain (W)–Post				-	.69**	-.23*	-.18	-.21	-.19	.35**	.40**	-.08	-.09
6. Pain (W)–FU					-	-.28**	-.30**	-.34**	-.47**	.33**	.56**	.01	.08
7. Sexual function–Post (W)						-	.69**	.36**	.33**	-.69**	-.55**	-.24*	-.20
8. Sexual function–FU (W)							-	.33**	.37**	-.51**	-.66**	-.19	-.30**
9. Sexual function–Post (P)								-	.62**	-.37**	-.37**	-.40**	-.37**
10. Sexual function–FU (P)									-	-.21	-.41**	-.27*	-.45**
11. Sexual distress–Post (W)										-	.71**	.36**	.32**
12. Sexual distress–FU (W)											-	.30**	.40**
13. Sexual distress–Post (P)												-	.77**
14. Sexual distress–FU (P)													-

Note. W = Women; P = Partners. Post = post-treatment; FU = Follow-up. * $p < .05$. ** $p < .01$

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Table 4

The Total Effects, Direct Effects, Actor Indirect Effects and Partner Indirect Effects for Concurrent Models

Outcomes	Total Effects	Direct Effects	Indirect Actor Effects	Indirect Partner Effects
	b (95%CI)	b (95%CI)	b (95%CI)	b (95%CI)
Model 1				
Pain intensity–Post-treatment (W)	-0.41 (-1.21, 0.43)	0.00 (-0.90, 0.84)	-0.44 (-0.99, -0.04)*	0.03 (-0.21, 0.37)
Model 2				
Sexual function–Post-treatment (W)	0.66 (-1.20, 2.50)	-1.27 (-3.12, 0.47)	1.67 (0.78, 2.91)*	0.26 (-0.18, 1.07)
Sexual function–Post-treatment (P)	-0.21 (-2.25, 1.79)	-1.92 (-3.76, -0.17)*	0.97 (0.22, 2.32)*	0.73 (-0.09, 1.85)
Model 3				
Sexual distress–Post-treatment (W)	-8.53 (-13.01, -3.61)*	-3.09 (-7.72, 1.68)	-4.36 (-7.22, -2.16)*	-1.09 (-3.26, -0.09)*
Sexual distress– post-treatment (P)	-0.44 (-3.62, 2.92)	1.07 (-1.71, 3.97)	-1.92 (-4.21, -0.42)*	0.42 (-0.91, 2.34)

Note. W = Women. P = Partners. CI = Confidence interval. Bootstrap sample size = 10 000. * = Evidence of an effect as 95% bias corrected bootstrap confidence interval did not include zero.

Table 5

The Total Effects, Direct Effects, Actor Indirect Effects and Partner Indirect Effects for Temporal Models

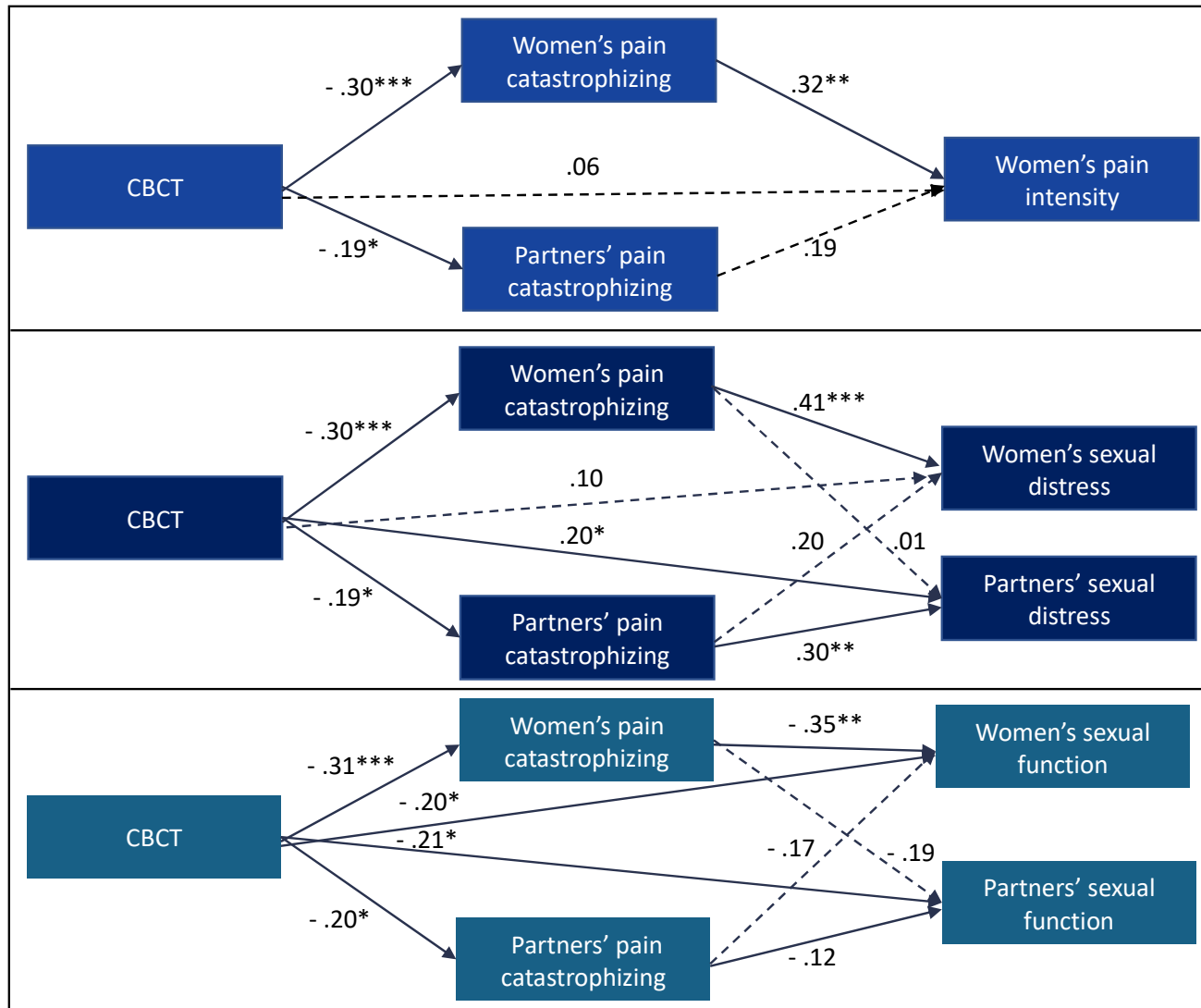
Outcomes	Total Effects	Direct Effects	Indirect Actor Effects	Indirect Partner Effects
	b (95%CI)	b (95%CI)	b (95%CI)	b (95%CI)
Model 1				
Pain intensity–Follow-up (W)	-0.36 (-1.30, 0.65)	0.32 (-0.68, 1.36)	-0.49 (-1.06, -0.11)*	-0.19 (-0.66, 0.03)
Model 2				
Sexual function–Follow-up (W)	0.63 (-2.50, 1.21)	-2.06 (-4.09, -0.15)*	1.10 (0.29, 2.39)*	0.34 (-0.09, 1.35)
Sexual function–Follow-up (P)	-2.10 (-5.20, 1.08)	-3.43 (-6.89, 0.21)	0.39 (-0.60, 1.96)	0.94 (-0.01, 2.18)
Model 3				
Sexual distress–Follow-up (W)	-1.55 (-6.73, 3.92)	2.92 (-2.42, 8.77)	-3.39 (-6.49, -1.21)*	-1.09 (-3.95, 0.12)
Sexual distress–Follow-up (P)	2.92 (-0.58, 6.98)	4.21 (0.44, 8.54)*	-1.22 (-3.41, -0.13)*	-0.06 (-1.74, 1.64)

Note. W = Women. P = Partners. CI = Confidence interval. Bootstrap sample size = 10 000.* = Evidence of an effect as 95% bias corrected bootstrap confidence interval did not include zero.

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Figure 1

Results of temporal mediation models.



Note. Research site, pain duration, and relationship duration were included as covariates in the mediation models. Coefficients are standardized. * $p < .05$. ** $p < .01$. *** $p < .001$. Dotted lines represent non-significant associations.