A feasibility trial of a cognitive-behavioural symptom management program for chronic pelvic pain for men with refractory chronic prostatitis/chronic pelvic pain syndrome

Dean A Tripp; PhD; J. Curtis Nickel, MD, FRCSC;† Laura Katz, BA§*

*Departments of Psychology, Anesthesiology & Urology, Queen's University, Kingston, ON; †Department of Urology, Queen's University, Kingston, ON; §Department of Psychology, Queen's University, Kingston, ON

Abstract

Background: Our objective was to determine the feasibility of a cognitive behavioural symptom management program for the acute improvement of psychosocial risk factors of diminished quality of life (QoL) in men suffering from chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS).
Materials and Methods: We assessed CP/CPPS symptoms and impact (i.e., chronic prostatitis symptom index [CPSI] pain, urinary, QoL domains), psychosocial risk factors were assessed at baseline and weekly for 8 weeks. We included the following psychosocial risk factors: catastrophizing (Pain Catastrophizing Scale, PCS), mood (Center for Epidemiological Studies in Depression Scale, CES-D), social support (Multidimensional Scale of Perceived Social Support, MSPSS) and general pain (McGill Pain Questionnaire). Patient sessions dispute and replace pessimistic thinking with health-focused thinking and behaviour.
Results: Eleven men completed the psychosocial management program (mean age = 51.3, standard deviaton [SD] = 12.49). Mean CPSI baseline total score was 25.2 (SD = 10.21). Repeated measures ANOVAs showed the program was associated with significant linear reductions for pain ($p = 0.051$), disability ($p= 0.020$) and catastrophizing ($p = 0.005$), but no changes in depressive symptoms or social support. The CPSI baseline scores compared to follow-up scores (n = 8) were significantly reduced ($p = 0.007$), with CPSI pain ($p = 0.015$) and QoL impact ($p = 0.013$) reduced, but not for urinary scores. Correlations between change scores at the baseline and at 8 weeks for CPSI and psychosocial risk factors indicated that reductions in catastrophizing were most strongly associated with score reductions for the CPSI; these reductions, however, were not significant.
Conclusions: The psychosocial management program targets and significantly reduces several empirically supported psychosocial risk factors associated with poorer CP/CPPS outcomes. Psychosocial management for CP/CPPS is feasible, but requires a randomized controlled trial with longitudinal follow-up.

Introduction

Prostatitis has been an exasperating disease for physicians and patients for much of the last century. The diagnosis of chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is common in urologic practice, but its etiology is not understood and most biomedical treatments lack efficacy.[1] The prevalence of CP/CPPS is alarming among adults[2,3] and adolescents.[4] Males suffering from CP/CPPS report significant pain and diminished quality of life (QoL).[5-9]

Physical disease and psychiatric disorders coexist in CP/CPPS,[10] with as many as 78% of patients with CP/CPPS reporting depression[11] and 60% having met criteria for a major depressive disorder.[12] Further, greater depression and not having a partner for support were associated with poorer CP/CPPS outcomes.[7] Adding to the depression concern, CP/CPPS pain and QoL outcomes are predicted by a particular set of psychosocial risk factors, including low social support and pain catastrophizing.[7,8,9] Pain catastrophizing is associated with chronic pain[13] and it may be a key component in the clinical phenotypic classification of male urologic chronic pelvic pain.[14] Catastrophizing is the tendency to employ a set of pain-associated cognitive appraisals referred to as ruminatory ("can't keep it out of my mind"), magnifying ("makes me think about other pains") and helpless ("there is nothing I can do") when undergoing or anticipating pain.[15] Catastrophizing is associated with anxiety and depression, but is considered a unique factor in pain.[8,15] Controlling for urinary symptoms and depression, catastrophizing was the strongest biopsychosocial predictor of CP/CPPS pain[8] and was shown to be a robust predictor of diminished mental status QoL in men with CP/CPPS.[9]

CP/CPPS research supports the necessity and rationale for a specific cognitive behavioural treatment model. There has been interest in considering psychosocial treatments[16] and approaches to reduce the psychosocial risk factors associated with poor CP/CPPS outcomes;[17] yet, there are

no published reports examining risk factor reduction in CP/CPPS. The Chronic Prostatitis psychosocial management program is the first comprehensive attempt to specifically target empirically supported psychosocial risk factors for change in CP/CPPS (i.e., catastrophizing, social support and depression). This study was designed to assess the feasibility of this management program and its short-term effectiveness in reducing psychosocial risk factors and symptoms and in improving QoL.

Methods

As approved by the local research and ethics board, men with a CP/CPPS diagnosis were recruited through the Urology Prostatitis Clinic (JCN). All men were invited to participate by letter, and then a discussion of the program ensued with potential participants. Once men agreed to participate in the program, we collected informed consent. All participants were suffering from refractory CP/CPPS. There was no monetary incentive for participating in the program.

A weekly 8-session self-management program designed specifically for men diagnosed with CP/CPPS was developed. One author (DT) has experience developing similar risk factor reduction programs.[18] The session content was defined in the patient and provider workbooks, including weekly agendas outlining patient tasks and discussion topics between patients and program providers.[17] A urology nurse or an equivalent health care worker lead each of the weekly 1-hour sessions. The weekly agendas, task assignments and semi-structured discussions helped to manage patient burden or confusion. The initial session included the program rationale, stating the value of the cognitive and behavioural approach used in the management program. In sessions 2 and 3, patients were actively instructed to use the "Reaction Record" tool, an approach used for self-identifying and modifying illness-focused or catastrophic cognitions associated with becoming sedentary or losing enjoyable social activities. During sessions 4 to 6, patients practiced positive communication with their instructor and their significant others, guided by completed Reaction Records. Sessions 6 and 7 used Reaction Records to modify illness-focused behavioural coping strategies and reengage patients in abandoned physical and social activities. In the final session (week 8), patients reviewed their risk factor modifications and discussed continued problem-solving for future self-management challenges.

Pain severity was assessed using the Short-Form McGill Pain Questionnaire (SF-MPQ) (range: 0 to 45), shown to be sensitive and valid in many clinical populations.[7-9,19] The NIH Chronic Prostatitis Symptom Index (NIH-CPSI) is a 9-item reliable and validated self-report measure (range: 0 to 43) assessing prostatitis-like symptoms and their impact.[20] The pain domain is summed as a total score (range: 0 to

21), while urinary scores reflect incomplete emptying and frequency of urination (range: 0 to 10) and QoL impact assesses activity limitation, distress and overall QoL (range: 0 to 12). Depressive symptoms were assessed using the Center for Epidemiological Studies Depression Scale (CES-D),[21] a reliable and valid scale that measures 20 depressive symptoms within the last week (range: 0 to 48). The Pain Catastrophizing Scale[22] uses 13 reliable and valid items to assess patients' catastrophizing (range: 0 to 52). The Multidimensional Scale of Perceived Social Support (MSPPS)[23] uses 12 reliable and valid items assessing support (range: 12 to 84).

Statistics

Descriptive statistics were used for demographic information (medians, means, standard deviations). We assessed changes in subject scores across various sessions by repeated measures ANOVAs expecting linear models. Planned follow-up contrasts, using a difference analysis, were used for significantly reduced risk factors. Differences between pre/post-treatment NIH-CPSI Total and domain scores were computed with repeated measures ANOVAs. Alpha was set at $p < 0.05$ using SPSS version 18 (SPSS for Windows, 2008, SPSS Inc., Chicago, IL).

Results

In total, 13 subjects were eligible and 11 consented to participate. These 11 patients enrolled in and completed the program (mean age: 51.3, SD = 12.49; range: 29 to 66). In terms of ethnicity, 10 self-identified as white and 1 self-identified as First Nations. The mean education was greater than 15 years and the mean symptom duration was reported as greater than 5 years; every participant, except for 1, was married and the group reported an average relationship length in excess of 24 years (Table 1). In this sample, 46% reported working, 36% retired and 18% as student or other.

Of the 13 patients approached for this study, 11 enrolled which reflects positively on potential recruitment feasibility for the study. The patients readily underwent baseline and weekly assessments, as provided in their workbooks. Compliance with the protocol was excellent; the only missing data was upon termination in 3 of the 11 in completing the CPSI follow-up. Of these 3 men, 2 did not complete the full set of questions making their CPSI data void, while the third man could not be contacted. All patients completed the assigned short readings and were able to produce reaction records for weekly review. There were 3 missed appointments with 3 patients throughout the program, but all missed sessions were completed within a week of the previous appointment. All sessions were completed within the time suggested in the program (i.e., 50-70 minutes per

Table 1. Patient demographic information

	Age	Years of education	Length of CP/CPPS symptoms	Length of relationships with partners
Mean	51.30	15.50	5.42	21.85[M]
SD	12.49	2.84	3.06	11.51
Minimum	29.00	12.00	1.10	3.20
Maximum	66.00	21.00	10.00	39.00
Valid n	11	11	11	10

SD= Standard Deviation; [M]=Median value; CP/CPPS = chronic prostatitis/chronic pelvic pain syndrome.

visit). The use of multiple symptom scales was informative to patients and providers; these scales allowed patients to identify the functional aspects of constructs, like catastrophizing, by completing the associated scales.

Repeated measures ANOVA models showed the program was associated with significant linear reductions over the 8 weeks for McGill Pain ($p = 0.050$), disability ($p = 0.020$) and pain catastrophizing ($p = 0.005$), but not for depression ($p = 0.399$) or levels of perceived social support ($p = 0.532$) (Table 2). The follow-up planned comparisons for the significant psychosocial risk factor models indicated significant decreases in disability between the baseline assessments in sessions 4 to 8, consecutively (Table 3, Fig. 1). Pain was significantly reduced from baseline and sessions 4 to 7 and 8. Finally, similar to disability, catastrophizing was reduced significantly from baseline assessment from sessions 4-8.

The pretreatment NIH-CPSI baseline total score mean was 25.2 (moderately severe symptoms) out of a maximum value of 43 (SD = 10.21). We tallied the NIH-CPSI total baseline score and its domain scores, along with NIH-CPSI total and domain follow-up scores (n = 8) (Table 4). (Three patients did not complete the NIH-CPSI upon termination.) Patients reported an overall significant and clinically meaningful improvement of 7.25 points ($p= 0.007$). Patient self-reports also indicated significant improvements in the NIH-CPSI Pain domain from baseline to treatment completion

(3.38 points; $p = 0.015$), as well as the QoL Impact domain ($p = 0.013$). No significant reduction was reported for the NIH-CPSI Urinary domain scores ($p = 0.087$).

Correlations between the change scores for the NIH-CPSI Total score and its domains and the significantly reduced psychosocial risk factors were produced to test whether the magnitude of changes in any particular psychosocial risk factor was associated with corresponding reductions in the NIH-CPSI (Table 5). Due to NIH-CPSI sample size (n = 8), none of the correlations reached significance. However, it is interesting to note that these data suggest trends towards differential associations between risk factor reduction and NIH-CPSI changes over treatment. In particular, reductions in catastrophizing were most strongly associated with reductions in the NIH-CPSI Total and all domain reductions. Changes in disability and pain were also shown to have expected trends in associations, with reductions in each corresponding to reductions in NIH-CPSI scores.

Discussion

Although previous studies show psychosocial risk factors are associated with poorer CP/CPPS outcomes,[8,9] and programs have been suggested,[17] no clinical research has targeted such factors for changes. This feasibility study confirms that a psychosocial management program is potentially an effective and feasible management approach for men suffering with CP/CPPS. The program was associated with significant reductions in patient disability, pain and catastrophizing, as well as clinically meaningful reductions in NIH-CPSI total scores and particular domains of Pain and QoL Impact. Results also suggest that significant changes in disability, pain and catastrophizing can take about 4 sessions.

The non-significant correlational trends suggest that reductions in catastrophizing were most strongly associated with reductions in patient symptoms (NIH-CPSI). Repeated in a larger study, such results would mirror the studies showing catastrophizing as a prime target of psychosocial interven-

Table 2. Planned repeated measures ANOVA model output for all psychosocial risk factors

Model	Source	df	Mean square	F	Significance
Disability	Intercept	1	2457.778	7.702	.020
	Error	10	319.089		
McGill pain	Intercept	1	822.687	4.875	.049
	Error	10	168.754		
Catastrophizing	Intercept	1	2582.869	12.896	.005
	Error	10	200.291		
Dep symptoms	Intercept	1	310.869	.776	.399
	Error	10	400.824		
Social support	Intercept	1	195.091	.438	.532
	Error	10	445.069		

df: degree of freedom; Disability: Pain Disability Index (PDI); McGill Pain: McGill pain questionnaire (SF-MPQ); Catastrophizing: Pain Catastrophizing Scale (PCS); Dep Symptoms: Center for Epidemiological Studies in Depression Scale (CES-D); Social Support: Multidimensional Scale of Perceived Social Support (MSPPS).
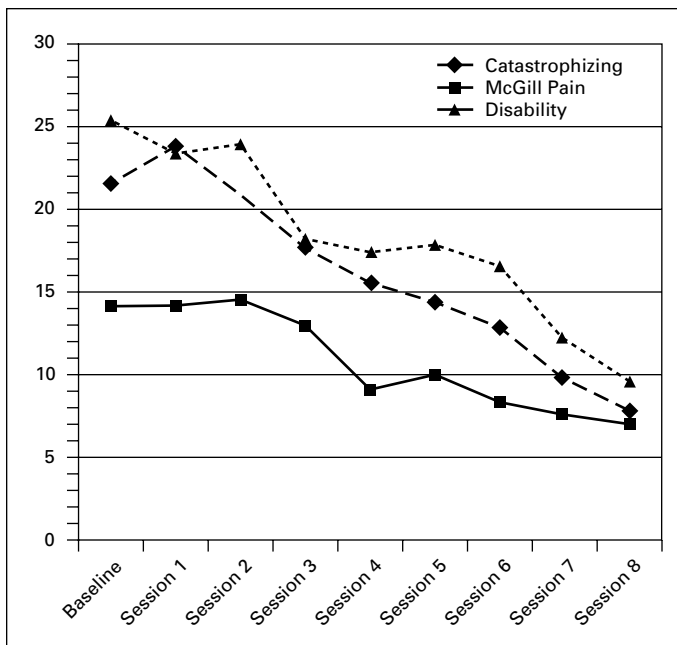
Fig. 1. Mean score changes in significant psychosocial risk factors from baseline to treatment termination (N=11).

Table 3. Planned repeated measures ANOVA model contrasts for disability, pain, and catastrophizing

Measures	df	F	Significance
Disability			
Session 1 vs B	1,10	1.502	0.248
Session 2 vs B		0.291	0.601
Session 3 vs B		3.997	0.073
Session 4 vs B		11.175	**0.007**
Session 5 vs B		6.582	**0.028**
Session 6 vs B		17.189	**0.002**
Session 7 vs B		12.395	**0.006**
Session 8 vs B		25.664	0.000
McGill Pain			
Session 1 vs B	1,10	0.000	0.990
Session 2 vs B		0.008	0.930
Session 3 vs B		0.447	0.519
Session 4 vs B		11.364	**0.007**
Session 5 vs B		3.850	0.078
Session 6 vs B		9.200	**0.013**
Session 7 vs B		9.097	**0.013**
Session 8 vs B		12.030	**0.006**
Catastrophizing			
Session 1 vs B	1,10	2.883	0.120
Session 2 vs B		0.052	0.825
Session 3 vs B		2.918	0.118
Session 4 vs B		5.657	**0.039**
Session 5 vs B		10.918	**0.008**
Session 6 vs B		13.012	**0.005**
Session 7 vs B		16.576	**0.002**
Session 8 vs B		22.774	**0.001**

df: degree of freedom; B: baseline assessment; Disability: Pain Disability Index (PDI); McGill Pain: McGill pain questionnaire (SF-MPQ); Catastrophizing: Pain Catastrophizing Scale (PCS); **BOLD**: significant finding.

tion in patient QoL[9] or pain reduction.[8] Indeed, catastrophizing is viewed as a prominent feature in CP/CPPS classification,[14] and is a common target in depression, anxiety and pain therapy.[15] Psychosocial management programs help urology patients identify, evaluate and reframe their catastrophizing tendencies in relation to symptoms of CP/CPPS.

Patients often have difficulty identifying, expressing or reporting the details of distressing experiences. To alleviate such pressure, patients were asked to complete a weekly pain, mood, social support and disability assessment. Encouraging patients to take an active role in their own treatment is an effective treatment process for chronic pain.[24] This management program appears to initiate a sense of hope by helping patients believe that they can manage their symptoms and move from feeling helpless to feeling empowered by establishing new wellness-focused coping strategies.

The results of this study are subject to specific limitations. Foremost, this uncontrolled study examined the feasibility of a psychosocial management program in a small cohort of specifically selected men suffering from refractory CP/CPPS and based on selection bias; their motivation may have been higher than the general population of men with CP/CPPS. This is important because patient expectations for treatment success for this type of therapy may be an important predictor of outcomes.[25,26] Previous treatment models have guided the number of sessions and, although it shows successful risk factor and symptom reductions, we cannot suggest this is a maximized treatment length. This is especially true with no short- or long-term follow-up of risk factor tracking or gains made in prostatitis symptom reduction in this study. Therapy

studies have long suggested that maintenance or follow-up sessions are crucial to maintaining positive gains.[27]

Future research should examine this therapy within a randomized controlled trial that employs 3- and 6-month follow-up assessments. Such a trial will allow for extensive testing of the risk factor reductions and the associations between changes in patients in a control condition. Future

Table 4. Change in the NIH-CPSI total and domain scores from baseline to treatment termination (n=8)

Measure	Mean	SD	Significance
NIH-CPSI Total baseline	23.50	10.73	.007
NIH-CPSI Total follow-up	16.25	7.42	
NIH-CPSI Urinary baseline	4.12	3.76	.087
NIH-CPSI Urinary follow-up	3.25	3.10	
NIH-CPSI Pain baseline	11.25	5.00	.015
NIH-CPSI Pain follow-up	7.87	5.08	
NIH-CPSI QoL impact baseline	8.12	3.68	.013
NIH-CPSI QoL impact follow-up	5.12	2.36	

NIH-CPSI: National Institutes of Health/Chronic Prostatitis Symptom Index (NIH-CPSI); QoL: Quality of Life. **BOLD**: significant result; SD: standard deviation.

Table 5. Correlations between the change in psychosocial risk factors and the NIH-CPSI from baseline to treatment termination

	NIH-CPSI total score change	NIH-CPSI Pain Domain change	NIH-CPSI Urinary Domain change	NIH-CPSI QoL Impact Domain change
Catastrophizing change	0.602	0.537	0.266	0.533
McGill Pain change	0.480	0.589	-0.031	0.372
Disability change	0.553	0.518	0.023	0.516

No correlations were significant at the 0.05 level; NIH-CPSI: National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI); Catastrophizing Change: Pain Catastrophizing Scale (PCS) scores; McGill Pain Change: Short-Form McGill Pain Questionnaire (SF-MPQ) scores; Disability Change: Pain Disability Index (PDI) scores.

designs may consider using a wait-list control, a more active treatment control (i.e., complete measures each week and meeting with nurse to check on these, but no therapy-based communications), with a treatment arm receiving the active therapy.

Conclusions

This study indicates that the psychosocial management program's goal of targeting and ameliorating empirically supported psychosocial risk factors in poor patient outcomes is effective and that noticeable reductions start to occur around session 4. Further, this management program is associated with clinically significant reductions in disease-specific symptoms (NIH-CPSI scores) for patients with moderately severe CP/CPPS.

Competing interests: None declared.

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Correspondence: Dr. Dean A. Tripp, Associate Professor, Departments of Psychology, Anesthesia & Urology, Queen's University, Kingston, ON K7L 3N6; fax: 613-533-2499; dean.tripp@queensu.ca; www.queensu.ca/psychology/painlab/home.html