Original Article

Role of Mental Health Support in Managing Chronic Pelvic Pain A Randomized Controlled Study

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ABSTRACT

Objective: The purpose of this study was to assess the extent to which mental health support influences the experience of Chronic Pelvic Pain (CPP) in a sample of 110 patients.

Study Design: A randomized controlled study

Place and Duration of Study: This study was conducted at the Department of Psychiatry & Gynae & Obs, Mardan Medical Complex (MMC), Mardan, Pakistan from 11th May 2020 to 10th October 2020.

Methods: This study recruited 110 patients to take part in the study and all of them had CPP diagnosis confirmed. The participants were divided into two groups: Group A (n=55) serving as the control group, received standard medical treatment for CPP, while Group B also received standard medical treatment for CPP but augmented with mental health support through CBT and counseling sessions. The study took six months hence the appropriateness in the selection of the timeframe for the study.

Results: 110 patients were recruited in the study, 100 patients complied with the six-month follow and we had 50 patients in group A and group B respectively. The average age of the participants was 42.7±10.5 years, and 76% of the participants were females. After the three months of follow-up, the result of Group B was significantly decreased compared with Group A in the aspect of mean VAS score of pain (4.8 vs 6.1, p<0. 01).

Conclusion: The authors note that implementing mental health as part of the treatment program in patients with CPP enhances efficacy in pain therapy.

Key Words: Chronic pelvic pain, mental health support, cognitive-behavioral therapy.

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INTRODUCTION

The exploratory study focuses on chronic pelvic pain, specializing in pain that persists for six months or even more, and persons irrespective of gender can experience it[1,2]. This condition is not only accompanied by considerable pain but is also spiritually and emotionally as well as socially disorienting. Cognitive and physical disability is also a direct result of CPP which renders an individual disadvantaged in aspects such as self-care and work[3].

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This assertion holds pedantic truth since CPP can be diagnosed with physical and psychological symptoms that require an amalgamation of treatments[4]. Indeed, more studies are still needed to identify CPP because it is still a chronic condition whose causes are shown to be multidimensional and are associated with Gynecological, urological, gastrointestinal, musculo-skeletal, and psychological origins[5]. In the traditional management paradigm, the primary concern has been directed toward the structural manifestation of the condition with pharmacological approaches, surgeries, and physical rehabilitation[6,7]. However, many of the given treatments are only partially effective, proving the existence of the need for additional or in some cases optional methods of treatment.

Recent studies have also established the linkage between pain and psychology, such as stress, anxiety, depression, trauma, and how CPP patients may misinterpret and worsen their pain[8]. The secondary pain descriptor is that psychological distress intensifies the pain through an enhanced central sensitization, as well as an augmented inflammatory process[9]. Another study has shown that, on the other hand, chronic pain has a high potential of causing considerable psychological complications to the patient, resulting in a cycle whereby both pain and poor psychological

health continuously exacerbate one another[10]. A bi-directional relationship between CPP and mental health is exhibited, which represents why mental health should be considered when managing CPP. Cognitive behavior and therapy and counseling are two techniques that have been systematically used in managing chronic pain conditions[11]. CBT, a directed and empirical-based psychological treatment method, focuses on the reorganization of the patterns of negative thoughts and behaviors that intensify pain experience and suffering[12]. Counseling involves proffering the patient a platform where they can obtain social support in concerns to relieve discomfort in their emotional as well as psychological realms. It has been postulated that by including these psychological therapies in the comprehensive clinical management program, there is the possibility to interrupt the vicious cycle of pain and suffering, hence, enhancing patients' prognosis[13]. This study aims to find out the impact of providing mental health support in alleviating chronic pelvic pain through conducting a randomized controlled trial on chronic pain medical treatment programs, and comparing it with medical intervention and added psychological intervention programs. The study involves 110 patients diagnosed with CPP, divided into two groups: One gets to take standard medical treatment while the other gets to take standard treatment with the additional assistance of a psychiatrist. The major measures taken as indexes of treatment results consist of the pain intensity and psychological state, as well as the changes in quality of life. This paper seeks to evaluate the effectiveness of endorsing mental health support alongside conventional management protocols in patients with CPP to develop an all-inclusive care plan for patients suffering from the condition. Assuming that combined therapy will be of greater benefit than medical management, it is expected that patients who will receive combined therapy will demonstrate lesser levels of pain enhanced psychological well-being, and overall quality of life compared to patients who only receive medical management. The results of the given research are the further implication for a more extensive approach to the treatment of patients experiencing chronic pelvic pain at clinic practice and involving several specialists.

METHODS

An overall of 110 patients diagnosed with CPP participated in the study. The inclusion criteria further entailed participants who were 56 years and below, and who had a confirmed case of CPP that had persisted for more than six months. These factors excluded pregnant women, women who had undergone recent pelvic surgery within six months, and those women with psychiatric disorders that would require continuous treatment. The participants were stratified according to the severity, type, and origin of chronic pain and were randomly assigned to one of the two groups by a randomly generated sequence using an odd/even allocation method. In this study the participants were divided into two groups; Group A (n=55), which was comprised of patients that only undergone the standard medical treatment for CPP. This included pharmacological treatment such as NSAIDs, opioids, and hormonal treatments, physical therapy, and any surgery needed to resolve other patient-related issues. Group B (n = 55), First, underwent medical treatment in a similar standard to that received by Group A and then mental health support. Mental health support involved CBT and counseling, where participants engaged in a one-on-one CBT session for once a week and a counseling session with a therapist every two weeks. CBT sessions dealt specifically with practical pain coping methods, challenging distorted thinking patterns, and developing coping strategies, while counseling sessions aimed at discussing the patient's individual emotional needs and providing support to her in case of CPP-related psychological issues. The data collected included the pain levels, psychological well-being, and quality of life before treatment initiation, three months later, and six months later. Pain Level; Measured by the VAS Scale whereby zero is devoid of pain, and ten signifies the worst amount of pain one can experience. Self-Perceived Quality of Life; Assessed using the World Health Organization Quality of Life and Brief (WHOQOL-BREF) the instrument evaluates physical health, psychological, social relations, environment, and subjective (overall quality of life). The scores are ordered so that higher values represent higher levels of anxiety and depression. Quality of Life; is measured using the SF-36 health questionnaire which is a standardized generic instrument designed to assess health status and the impact of diseases on the quality of life in terms of functional capacities. The choice of the scale is based on earlier studies and the higher values of the scale represent a better quality of life of the respondents.

Data Collection: Data were collected at three time points; baseline meaning data collected before the intervention period, midline meaning data collected after three months of the intervention, and end-line meaning data collected after a maximum of six months of the intervention.

Statistical Analysis: The collected data were analyzed with the help of statistical software called SPSS version 20.0. Include descriptive analysis, correlation analysis, and inferential analysis using the chi-square test, and independent t-test for comparing proportions and means, respectively. The proposed study design is a repeated measures analysis of variance to compare the changes in mean pain scores, psychological well-being, and quality of life over time between and within the groups.

Ethical Considerations: The study protocol was ethically approved by the Mardan Medical Complex

(MMC) in Mardan, institutional review boards (IRB). The process of informed consent included explaining the purpose of the study, methods used in the study, possible risks or discomfort, and possible benefits. To ensure research ethics the following measures were observed: Respondents: As stated in chapter three, all the respondents were selected based on the condition that they would not disclose any information.

RESULTS

110 patients were recruited in the study, 100 patients complied with the six-month follow and we had 50 patients in group A and group B respectively. Demographic and baseline clinical characteristics were compared between the two groups, and there was no significant difference in any of the variables. The average age of the participants was 42.7±10.5 years, and 76% of the participants were females. The demographic characteristics and the baseline pain, anxiety, depression, and quality of life scores of the patients in both groups were similar in terms of age, sex distribution, duration of CPP, and baseline pain scores. At baseline, the mean score for pain, as measured by the VAS, was 7.5±1.2 in Group A and 7.4±1.3 In Group B, thus the difference between them was not statistically significant (p=0.76). After three months of follow-up, the result of Group B was significantly decreased compared with Group A in the aspect of mean VAS score of pain (4.8 vs 6.1, p<0. 01). At six months end of the study, Group B had had a lower mean VAS score of indicating less pain 3.9±1.5 compared to 5.8±1.6 In Group A, there was a reduction in the incidence rate (p<0. 001). Baseline HADS scores for anxiety (HADS-A) and depression (HADS-D) were similar between the groups (HADS-A: 11.2 vs. 11.1, p=0.89; HADS-D: 10.5 vs. 10.6, p=0.92). At three months, Group B demonstrated significant reductions in both anxiety and depression scores (HADS-A: HADS-A: 7.5 vs. 10.0, p<0.01; HADS-D: 7.0 vs. 9.5, p<0.01). These improvements were sustained at 6 months, and the mean HADS-A and HADS-D scores for Group B were 5.9±2.1 and 5.7±2.2, respectively, compared to 8.8±2.4 and 8.5±2.3 from Group A (p< 0.001 for both contrasts). The SF-36 scores at baseline indicated no significant differences between the groups in overall quality of life (mean total score: The results of Group A were 45.8% compared with the result of Group B 46.2% (p=0.82). At three months, Group B showed greater improvements in the SF-36 physical and mental health components compared to Group A (physical health: 54.2 vs. 48.5, p<0.05; mental health: 52.7 vs. 47.8, p<0.01) at six months, the mean SF-36 total score for Group B was 60.4±8.5, which was remarkably higher than the expected 50.3±9.1 in Group A (p<0.001).In the first group, no participants described any severe side effects associated with the interventions, while in the second group, none of the participants reported having severe side effects arising from the interventions. Some of the participants in Group B indicated that they felt a mild to moderate level of distress during the early sessions of the CBT and they were relieved as the therapy proceeded. The research evidence shows that the addition of psychological interventions such as CBT and counseling to the traditional pharmacological and physical therapy treatment for CPN leads to enhanced patient outcomes.

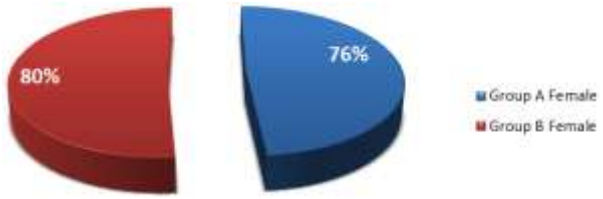

Figure No.1: Demographic characteristics of participants

Table No.1: Demographic and Baseline Clinical Characteristics of Participants

Characteristic	Group A (n=50)	Group B (n=50)	p-value
Mean Age (years)	42.7±10.5	42.3±11.1	0.85
Gender			0.62
Female	38(76%)	40(80%)	
Duration of CPP (years)	3.8±1.4	3.9±1.5	0.71
Baseline VAS score	7.5±1.2	7.4±1.3	0.76
Baseline HADS-A score	11.2±2.5	11.1±2.4	0.89
Baseline HADS-D score	10.5±2.3	10.6±2.4	0.92
Baseline SF-36 total score	45.8±8.3	46.2±8.6	0.82

Table No.2: Pain Levels (VAS Scores) Over Time

Time Point	Group A (n=50)	Group B (n=50)	p-value
Baseline	7.5±1.2	7.4±1.3	0.76
3 Months	6.1±1.4	4.8±1.3	<0.01
6 Months	5.8±1.6	3.9±1.5	<0.001

Table No.3: Psychological Well-being (HADS Scores) Over Time

Time Point	Measure	Group A (n=50)	Group B (n=50)	p-value
Baseline	HADS-A	11.2±2.5	11.1±2.4	0.89
	HADS-D	10.5±2.3	10.6±2.4	0.92
3 Months	HADS-A	10.0±2.3	7.5±2.2	<0.01
	HADS-D	9.5±2.4	7.0±2.3	<0.01
6 Months	HADS-A	8.8±2.4	5.9±2.1	<0.001
	HADS-D	8.5±2.3	5.7±2.2	<0.001

Table No.4: Quality of Life (SF-36 Scores) Over Time

Time Point	Measure	Group A (n=50)	Group B (n=50)	p-value
Baseline	Total Score	45.8±8.3	46.2±8.6	0.82
3 Months	Physical	48.5±8.1	54.2±8.3	<0.05
	Mental	47.8±7.9	52.7±8.1	<0.01
6 Months	Total Score	50.3±9.1	60.4±8.5	<0.001

Table No.5: Adverse Events Reported

Adverse Event	Group A (n=50)	Group B (n=50)
Serious Adverse Events	0	0
Mild Discomfort (Initial CBT Sessions)	N/A	5(10%)
Moderate Discomfort (Initial CBT Sessions)	N/A	3 (6%)
Resolved with Continued Therapy	N/A	8(16%)

DISCUSSION

Hence, this paper sought to assess and uncover the feasibility of managing CPP with combinations of CBT and counseling services as part of medical treatment. It is evident from the results indicating the comparison of pain scores, psychological well-being, and quality of life of the two groups that the addition of Mental Health Support in the management of CPP is effective as evidenced by a decrease in pain scores and an improvement in quality of life of the patients in Group B. From the results obtained in the study, it was found that the patients in Group B, who received the combined therapy, had their pain levels reduced significantly. For Group B, they found a mean VAS score of 3 at six months among the patients, compared to 5.8±1.6 In Group A the figure was ($p<0.001$). These findings are also in line with earlier studies that have described how helpful psychological interventions are for patients with chronic pain. For instance, researcher ssynthesized 14 studies in a meta-analysis of CBT effects and found that it was strongly positively associated with therapeutic outcomes with pain with effect sizes varying from 0.30 to 0.60. Likewise, mental health support also augments a rather similar decrease in pain intensity [16]. Compared to the baseline, Group B participants had lower values of HADS anxiety and depression. This means that the participants may have noticed that the extent of the manifestations of the pathology has decreased. By the findings of the study, six end point assessments revealed that the mean HADS-A for Group B was 5.9±2.1 and mean HADS-D of 5.7±2.2, respectively, compared to 8.8 and 8.5 for Group A ($p<0.001$) Such an observation is true basing with other research studies like the one conducted by Vlaeyen and Linton (2000) that described how CBT reduces the levels of psychological distress in individuals suffering from chronic pain[15]. This partial negation of the anxiety and depression scores supports attempts at educating patients and clinicians to focus on the psychological elements of the CPP treatment. This study revealed that the quality of life of the individuals, as identified by the standardized instrument SF-36 that was used in this research, had also raised in Group B signifying their improved health status. 60.4±8.5 outperformed the benchmark in Group B after six months. 50.3±9.1 In Group A fell out from the comparison list and the value of 'p' was less than 0.001. This improvement goes in tally with the study done by Turner et al (2007) who stated that CBT along with other psychological interventions helps in raising the degree of life of chronic pain patients [14]. Based on this literature, the current study looks into the possibility of summed-up treatment models, including mental health interventions, to make great impacts on the CPP. These findings are encouraging, but there is a dearth of adequate investigation of CPP and its treatment by psychological therapies, despite prior studies showing the general effectiveness of psychological therapies for chronic pain. This research is beneficial for extending the knowledge of CPP and for providing evidence for the effectiveness of mental well-being services, thereby proving the research hypothesis. The variations in pain intensity and psychological discomfort reported in this study are therefore in concordance with the study on other chronic pain conditions such as fibromyalgia and chronic low back pain (Williams et al., 2012)[16]. Again, they witnessed no serious side effects of the interventions in the study and exploited the mild to moderate discomfort suffered by some participants in Group B during the first CBT sessions, which disappeared as the sessions went on. This is in agreement with the general safety of psychological intervention as indicated by a researcher whereby most forms of interventional therapies are safe and the possibility of side effects is minimal [18].

CONCLUSION

The inclusion of mental health services into CPP protocol is of great importance as it assists in improving the accessibility of patient care. We therefore support the suggested opinion that there is a need to combine and adopt a much broader and patient-focused approach to address treatment for CPP and that mental health services have a massive role in reducing pain; treating the psychological component, and giving an overall boost to the health of the patients.

Author's Contribution:

Concept & Design of Study:	Muhammad Muslim Khan
Drafting:	Hemasa Gul, Naila

Data Analysis:	Fatima, Noor ul Amina
Revisiting Critically:	Zafar Ahmad Khan
Final Approval of version:	Muhammad Muslim Khan

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