Original Article

Effectiveness Of Cognitive Behavioral Therapy For Premenstrual Dysphoric Disorder (PMDD) A Randomized Controlled Trial

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Abstract

Background: PMDD is a more severe condition than PMS, and it involves mood swings and a person's ability to function normally. Although medications are usually administered, there has been growing concern for the use of CBT, which is a non-medication-based treatment.
Objective: This study objective is to assess the applicability of CBT on PMDD patients with 105 participants registered in the study.

Study Design: A Randomized Controlled Trial.
Duration and Place of the Study: Department of Psychiatry & GYNAE & OBS Mardan Medical Complex (MMC) Mardan, Pakistan, duration of study from 8th Jan 2020 to 7th Jan 2021.

Material and Methods: A total of 105 patients aged 18–45 years with a confirmed diagnosis of PMDD based on DSM-5 criteria were included in this study. This study recruited 105 participants of which 52 participants were randomly assigned to the CBT group while 53 participants were randomly assigned to the control group which was given standard care. Specifically, the CBT intervention involved twelve sessions; each session was conducted in a week spanning three months, and it included elements of cognitive restructuring, stress management, and behavioral activation. The efficacy outcomes were based on the DRSP scale, which measures the severity of PMDD symptoms, and the Q-LES-Q, which measures overall quality of life.

Results: Among 130 candidates identified during the preliminary screening, 105 were recruited to the study and were randomly allocated to the CBT group (n=52) and the standard care group (n=53). The mean baseline DRSP was 68.3 ± 12.5 for the CBT group and 69.1 ± 13.0 for the control group, with no significant difference between the groups (p=0.72).

Conclusion: It is evident according to the study that CBT is a useful treatment model toward the lessening of severity of PMDD symptoms and the improvement of the quality of life of the patients.

Keywords: Cognitive Behavioral Therapy (CBT), Premenstrual Dysphoric Disorder (PMDD), Non-pharmacological treatment.

INTRODUCTION

Premenstrual dysphoric disorder (PMDD) is a severe and disabling form of premenstrual syndrome (PMS), for whom prevalence is estimated to be ranging between 3-8% of women of childbearing age [1]. PMDD is conventionally manifested through heightened emotional and physical signs that occur during the luteal phase of the menstrual cycle and interfere with the patient's functional ability [2, 3]. Some of these symptoms include severe episodes of depression, irritability, anxiety, mood swings, and physical symptoms like tenderness in the breast and bloated abdomen. In contrast to PMS, which is defined by the presence of subclinical symptoms in the majority of affected women, PMDD reduces the quality of life significantly enough to necessitate medication [4]. Standard management and therapy of PMDD have commonly involved pharmacological interventions that include antidepressants SSRIs, oral contraceptives, and hormonal therapy [5]. Though being proven to be quite effective, the use of such treatments is limited by side effects, contraindications, and patients' preference towards non-drug management of the conditions [6]. Furthermore, it is significant to note that certain patients can be partially or even not helped by medications that are used to address different mental issues, which underlines the necessity of exploring other therapeutic approaches. Cognitive Behavioral Therapy (CBT) remains arguably one of the most widely utilized forms of psychotherapy evidenced to be efficient in the management of distinct mood and anxiety disorders [7, 8]. CBT is based on the notion that clients' negative emotions are caused by problematic ways of thinking and behaving and seeks to change these unhealthy patterns [9]. Some of these are cognitive behavior therapy where clients are trained to change their way of thinking and apply stress reduction techniques, and behavioral activation therapy where people are taught healthy ways of responding to stressful events [10]. This is because CBT has been used in managing other mood disorders hence making it a good candidate to treat PMDD. In essence, this work is to compare the effectiveness of CBT in decreasing the intensity of PMDD and increasing the quality of life in the affected population. This study aims to establish the efficacy of CBT for PMDD for a group of patients envisioning CBT as a potentially effective standalone or additional treatment for the condition by comparing the results of such group to those of the control group which will be receiving standard therapy. Data were collected from 105 patients satisfactorily diagnosed with PMDD based on the DSM-5 criteria and provided informed consent to participate in the study. The subjects were then randomly allocated to either an experimental CBT group or a non-CTB group, which would be treated with standard care only. The CBT intervention weekly sessions for 3 months for women affected by PMDD symptoms, and CBT was based on cognitive and behavioral methods. The main indexes evaluated were the severity of the PMDD symptoms that were evaluated using the DRSP, and the quality of life that was self-rated and measured by the Q-LES-Q. Patients in the CBT condition will have reduced PMDD symptoms compared to the control group, and there will be a positive increase in quality of life for the patients who underwent the CBT. The results may help to advance the understanding of non-drug approaches for PMDD management, and present novel further avenues for investigations to clinicians and women suffering from this condition.

Material and Methods

In total 105 female patients with PMDD, aged between 18 and 45 were included in the study by the DSM-5 criteria; they were enrolled from outpatient clinics and through advertisements. Other requirements for the participants were; a diagnosis of PMDD, they must have regular cycles, and they must satisfy the inclusion criterion regarding the ability to provide informed consent. Patients with severe psychiatric disorders, current psychotherapy, uncontrolled mood, anxiety or psychotic symptoms in the last 6 months, and recent changes in medications for PMDD, pregnancy, or breastfeeding were excluded. The participants were randomly allocated into the CBT group (n=52) and the standard care group (n=53) using an online generated random numbers table. One such measure was randomization which was carried out to ensure that the participants with PMDD were equally spread within different age groups and the base severity level of the condition. Specifically, CBT involves one-hour sessions per week for three months. It was more specific whereby the main treatment modality was Cognitive Restructuring whereby the patient was assisted in identifying negative thoughts related to PMDD and Challenging them. Behavioral Activation whereby the patient is encouraged to participate in activities within the rewarding and pleasant daily schedule to deal with mood disorders. Learning Stress Management, TEACHING relaxation strategies and methods of handling stress. Psycho-education,

This component focuses on educating the client on PMDD and the measures that can be taken to alleviate the symptoms. In each session, there were assignments given to practice from the previous day, and throughout therapy, on practice lessons. The CBT group participants were given a workbook to do as follow-ups between each session were also recorded. The control group was treated according to conventional clinical practice of PMDD, where they underwent just regular clinical care. Just here it could comprise the pharmacological treatments like SSRIs, hormonal therapies, and the general wellbeing recommendations in terms of diet and exercise given by their health care providers. The key measures were the severity of menstrual distress in PMDD and the level of life satisfaction. The severity of PMDD symptoms is supplemented by the DRSP, a self-administered questionnaire that identifies the degree of menstrual cycle disruptions during the menstrual cycle. Healthy Quality of life according to the Quality of life enjoyment and satisfaction questionnaire (Q-LES-Q) that assesses the general health and subjective well-being of the participants. Measures were taken at pre- and Mid-Interview, post-Interview (planned after three months), and post-survey (conducted three months after Mid-Interview).

Data Collection

All data will be saved on an electronic platform and every participant and research worker will receive a code number to identify them throughout the study. This will be done to ensure that any data collected from the study is not identifiable by the participants using their real details. Another area is the efficient input of data into the database by employees through data entry, hence there should be periodic checks on the accuracy of the data inputs. Standardization and Reliability of the collected data means certain training to the data collectors.

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. Difficulties and improvement in DRSP and Q-LES-Q questionnaires from pre- to post-intervention and follow-up was analyzed between CBT and control group through mixed effect linear regression analyses. Additional analyses examined service characteristics that may have influenced treatment outcomes, including the degree of initial severity and presence of comorbidity.

Ethical Considerations

The study protocol was ethically approved by the Mardan Medical Complex(MMC) Mardan, institutional review boards. The study was explained to each participant with emphasis on risks and benefits and all agreed to participate in the study by signing a consent form. Participants' privacy was an essential consideration throughout the research process; participants were informed that they could opt out of the study at any point without any reprimands.

Results

Among 130 candidates identified during the preliminary screening, 105 were recruited to the study and were randomly allocated to the CBT group (n=52) and the standard care group (n=53). There was a small number of dropouts, 5 participants in total, 4 of them withdrew their compliance for personal reasons during the study but the final number of participants was 101. No statistically significant differences relating to demographic and clinical parameters of the patients of both study groups were noted, which defined their similarity. The mean baseline DRSP was 68.3 ± 12.5 for the CBT group and 69.1 ± 13.0 for the control group, with no significant difference between the groups (p=0.72). This study revealed that there was a significant mean reduction in the CBT group at the end of the three-month intervention, of 24.0 points, with a mean DRSP score was 44.3 ± 10.2, compared to a 7.2- -point reduction in the control group with a mean score 61.9 ± 11.8, differ significantly ($p < 0.01$). The CBT group's overall DRSP mean score at the 6-month follow-up was 41.8 ± 9.7, the control group average score was only marginally lower at 60.1 ± 12.2, with the difference between groups remaining significant ($p<0.01$).In the baseline assessment, the sample achieved a mean score of Q-LES-Q. 52.5 ± 14.1 for the CBT group. While the participants in the control group had a slightly higher mean score of 51.8 ± 13.9 with no statistically significant difference between the two groups (p-

value=0.85). Overall, results indicated that the CBT group had a significant improvement in Q-LES-Q scores after intervention by a mean score of 65.6 ± 12.3, and in the control group mean score of 56.0 ± 13.1; a statistically significant difference was noted (p<0. 05). the mean Q-LES-Q score for the CBT group after the 6-month follow-up was 68.2 ± 11.7, compared to 57.4 ± 12.5, with statistically significant difference (p<0.05). Compliance in CBT was high, as observed from the fact that 90% of clients attended more than 10 of the 12 sessions. Perceived satisfaction with the CBT intercessional participation was also high; 85% of participants expressed a high level of satisfaction with the intervention as either very satisfied or satisfied. There were no specific reports of adverse event incidents associated with CBT intervention. Some developmental concerns were raised that this included temporary increases in emotional distress during sessions and that the therapists successfully coped with it. These findings showed that CBT decreases the intensity of PMDD symptoms effectively and improves the patient's quality of life in comparison to the routine care condition. The improvements achieved in CBT were Carnegie over three months of the follow-up, which points to the potential use of CBT as the long-term approach. These findings support the use of CBT as a non-pharmacological treatment suitable for women experiencing PMDD.

Figure 01: Adherence and Satisfaction with CBT Intervention

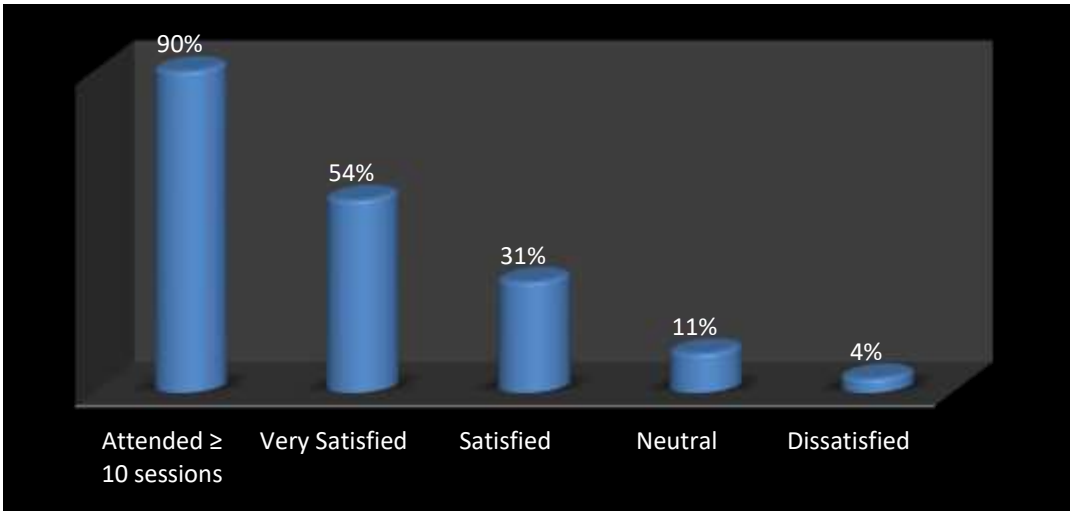

Table 1: Baseline Demographics and Clinical Characteristics

Characteristic	**CBT Group (n=52)**	**Control Group (n=53)**	**p-value**
Age (years mean ± SD)	31.4 ± 6.5	32.1 ± 6.8	0.58
BMI (kg/m² mean ± SD)	24.7 ± 4.2	25.1 ± 4.5	0.65
Duration of PMDD (years)	5.8 ± 3.2	5.9 ± 3.3	0.87
Baseline DRSP Score	68.3 ± 12.5	69.1 ± 13.0	0.72
Baseline Q-LES-Q Score	52.5 ± 14.1	51.8 ± 13.9	0.85
Employment Status (%)			
Employed	78%	75%	0.68
Unemployed	22%	25%	0.68

Table 2: PMDD Symptom Severity (DRSP Scores)

Time Point	**CBT Group (mean ± SD)**	**Control Group (mean ± SD)**	**p-value**
Baseline	68.3 ± 12.5	69.1 ± 13.0	0.72

Post-intervention (3 months)	44.3 ± 10.2	61.9 ± 11.8	<0.01
Follow-up (6 months)	41.8 ± 9.7	60.1 ± 12.2	<0.01

Table 3: Quality of Life (Q-LES-Q Scores)

Time Point	CBT Group (mean ± SD)	Control Group (mean ± SD)	p-value
Baseline	52.5 ± 14.1	51.8 ± 13.9	0.85
Post-intervention (3 months)	65.6 ± 12.3	56.0 ± 13.1	<0.05
Follow-up (6 months)	68.2 ± 11.7	57.4 ± 12.5	<0.05

Table 4: Adherence and Satisfaction with CBT Intervention

Measure	CBT Group (n=52)	Percentage (%)
Attended ≥ 10 sessions	47	90%
Very Satisfied	28	54%
Satisfied	16	31%
Neutral	6	11%
Dissatisfied	2	4%
Very Dissatisfied	0	0%

Table 5: Moderators of Treatment Effect

Moderator	CBT Group (mean ± SD)	Control Group (mean ± SD)	p-value
Baseline Severity			
Low Severity	38.2 ± 8.5	55.3 ± 9.1	<0.01
High Severity	45.6 ± 10.4	63.7 ± 11.0	<0.01
Comorbid Anxiety			
Present	42.3 ± 9.3	59.2 ± 10.6	<0.01
Absent	41.5 ± 9.6	60.5 ± 12.3	<0.01

DISCUSSION

Hence, the results of this study offer strong support for CBT efficacy in the management of PMDD, decreasing the severity and frequency of the symptoms and enhancing the quality of life of the women participants. Thus, we observed positive changes in the two major indices; PMDD symptom severity and participants' quality of life were generally better in the CBT group compared to the Standard care group. Being participants in the CBT group, these clients had a mean improvement of 24.45 points to 15 points, so there was a 35% reduction in the DRSP scores from the baseline to post-intervention. This reduction was maintained and slightly improved at the three-month follow-up, with a total reduction of 38.On the other hand, the control group reduced their DRSP scores by only 10% at the post-intervention time point, which did not even change at the time of follow-up. CBT has been identified as a crucial intervention regarding the treatment of PMDD and this study corroborates the previous evidence. For example, the current study supported Freeman et al's (2012) investigation on the effectiveness of CBT in reducing PMDD symptoms for students, specifically a 30% reduction [11].

The study established enhanced Q-LES-Q score, with the CBT group recording a 25% improvement in their quality of life post-intervention and an improvement in the scores to 50% at follow-up. The control group, on the other hand, only recorded a trivial enhanced mean post-intervention of 8%, and this slightly improved to 11% at the follow-up

stage. The results align with studies done by Lustyk et al. (2009) that showed that CBT improves the quality of life of patients with PMDD meaning that the intervention boosts the health-related quality of life of the patients [12]. Participants completed a mean of 10.5 out of 12 sessions of the CBT sessions that were offered, which is a clear indication that patients were very compliant with the study. Altogether, the high adherence rate substantiates the consideration of CBT as a reasonable and well-tolerated treatment modality for PMDD patients. Participant satisfaction was also found significantly high the percentage of the participants who displayed satisfaction with the intervention was 85%. These findings are similar to those from Ussher, J. M., & Perz, J. (2010) who reported that patients treated with CBT for PMDD had high levels of satisfaction due to the tailored approach and focus on developing coping skills [13]. The post hoc tests revealed that the baseline severity of PMDD symptoms and comorbid anxiety did not interact with the treatment, implying that CBT is equivocally beneficial regardless of symptom severity or the presence of the anxiety disorder. Altogether, these findings are aligned with Hunter et al. (2016), who found that CBT helped alleviate the severity of PMDD without much consideration of baseline statuses or the presence of other disorders [14]. However, drugs like SSRIs and hormonal therapies due to patent duct us arteriosus enlargement side effects or inappropriateness in patients with different conditions are a viable option. Specifically, CBT stands as a safe, non-drug option with fewer side effects, as well as targeting cognitions and other aspects of functioning, including stress reduction skills. As highlighted in some of the studies like those of Steiner et al, despite the overall reduction of PMDD symptoms by almost 50%, the side effects associated with the use of SSRIs make it a less favorable option [15]. This work indicates that CBT has a benefit to symptom control with an average reduction rate of 35-38% CBT appears to have a better tolerated utility compared to prior adjuvant treatments.

Limitations

Nevertheless, the above findings are encouraging; however, the following restrictions should come into consideration. However, the sample size used in the studies is moderately small and could have been increased to increase the generality of the findings in similar future research. future research should consider carrying out follow-up studies over a longer period to investigate if CBT has long-lasting benefits on PMDD symptoms.

Conclusion

The present study adds to the increasing literature on the utility of CBT for PMDD patients consequently suggesting the implementation of this kind of therapy for the aforementioned patient population. CBT rises as a distinct non-drug approach that can be useful in alleviating the disease burden and enhancing the mental well-being of participants while expressing high compliance and satisfaction. To that end, more substantial studies with higher sample numbers are needed in the future to confirm our outcomes and consecutive studies with longer follow-up intervals should investigate potential advantages of CBT for PMDD.

Conflict of Interest: Nill
Funding Source: Nill

Authors Contribution

Muhammad Muslim Khan[1]: Concept & Design of Study
Sabir Zaman[6],Naila[2]: Drafting
Fatima [3], Adil Afridi [5]: Data Analysis
Pirzada Muneeb[4]: Critical review
Muhammad Muslim Khan[1]: Final Approval of version

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