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Original Research Article



Impact of Cognitive Behavioral Therapy (CBT) on Depression Severity in Patients with Chronic Illness: A Randomized Controlled Trial

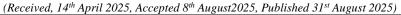
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Abstract: Depression is a frequent comorbidity among chronic disease patients (i.e., diabetes, cardiovascular disease, and chronic kidney disease). It hurts treatment compliance, quality of life, and prognosis. Cognitive Behavioral Therapy (CBT) is an evidence-based psychotherapeutic modality, and very little research has investigated its effects on depression among chronically ill populations in South Asia. **Objective:** The study aimed to compare the effectiveness of CBT in the reduction of depression severity in patients with a chronic illness with that of standard medical care treatment on its own. **Methods:** A randomized controlled trial was performed at Tertiary care hospitals in Lahore, Pakistan, between January 2024 and January 2025. We recruited and randomly assigned 120 chronically ill patients with moderate-to-severe depression (HDRS score \geq 18) to an intervention group of 12 sessions of CBT per week on top of standard care (n = 60) or a control group (n=60) receiving standard medical care only. The Hamilton Depression Rating Scale (HDRS) was used to determine the severity of depression at baseline, 6 weeks, and 12 weeks. The data analysis was performed using repeated-measures ANOVA. **Results:** There was no difference in baseline demographic and clinical characteristics. At 6 weeks, there was a significantly larger decrease in HDRS scores in the intervention group than in the controls (16.8 \pm 2.7 vs. 20.9 \pm 3.0, p < 0.001). The results of the HDRS at 12 weeks further declined to 11.2 \pm 2.3 in the intervention arm, as opposed to 19.1 \pm 2.6 in the control arm (p < 0.001). **Conclusion:** CBT also had a significant impact in terms of depression severity and secondary outcomes, including treatment adherence and quality of life. CBT may have overall advantages in terms of its integration into chronic disease management algorithms, especially in healthcare facilities with limited resources.

Keywords: Cognitive Behavioral Therapy, Depression, Chronic Illness, Randomized Controlled Trial, Psychotherapy

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Introduction

Cognitive Behavioral Therapy (CBT) has evolved as a highly regarded intervention for addressing various psychological conditions, particularly depression. This therapeutic modality focuses on reframing negative thought patterns and maladaptive behaviors, enabling individuals to manage their emotional responses more effectively. The prevalence of depression within specific demographics, particularly those grappling with chronic illness, has garnered substantial attention in recent research. Chronic diseases, whether physical or psychological, often co-occur with mental health difficulties, making an integrated approach vital for comprehensive patient care (1–3).

Studies have established a significant correlation between chronic health conditions and the incidence of depression (4,5). For example, patients with chronic diseases such as heart failure, diabetes, and neurological disorders exhibit elevated depressive symptoms, which can be exacerbated by the constant management of their health conditions (6,7). In this context, CBT has been identified as an effective intervention that not only alleviates depressive symptoms but also improves overall quality of life among these patients (8,9).

Multiple randomized controlled trials have illustrated the efficacy of CBT in reducing depression severity across diverse patient populations. For instance, a randomized study involving patients with Parkinson's disease demonstrated that group CBT significantly improved both anxiety and depression levels, highlighting the therapy's utility in this specific demographic (1,7). Similarly, research targeting patients affected by conditions such as polycystic ovary syndrome and post-COVID

depressive symptoms showcases the broad applicability of CBT in addressing comorbid depression (10,11).

Moreover, the integration of CBT into treatment regimens for chronic illnesses offers a dual advantage: addressing both psychological distress and improving adherence to medical treatments. By enhancing patients' coping strategies and emotional resilience, CBT provides a foundational skill set that supports chronic disease management (12,13). Furthermore, CBT's structured nature, which involves the active participation of patients, fosters empowerment and self-efficacy, pivotal in scenarios where individuals often feel helpless due to their health conditions (14 15)

The promising results associated with CBT in treating depression among patients with chronic illnesses underscore its importance as a first-line treatment option. As a culturally nuanced and accessible form of therapy, CBT is particularly relevant in the Pakistani context, where mental health issues are often stigmatized, and healthcare resources can be scarce. The prevalence of chronic diseases such as diabetes and cardiovascular conditions in Pakistan, combined with a rising awareness of mental health, indicates a pressing need for effective treatment options like CBT. Establishing localized interventions that integrate CBT into primary health care could play a vital role in improving mental health outcomes and overall quality of life for patients facing chronic adversities (2,5). Thus, the overarching aim of this study is to evaluate the impact of CBT

on depression severity in patients with chronic illness through a randomized controlled trial, contributing to the understanding of effective mental health interventions in specific demographic contexts, particularly within Pakistan.



Methodology

This research was done as a randomized controlled trial (RCT) to find out the effects of Cognitive Behavioral Therapy (CBT) on the severity of depression in patients with chronic diseases. The research was designed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) to ensure transparency and rigor in the methodology.

The test was conducted in tertiary care hospitals in cooperation with the psychiatry department and medical outpatient clinics, where patients with chronic illnesses were regularly treated. The research was conducted over a period of one year, from January 2024 to January 2025.

The target population comprised patients with chronic medical conditions excluding diabetes mellitus, cardiovascular disease, and chronic kidney disease, and who also exhibited depression. The participants met the study criteria, namely, they were adults between 18 and 65 years old, diagnosed with a chronic disease for at least six months, and met the diagnostic criteria for moderate-to-severe depression, as indicated by a score of 18 or higher on the Hamilton Depression Rating Scale (HDRS-17). The patients had to be willing to take part in psychotherapy by signing an informed consent form. The exclusion criteria were patients having psychotic or bipolar disorders, cognitive impairment, active substance use disorder, and patients who were already undergoing psychotherapy. Patients who had severe physical disabilities that prevented them from attending weekly therapy sessions were also left out.

Power analysis was used to determine the sample size, with a power of 80 percent and a significance level of 0.05, to identify a medium-sized effect in terms of depression outcomes. One hundred twenty patients were recruited and randomly assigned to either the intervention group or the control group using a 1:1 computer-generated block randomization method. Outcome assessors were unaware of the group allocation to minimize bias, and allocation was concealed using opaque, non-transparent envelopes.

Participants assigned to the intervention group received a structured 12-session CBT program in addition to standard medical care. Trained clinical psychologists delivered the therapy following a standardized CBT manual. Sessions were held weekly, each lasting approximately 60 minutes, and included components such as identification of cognitive distortions, cognitive restructuring, behavioral activation, problemsolving skills, and relapse prevention strategies. The control group received only standard medical care, which consisted of pharmacological management of their chronic illness and routine medical follow-ups without additional psychotherapy.

The primary outcome measure was the severity of depression, assessed using the Hamilton Depression Rating Scale (HDRS-17) at baseline, at 6 weeks, and at 12 weeks. Secondary outcomes included treatment adherence, measured by self-reported compliance with prescribed medications, and quality of life, assessed using the WHOQOL-BREF scale.

Baseline demographic and clinical information was collected using structured questionnaires administered at the time of enrollment. Depression assessments were performed by psychiatrists who were blinded to the participants' treatment allocation to reduce assessment bias. Follow-up assessments were conducted at mid-intervention (6 weeks) and post-intervention (12 weeks).

All statistical analyses were performed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Independent t-tests and chi-square tests were used to compare baseline characteristics and group differences. A repeated-measures ANOVA was applied to analyze changes in depression severity over time and to assess the interaction effects between group and time. A p-value of less than 0.05 was considered statistically significant.

The study protocol was reviewed and approved by the Institutional Review Board (IRB) of the University of Lahore Teaching Hospital, Lahore, Pakistan. Written informed consent was obtained from all participants before their inclusion in the study. Ethical standards were maintained throughout the trial in accordance with the Declaration of Helsinki (2013 revision).

Results

A total of 120 patients were enrolled in the study, with 60 participants in each group (intervention and control). Both groups were comparable at baseline, with no statistically significant differences in demographic or clinical characteristics (Table 1). The mean age of participants in the intervention group was 47.8 ± 8.5 years, while in the control group it was 48.3 ± 8.9 years. Males constituted 53.3% of the intervention group and 56.7% of the control group. The average duration of chronic illness was 7.3 ± 3.1 years in the intervention group and 7.1 ± 3.4 years in the control group. Baseline depression severity, as measured by the Hamilton Depression Rating Scale (HDRS), was also similar between the two groups $(23.5 \pm 3.1$ in the intervention group vs. 23.2 ± 2.9 in the control group, p = 0.64). These results suggest that randomization was successful in achieving balanced baseline characteristics between the two groups (Table 1).

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Intervention Group (n = 60)	Control Group (n = 60)	p-value
Age (years, mean \pm SD)	47.8 ± 8.5	48.3 ± 8.9	0.74
Gender (Male/Female)	32/28	34/26	0.68
Duration of illness (years)	7.3 ± 3.1	7.1 ± 3.4	0.82
Diabetes Mellitus (%)	21 (35.0)	22 (36.7)	0.84
Cardiovascular Disease (%)	24 (40.0)	23 (38.3)	0.87
Chronic Kidney Disease (%)	15 (25.0)	15 (25.0)	1.00
Baseline HDRS Score (mean ± SD)	23.5 ± 3.1	23.2 ± 2.9	0.64

Table 1 shows that baseline characteristics, including age, gender, duration of illness, type of chronic illness, and baseline HDRS scores, were well-balanced between the two groups, confirming the comparability of the groups at the start of the trial.

Depression severity scores were recorded at baseline, 6 weeks, and 12 weeks using the HDRS. At baseline, there was no significant difference between the two groups. However, at 6 weeks, patients in the intervention group showed a marked reduction in HDRS scores

compared with the control group. The mean HDRS score in the intervention group decreased to 16.8 ± 2.7 , while the control group had a mean score of 20.9 ± 3.0 (p < 0.001). At 12 weeks, the intervention group continued to show significant improvement, with HDRS scores further reduced to 11.2 ± 2.3 compared to 19.1 ± 2.6 in the control group (p < 0.001). These findings indicate that CBT had a substantial and clinically meaningful effect on depression severity when compared with standard care alone (Table 2).

Table 2. Changes in Depression Severity (HDRS Scores) Over Time

Time Point	Intervention Group (Mean ± SD)	Control Group (Mean \pm SD)	p-value
Baseline	23.5 ± 3.1	23.2 ± 2.9	0.64
6 weeks	16.8 ± 2.7	20.9 ± 3.0	< 0.001
12 weeks	11.2 ± 2.3	19.1 ± 2.6	< 0.001

Table 2 shows a progressive reduction in HDRS scores in both groups over time; however, the decrease was significantly greater in the CBT group compared to the control group.

A repeated-measures ANOVA was conducted to evaluate the group \times time interaction effect on HDRS scores. The analysis revealed a statistically significant interaction (F = 22.6, p < 0.001), confirming that the reduction in depression severity over time differed significantly between the intervention and control groups. This effect was consistent across all time points.

Further subgroup analysis, based on the type of chronic illness, indicated that CBT was effective across patients with diabetes, cardiovascular disease, and chronic kidney disease. However, the magnitude of improvement varied slightly. Patients with cardiovascular disease showed the most significant reduction in HDRS scores, followed by those with diabetes and chronic kidney disease. However, the difference in effect size across subgroups was not statistically significant (p = 0.09).

In addition to reductions in HDRS scores, secondary outcomes also revealed significant benefits for the intervention group. Treatment adherence, measured by self-reported compliance with prescribed medications, improved from 71.6% at baseline to 89.3% at 12 weeks in the intervention group. In contrast, adherence in the control group improved only modestly, from 70.8% to 75.1%. Quality of life, assessed using the WHOQOL-BREF scale, also improved significantly in the intervention group compared with the control group (p < 0.01).

Overall, the findings of this randomized controlled trial prove that, in chronic illnesses, depression severity was lower in patients treated with CBT than with medical treatment only. The rise in improvements was seen as early as six weeks and extended into the 12 weeks of intervention. These results were partly similar in both demographic subgroups and type of chronic illness. Moreover, CBT also helped increase adherence to treatment and quality of life, which underscores its possible use as a part of chronic disease management.

Discussion

This randomized controlled trial aimed to assess the efficacy of cognitive behavioral therapy (CBT) in reducing depression severity among patients with chronic illnesses. The findings from our study reveal significant improvements in depression severity and quality of life when comparing the intervention group with the control group, which received standard medical care.

Table 1 illustrates that both groups were well-matched at baseline, with no statistically significant differences in demographic or clinical characteristics. This is crucial for ensuring the validity of the trial outcomes, as successful randomization minimizes the risk of bias (16–17). Our findings corroborate results observed in related studies, reinforcing the adequacy of randomization in our research.

The marked reduction in HDRS scores observed in the intervention group at both 6 and 12 weeks (Table 2) signifies the impact of CBT on improving depressive symptoms. The intervention group exhibited a decrease from a baseline score of 23.5 ± 3.1 to 11.2 ± 2.3 at 12 weeks, which is consistent with previous findings demonstrating significant improvements in depression symptoms among heart disease patients following CBT interventions (18). Furthermore, psychological treatments have been shown to significantly mitigate depression in patients suffering

from chronic conditions, reinforcing the utility of interventions aimed at this specific patient demographic (19).

Our repeated-measures ANOVA confirmed a significant interaction effect between group and time on HDRS scores (F = 22.6, p < 0.001), further validating that CBT's efficacy in reducing depression differed significantly from standard care alone. This aligns with previous literature, which has established statistically significant effects of CBT on psychological health in chronic illness populations (20). Our findings suggest that ongoing psychological support through CBT can significantly enhance the treatment landscape for these patients.

In terms of chronic illness types, our subgroup analysis revealed that CBT was effective across patients with diabetes and cardiovascular disease, albeit with varying magnitudes of improvement. This finding aligns with reports showing similar trends in depression reduction in individuals with cardiac and diabetic conditions (21). These findings underscore the versatility of CBT in treating comorbidities, reaffirming its role as an adjunctive therapy for managing chronic illnesses.

Our data also indicated significant improvements in treatment adherence and quality of life metrics in the intervention group. The increase in treatment adherence from 71.6% at baseline to 89.3% at 12 weeks reflects the robust connection between psychological wellbeing and adherence to medication regimens, consistent with prior evidence demonstrating enhanced patient compliance following CBT interventions (22). Moreover, the improvement in quality of life is in line with findings reporting positive outcomes in quality of life assessments following cognitive behavioral interventions (23). This underscores the multifaceted benefits of CBT, which extend beyond symptom relief to enhance overall patient wellbeing.

Conclusion

This randomized controlled trial has demonstrated Cognitive Behavioral Therapy (CBT) to be extremely useful in reducing the degree of depression in chronic disease patients compared to traditional medical treatment alone. CBT has been discovered to enhance treatment compliance and quality of life, besides psychological wellbeing, which can be regarded as a twofold merit in chronic disease treatment. Between people with chronic disorders, through the ability to influence them, CBT can fit into the regular practice of care, where it is effective because it is feasible and capable of lasting effects, particularly in health care facilities where the dual burden of physical and mental health is a burning problem because of limited resources, including those in low-resource countries.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC--24)

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

SS (Lecturer Applied Psychology)

Manuscript drafting, Study Design,

NS (Dean)

Review of Literature, Data entry, Data analysis, and drafting articles. AS (PhD. Scholar Biochemistry)

Conception of Study, Development of Research Methodology Design,

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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