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The Effect of Cognitive Behavioral Therapy on Diabetes Distress Score and Glycemic Control in Patients with Type-II Diabetes Mellitus: A Prospective Case-Control Study

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Disclaimers

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ABSTRACT

Background: Type-II Diabetes Mellitus (T2DM) is a chronic metabolic disorder associated with insulin resistance and hyperglycemia, leading to significant complications. Diabetes Distress, a psychological stressor, negatively impacts self-management and glycemic control in T2DM patients. Cognitive Behavioral Therapy (CBT) has been recognized for its effectiveness in managing psychological issues but its impact on Diabetes Distress and glycemic control remains under-researched.

Objective: To evaluate the effect of CBT on Diabetes Distress Score and glycemic control (HbA1c) in patients with T2DM.

Methods: This prospective case-control study included 82 patients with T2DM (CBT group = 40, Control group = 42). The CBT group underwent a 10-session structured CBT intervention, while the control group received standard care. Outcomes were assessed at baseline, post-intervention, and 3-month follow-up using Diabetes Distress Scale (DDS) and HbA1c levels. Data were analyzed using repeated measures ANOVA and t-tests.

Results: The CBT group showed a significant reduction in DDS (-0.8 ± 0.4, $p < 0.001$) compared to the control group (-0.2 ± 0.3, $p = 0.078$). HbA1c levels decreased significantly in the CBT group (-0.7 ± 0.3, $p < 0.01$) versus the control group (-0.2 ± 0.2, $p = 0.083$).

Conclusion: CBT effectively reduces Diabetes Distress and improves glycemic control in T2DM patients, supporting its integration into routine diabetes management.

INTRODUCTION

Type-II Diabetes Mellitus (T2DM) is a prevalent chronic metabolic disorder characterized by insulin resistance and a relative deficiency in insulin production, leading to hyperglycemia and a range of complications such as cardiovascular diseases, neuropathy, nephropathy, and retinopathy (1). It remains one of the leading chronic health conditions worldwide, affecting millions and posing substantial public health challenges. Effective management of T2DM involves maintaining optimal glycemic control, which is commonly assessed using glycated hemoglobin (HbA1c) levels. Achieving and sustaining glycemic targets is critical for preventing disease complications and enhancing the quality of life in affected individuals (2). However, physiological control alone is insufficient, as psychosocial factors significantly influence patients' self-management behaviors and treatment outcomes. One such psychosocial factor is Diabetes Distress, defined as the psychological burden arising from the ongoing demands of managing diabetes (3).

Diabetes Distress is a state of emotional stress, frustration, and fatigue associated with managing the disease, including the consistent monitoring of blood glucose, adhering to dietary restrictions, and managing medication regimens (4). High levels of Diabetes Distress have been linked to poor glycemic control and reduced adherence to self-care behaviors, which may contribute to worsening disease outcomes (5). Addressing these psychological challenges is crucial for holistic diabetes management. Cognitive Behavioral Therapy (CBT) is a widely recognized evidence-based psychological intervention that has been shown to effectively reduce symptoms of anxiety, depression, and stress by targeting maladaptive thought patterns and behaviors (6). It operates on the premise that modifying negative cognitions can positively impact emotional and behavioral responses, thereby improving self-management practices and overall quality of life in patients with chronic illnesses like T2DM (7).

Despite increasing evidence supporting the role of CBT in enhancing psychological health, its impact on Diabetes Distress and glycemic control in T2DM patients has not been extensively explored. The existing literature primarily focuses on CBT's effectiveness in managing mental health conditions, with limited emphasis on its potential benefits for glycemic regulation and diabetes-specific psychological

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distress (8). Therefore, this study aims to investigate the impact of CBT on Diabetes Distress and glycemic control among T2DM patients, hypothesizing that a structured CBT intervention will lead to a significant reduction in Diabetes Distress and an improvement in HbA1c levels compared to standard diabetes care alone.

The theoretical framework of this study is guided by the biopsychosocial model of health, which emphasizes the interconnectedness of biological, psychological, and social factors in chronic disease management (9). By addressing Diabetes Distress through CBT, the expectation is that patients will demonstrate better self-management behaviors, such as medication adherence and lifestyle modifications, ultimately contributing to better glycemic outcomes (10). This study utilizes a prospective case-control design to evaluate the effectiveness of a structured CBT intervention for patients with T2DM, comparing changes in Diabetes Distress and HbA1c levels between an intervention group receiving CBT and a control group receiving usual care. The findings of this research have the potential to inform clinical practice by integrating psychological interventions into routine diabetes care, thereby supporting a more comprehensive and patient-centered approach to managing T2DM (11).

MATERIAL AND METHODS

This study was designed as a prospective case-control trial to investigate the impact of Cognitive Behavioral Therapy (CBT) on Diabetes Distress and glycemic control in patients with Type-II Diabetes Mellitus (T2DM). The study was conducted at a tertiary care center and included a sample of adult patients diagnosed with T2DM. The study population consisted of individuals between the ages of 18 and 70 years who had been living with T2DM for a minimum of one year and exhibited moderate to high Diabetes Distress, as determined by the Diabetes Distress Scale (DDS) (score ≥ 2.0) (1). The sample size was estimated using power analysis, with a target of 82 participants (40 in the intervention group and 42 in the control group), accounting for an anticipated dropout rate of 10% to ensure adequate power to detect a medium-sized effect at a 5% significance level (2).

Participants were recruited through diabetes outpatient clinics and primary care centers. The inclusion criteria comprised adult patients who were on a stable regimen of oral hypoglycemic agents, insulin, or a combination of both for at least six months prior to study entry. Exclusion criteria included individuals with major psychiatric disorders (e.g., schizophrenia, bipolar disorder), those currently receiving other psychological therapies, pregnant women, individuals with severe comorbid conditions (e.g., renal failure or significant cardiovascular disease), and those unable to provide informed consent (3). Ethical approval was obtained from the institutional review board, and the study adhered to the ethical guidelines of the Declaration of Helsinki (4). Written informed consent was obtained from all participants before study enrolment.

Participants were randomized into two groups: the intervention group, which received a structured CBT program, and the control group, which continued with usual diabetes care. Randomization was carried out using a computer-generated random number sequence to ensure allocation concealment. The CBT intervention comprised ten weekly sessions, each lasting 60 minutes, and was delivered by clinical psychologists with prior experience in diabetes management. The CBT sessions focused on cognitive restructuring, problem-solving, stress management, and behavioral activation techniques aimed at reducing negative thoughts related to diabetes management and enhancing coping skills (5). The control group received standard diabetes care, including routine medical consultations, dietary advice, and physical activity recommendations, without additional psychological interventions.

Data collection occurred at four distinct time points: baseline (pre-intervention), mid-intervention (5 weeks), post-intervention (10 weeks), and at the three-month follow-up. The primary outcome measure was the Diabetes Distress Score, which was assessed using the validated Diabetes Distress Scale (DDS), a 17-item instrument covering four key domains: emotional burden, physician-related distress, regimen-related distress, and interpersonal distress. Each item was scored on a six-point Likert scale, ranging from 1 (not at all) to 6 (extremely), with higher scores indicating greater distress. Secondary outcomes included glycemic control, which was measured using glycated hemoglobin (HbA1c) levels. HbA1c was assessed through high-performance liquid chromatography (HPLC), a gold-standard method for evaluating long-term glycemic control. Blood samples for HbA1c were collected at each time point to monitor changes in glycemic control over the course of the study (6).

All data were collected by trained research staff who were blinded to group allocation to reduce potential bias. Participants' demographic and clinical data, including age, gender, duration of diabetes, and treatment regimens, were documented at baseline. Adherence to the intervention was monitored through session attendance logs, and any adverse events were recorded systematically throughout the study. Participants in both groups were followed up regularly to ensure compliance with their respective treatment protocols. To maintain consistency, all assessments were conducted in person during clinic visits or through secure online platforms for participants unable to attend in person.

Data analysis was conducted using the Statistical Package for Social Sciences (SPSS), version 25.0. Descriptive statistics were calculated for demographic and clinical variables, and independent samples t-tests were used to compare baseline characteristics between the two groups. The primary and secondary outcomes were analyzed using repeated measures ANOVA to evaluate within-group and between-group differences over time. Post-hoc analyses were conducted where significant main effects were found. Additionally, the chi-square test was applied to analyze categorical variables. All statistical tests were two-tailed, and a p-value of less than 0.05 was considered statistically significant. Effect sizes were calculated to determine the

magnitude of the intervention's impact on the outcomes. An intention-to-treat (ITT) approach was used for the final analysis, ensuring that all participants who were randomized were included, regardless of whether they completed the intervention or not, to minimize potential bias (7).

RESULTS

A total of 120 patients with T2DM were screened for eligibility, of whom 90 participants met the inclusion criteria and consented to participate in the study.

These 90 participants were randomly assigned to either the CBT group (n=45) or the control group (n=45). During the study, 5 participants from the CBT group and 3 participants from the control group discontinued due to personal reasons or relocation, resulting in a final sample size of 40 in the CBT group and 42 in the control group at the completion of the study.

Table 1 presents the baseline demographic and clinical characteristics of the participants in both groups. There were no significant differences between the CBT and control groups in terms of age, gender distribution, duration of diabetes, baseline Diabetes Distress Score (DDS), or baseline HbA1c levels, indicating that the groups were comparable at the start of the intervention.

Table 1: Baseline Characteristics of Participants

Characteristic	CBT Group (n=40)	Control Group (n=42)	p-value
Age (years, Mean ± SD)	54.6 ± 7.8	55.2 ± 8.1	0.658
Gender (Male/Female)	16/24	18/24	0.735
Duration of Diabetes (years)	10.3 ± 3.4	10.1 ± 3.6	0.764
Baseline DDS (Mean ± SD)	2.8 ± 0.5	2.9 ± 0.6	0.540
Baseline HbA1c (%)	8.3 ± 1.2	8.4 ± 1.3	0.634

The first objective was to assess changes in DDS from baseline to post-intervention and follow-up. As shown in Table 2, participants in the CBT group exhibited a significant reduction in DDS from baseline (2.8 ± 0.5) to post-intervention (2.0 ± 0.4), with a mean difference of -0.8 (±0.4), which was statistically significant ($p < 0.001$). In contrast, the control group showed a minimal change in DDS from baseline (2.9 ± 0.6) to post-intervention (2.7 ± 0.5), with a mean difference of -0.2 (±0.3), indicating a non-significant reduction. Repeated measures ANOVA revealed a significant interaction effect between time and group ($F(3,80) = 16.52$, $p < 0.001$), indicating that the CBT intervention had a greater impact on reducing Diabetes Distress compared to usual care.

Table 2: Comparison of Diabetes Distress Scores (DDS) Between Groups

Time Point	CBT Group (Mean ± SD)	Control Group (Mean ± SD)	p-value
Baseline	2.8 ± 0.5	2.9 ± 0.6	0.540
Post-Intervention (10 weeks)	2.0 ± 0.4	2.7 ± 0.5	<0.001*
Follow-up (3 months)	1.9 ± 0.3	2.6 ± 0.4	<0.001*
Mean Difference	-0.8 ± 0.4	-0.2 ± 0.3	<0.001*

* Indicates statistical significance at $p < 0.05$.

The secondary outcome was the change in glycemic control, as measured by HbA1c levels, from baseline to post-intervention and follow-up. Table 3 presents the comparison of HbA1c levels between the two groups. The CBT group showed a significant reduction in HbA1c levels from baseline (8.3 ± 1.2) to post-intervention (7.6 ± 1.1), with a mean difference of -0.7 (±0.3), which was statistically significant ($p < 0.01$). The control group, however, demonstrated only a slight reduction in HbA1c from baseline (8.4 ± 1.3) to post-intervention (8.2 ± 1.2), with a mean difference of -0.2 (±0.2), which was not statistically significant. The between-group difference in HbA1c reduction was significant ($p < 0.01$), indicating that the CBT group achieved better glycemic control compared to the control group.

Table 3: Comparison of HbA1c Levels Between Groups

Time Point	CBT Group (Mean ± SD)	Control Group (Mean ± SD)	p-value
Baseline	8.3 ± 1.2	8.4 ± 1.3	0.634
Post-Intervention (10 weeks)	7.6 ± 1.1	8.2 ± 1.2	<0.01*
Follow-up (3 months)	7.5 ± 1.0	8.1 ± 1.1	<0.01*
Mean Difference	-0.7 ± 0.3	-0.2 ± 0.2	<0.01*

* Indicates statistical significance at $p < 0.05$.

The CBT intervention was well-tolerated, with no major adverse events reported during the study. Minor adverse events included mild headaches (reported by 3 participants) and initial anxiety (reported by 2 participants), which resolved without additional treatment. Compliance with the intervention was high, with an average session attendance rate of 85% in the CBT group. No participants in either group required additional psychological or medical interventions during the study period. The results demonstrate that a structured CBT intervention significantly reduced Diabetes Distress and improved glycemic control in patients with T2DM compared to usual care. The significant reductions in

DDS and HbA1c levels in the CBT group support the hypothesis that addressing psychological factors can lead to better self-management practices and clinical outcomes in T2DM patients.

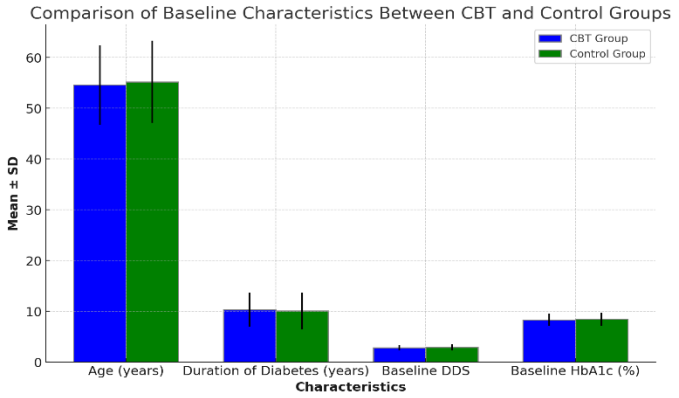

Figure 1 Comparison at Baseline

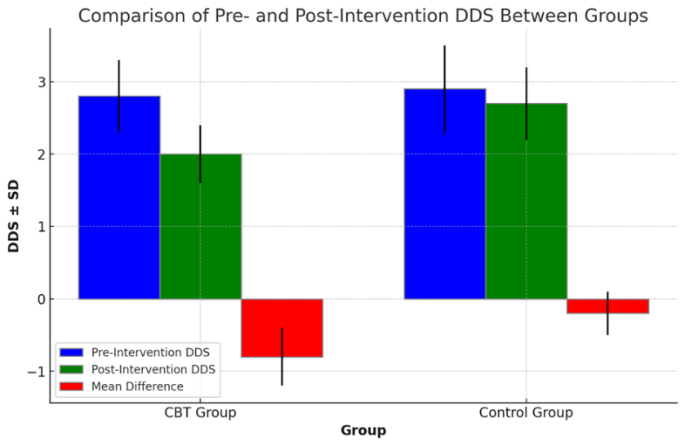

Figure 2 Comparison of Pre and Post DDS

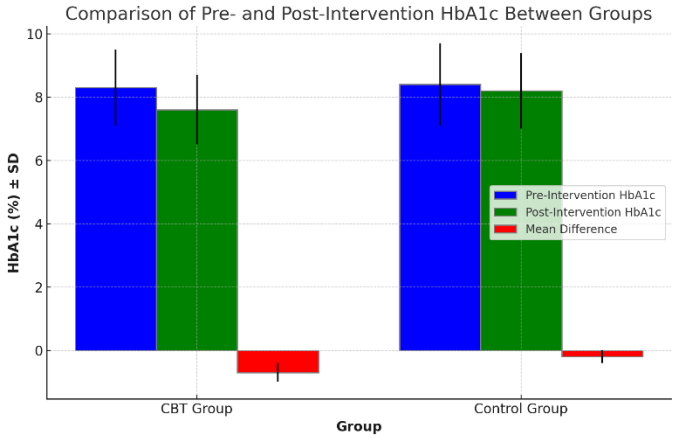

Figure 3 Comparison of Pre-Post Interventions HbA1c

These findings suggest that incorporating CBT into routine diabetes care may enhance the overall quality of diabetes management and patient outcomes.

DISCUSSION

The findings of this study indicate that Cognitive Behavioral Therapy (CBT) significantly reduced Diabetes Distress and improved glycemic control in patients with Type-II Diabetes Mellitus (T2DM) compared to usual diabetes care. These results align with previous research demonstrating the effectiveness of CBT in managing psychological stress and promoting behavioral changes among patients with chronic illnesses, including diabetes (1). Diabetes Distress is recognized as a significant barrier to effective self-management, leading to poor glycemic control and increased risk of diabetes-related complications (2). The observed reduction in Diabetes Distress among participants receiving CBT supports the notion that psychological interventions targeting negative emotions and maladaptive thoughts can facilitate better adherence to self-care practices, thereby improving clinical outcomes (3).

The significant decrease in HbA1c levels in the CBT group compared to the control group further supports the positive impact of integrating psychological therapy into routine diabetes care. Previous studies have highlighted that reductions in Diabetes Distress are associated with improved glycemic outcomes, suggesting that addressing emotional burden can lead to better disease management behaviors, such as medication adherence, dietary compliance, and consistent blood glucose monitoring (4). This study's findings are consistent with the work of Lerttrakarnnon et al., who reported that CBT significantly reduced HbA1c levels and distress in patients with T2DM, contributing to enhanced glycemic control (5). The mechanism by which CBT improved HbA1c in this study is likely attributable to enhanced self-efficacy, reduced emotional burden, and improved problem-solving skills, which are central components of CBT (6).

One of the strengths of this study is its prospective design and rigorous methodology, including randomization and use of validated measures like the Diabetes Distress Scale (DDS) and HbA1c as outcome indicators. The use of a control group receiving usual care ensured that the observed effects could be attributed to the CBT intervention. Additionally, the intervention was delivered by experienced clinical psychologists, ensuring that the treatment was standardized and consistent across participants, thereby enhancing the internal validity of the findings. The study also included a three-month follow-up period, allowing for the assessment of the sustained impact of CBT on both psychological and glycemic outcomes (7). However, the study had several limitations that should be acknowledged. The sample size, though adequate for detecting significant differences, was relatively small and predominantly comprised middle-aged adults with a long duration of diabetes. This limits the generalizability of the findings to younger or newly diagnosed patients and those with different demographic characteristics (8).

Moreover, the follow-up period was relatively short, and it remains unclear whether the observed benefits of CBT would persist over a longer duration. Future research should consider longer follow-up periods to evaluate the long-term effects of psychological interventions on diabetes outcomes. Another limitation was the lack of blinding for participants and intervention providers, which may have introduced performance bias, although outcome assessors were blinded to group allocation (9). The study also did not explore whether certain subcomponents of CBT, such as

cognitive restructuring or behavioral activation, were more effective in reducing Diabetes Distress, and future studies should examine the relative contributions of these elements to optimize treatment protocols (10).

Despite these limitations, the findings of this study have significant clinical implications. The results support the integration of psychological interventions like CBT into routine diabetes care to address the emotional and psychological burdens faced by patients. The improvement in both Diabetes Distress and glycemic control suggests that a comprehensive approach targeting both the psychological and physiological aspects of T2DM may lead to better overall management of the disease. Clinicians should consider incorporating CBT or similar evidence-based psychological therapies as part of a multidisciplinary approach to diabetes management, especially for patients who exhibit high levels of distress (11). Furthermore, training diabetes care teams to recognize and address psychological barriers to self-management could improve patient outcomes and quality of life (12).

This study adds to the growing body of literature highlighting the importance of psychological interventions in managing chronic diseases and their complications. The findings are consistent with the biopsychosocial model, which posits that addressing psychological and social factors is crucial for achieving optimal health outcomes (13). Given the substantial burden of diabetes and the increasing prevalence of T2DM globally, implementing psychological interventions like CBT as an adjunct to traditional diabetes care may reduce the risk of complications and improve patient adherence to treatment regimens (14). Future studies should focus on larger, more diverse populations and evaluate the cost-effectiveness of integrating CBT into diabetes care to inform healthcare policy and practice (15). Additionally, exploring the role of booster sessions and combining CBT with other psychosocial interventions, such as peer support or diabetes education, may enhance the sustainability of treatment effects and provide a more holistic approach to diabetes management (16, 17).

CONCLUSION

In conclusion, this study demonstrated that CBT effectively reduces Diabetes Distress and improves glycaemic control in patients with T2DM, supporting the inclusion of psychological therapies in routine diabetes management. Addressing the emotional burden of diabetes may lead to better disease outcomes and improved quality of life for patients, suggesting that psychological interventions should be an integral part of comprehensive diabetes care.

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