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Original Article

# Impact of a Structured Intervention on Health-Related Quality of Life in Women with Type 2 Diabetes Mellitus: A Randomized Controlled Trial Using the MDQoL-17

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## ABSTRACT

**Background:** Diabetes Mellitus (DM) is a long-term health condition that can greatly impact Health-Related Quality of Life (HRQOL), especially in women, who often encounter specific difficulties in managing the disease. **Objectives:** The current study aimed to evaluate the influence of the Modified Diabetes Quality of Life-17 (MDQoL-17) questionnaire on women diagnosed with Type 2 Diabetes Mellitus (T2DM). **Materials and Methods:** This prospective randomized controlled trial was conducted at a tertiary care teaching hospital in Belagavi, Karnataka. A total of 218 women diagnosed with T2DM were randomized into intervention and control groups (109 each). Participants were assessed using the MDQoL-17 questionnaire, which evaluates seven domains of HRQoL. Statistical analysis included independent-sample t-test and one-way ANOVA, with a *p*-value <0.05 considered significant. **Results:** At the baseline of the study, both groups showed similar HRQoL scores across all domains. After 9 months, the intervention group showed statistically significant improvements in mean scores in several areas, such as physical functioning ($p$=0.011), emotional well-being ($p$=0.023), role limitations ($p$=0.018), energy/fatigue ($p$=0.005), and general health perception ($p$=0.031), compared to the control group. Enhanced HRQoL was positively linked with better glycemic control, improved medication adherence, and the absence of diabetes-related complications. **Conclusion:** The study demonstrates that targeted interventions can significantly enhance HRQoL in women with T2DM. By addressing key domains such as physical functioning, emotional well-being, and general health perception, healthcare providers can support a more holistic approach to diabetes management. Utilizing tools like the MDQoL-17 enables the identification of specific areas where patients experience the most impact, facilitating tailored strategies to improve overall well-being and day-to-day functioning.

**Keywords:** Diabetes Mellitus, Quality of Life, MDQoL, Women's Health.

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## INTRODUCTION

Diabetes Mellitus (DM) is a group of metabolic disorders characterized by consistently elevated blood sugar levels, resulting from problems with insulin production, insulin function, or both (Das and Mosses, 2007). Type 2 Diabetes Mellitus (T2DM) is the most widespread form, accounting for over 95% of diabetes cases in adults. In India, T2DM poses a growing public health challenge, with an estimated 8.7% prevalence among individuals aged 20 to 70 years (Jha *et al*., 2021; Rannan-Eliya *et al*., 2023).

DM poses a significant global health challenge. In 2017, an estimated 425 million individuals were affected, with the number expected to rise markedly (Benedict *et al*., 2018). If not managed properly, diabetes can lead to various complications, contributing to raised morbidity, mortality, and reduced Health-Related Quality of Life (HRQOL) (Anjana *et al*., 2017).

India carries a significant share of the global diabetes burden. In 2015, it had the second-highest number of DM cases worldwide, with around 69 million individuals affected (Unnikrishnan *et al*., 2016). By 2021, the number increased to 74 million diagnosed and 40 million undiagnosed cases. DM-related complications-including retinopathy, neuropathy, nephropathy, cardiovascular disease, and stroke-are responsible for approximately 4 million deaths annually (International Diabetes Federation, 2019). While diabetes affects men and women at similar rates overall, its prevalence is generally higher in women aged 65 and above (Roglic, 2009). Women also face unique physiological and social barriers in managing diabetes. Conditions like Gestational Diabetes Mellitus (GDM) and

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Polycystic Ovary Syndrome (PCOS) further increase their risk of developing T2DM (Buchanan and Xiang, 2005; Parker, 2023).

Socioeconomic factors like restricted access to health care, low levels of health literacy, and caregiving duties often make it difficult for women to manage diabetes effectively (Hill-Briggs *et al*., 2020). Studies show that women often have lower awareness of DM, its complications, and the importance of consistent treatment adherence (Fatema *et al*., 2017; Kautzky-Willer *et al*., 2016). This highlights the importance of implementing gender-specific education and awareness programs to enhance diabetes management and care outcomes.

Effective diabetes management includes the use of Oral Hypoglycemic Agents (OHAs), insulin therapy, lifestyle modifications, and regular monitoring of blood glucose levels (Shrivastava *et al*., 2013). The primary goals of treatment are to prevent complications, extend life expectancy, and improve overall HRQOL. However, treatment adherence is a major challenge, particularly for women, due to socioeconomic and cultural constraints (Tipnis and Bajaj, 2011; Rezaei *et al*., 2019). Structured education and targeted awareness initiatives are essential to overcome these challenges and enhance disease control.

Quality of Life (QoL) has become a key area of emphasis in the management of DM. It is now recognized as a key outcome of medical intervention, reflecting the patient's overall well-being (Nyamagoud *et al*., 2024). DM often reduces QoL, especially when complications or comorbidities are present. The disease can impair physical functioning and place a psychological burden due to its lifelong nature and the demands of continuous self-care (Polonsky, 2000).

Various factors affect the Quality of Life (QoL) in people with diabetes, such as the type and duration of the disease, age, Body Mass Index (BMI), blood sugar control (indicated by $HbA_{1c}$ and fasting blood sugar levels), and the presence of complications or other health conditions (Rubin and Peyrot,1999).

The Modified Diabetes Quality of Life (MDQOL) is a diabetes-specific instrument designed to assess QoL by evaluating the impact of diabetes and its complications on physical, emotional, and social well-being. It helps in understanding how the disease affects day-to-day activities, emotional health, and treatment satisfaction (Harkhani *et al*., 2023). The MDQOL-17 questionnaire is an updated and refined version of the original tool, consisting of 17 items categorized under seven domains: physical functioning, role limitations due to physical and emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perception (Tare and Kothary, 2020).

The MDQOL-17 provides a structured, patient-centered tool to assess the QoL in people with diabetes by capturing physical, emotional, and social impacts. In our study, we intended to use MDQOL-17 to identify key areas affecting patients' well-being and guide targeted interventions to improve their overall QoL.

## MATERIALS AND METHODS

### Study design

The study used a prospective Randomized Controlled Trial (RCT) design, randomly assigning participants to either an intervention or a control group. This approach allowed for a direct comparison of outcomes between the two groups. As a gold standard for evaluating treatment effects, the RCT was chosen to assess the impact of a medication adherence intervention on the HRQoL in individuals with DM.

### Study Site

The study was conducted at KLE's Dr. Prabhakar Kore Hospital and MRC in Nehru Nagar, Belagavi, a tertiary care center catering to northern Karnataka. The hospital features modern infrastructure and advanced healthcare services, including a dedicated general medicine department that manages conditions like diabetes mellitus. With experienced doctors, nurses, and paramedical staff providing 24/7 care, along with well-equipped diagnostic labs, radiology units, imaging services, and an in-house pharmacy, the facility offered an ideal environment for clinical research.

### Ethical Clearance

The study protocol was approved by the Institutional Ethical Committee of KLE Academy of Higher Education and Research, Belagavi, with the reference number KAHER/EC/22-23/134. Prior to the commencement of the study, participants were thoroughly informed about the study's purpose and procedures, and written informed consent was obtained from each participant.

### Sample size

To determine the appropriate sample size for the study, a pilot test was initially conducted with 10 participants-5 in each group. The observed standard deviations for medication adherence were 1.02 in the intervention group (Group A) and 1.55 in the control group (Group B). The pooled standard deviation (S) was calculated using the formula: $S=S1+S2^2$.

After obtaining the pooled standard deviation, the sample size was estimated using the formula for comparing two means:

$$n = 2S^2(Z1\text{-}\alpha/2 + Z1\text{-}\beta)^2 / d^2$$

Where,

$n$ represents the sample size, $S$ is the overall standard deviation, $Z_1\text{-}\alpha/2$ equals 1.96, corresponding to a 5% level of significance, and $Z_1\text{-}\beta$ is 1.68, reflecting a test power of 95%. The minimum detectable difference ($d$) was set at 0.25.

Using these values in the sample size formula, the required number of participants was calculated to be 109 per group-resulting in a total of 218 participants divided equally between the intervention and control groups.

The selected sample size ensured that the study had sufficient statistical power to detect a meaningful difference in HRQOL between the intervention and control groups. It also aimed to achieve statistical significance, with a *p*-value threshold set at less than 0.05.

### Randomization

To minimize selection bias and ensure balanced allocation, participants were randomly assigned to either the intervention or control group using a computer-generated simple randomization method. The allocation process followed the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) technique. An independent researcher, not involved in recruitment or data collection, managed the randomization. Envelopes were opened only after participants provided written informed consent and fulfilled all inclusion criteria.

### Study Procedure

The study was conducted at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, located in Nehru Nagar, Belagavi. Participants were selected from the inpatient wards of the General Medicine Department and were randomly assigned to either the intervention or control group.

Women aged 18 years or older, diagnosed with DM and undergoing treatment with anti-diabetic medications, were deemed eligible to participate in the study. Patients were not included in the study if they had terminal co-morbid conditions with an expected survival of less than 9 months (such as stage IV cancer or severe psychiatric illness), untreated hyperthyroidism, or if they were critically ill due to diabetic emergencies. Additionally, pediatric patients, pregnant or lactating women, those unwilling to participate, or individuals likely to be lost to follow-up were not included in the study.

Upon obtaining written informed consent, participants were randomized into two groups. Participants in the control group were provided with routine diabetes care in accordance with hospital guidelines. In contrast, those in the intervention group received the same standard care in addition to structured counseling sessions. These sessions, conducted by trained healthcare professionals, included education on medication adherence, lifestyle modifications, and comprehensive guidance on topics such as disease understanding, proper medication usage, possible complications, adherence strategies, adverse drug reactions, and commonly encountered side effects.

Data collection was performed using the MDQOL questionnaire, a validated instrument for assessing HRQoL in diabetic patients. The questionnaire comprised 17 questions grouped into seven domains, with higher scores indicating better HRQoL and lower scores reflecting poorer health status.

Participants in the interventional group were followed up for nine months, during which additional counseling sessions were provided at each visit. HRQoL data was gathered from both groups throughout the study without differentiating between inpatient and outpatient participants.

### Statistical Analysis

Data were analyzed using SPSS software version 26.0. Descriptive statistics summarized the demographic and clinical characteristics of the participants. Independent-sample *t*-tests were applied to compare MDQoL-17 scores between the intervention and control groups for continuous variables. For comparisons involving more than two groups, one-way ANOVA was conducted. A *p*-value of less than 0.05 was considered statistically significant.

## RESULTS

The study included a total of 218 participants, evenly divided between the control and intervention groups, with 109 individuals in each. Table 1 presents the demographic and clinical characteristics of the participants. The majority were between 41 and 50 years old (37.2%), followed by those aged 31 to 40 years (26.6%). A greater percentage of participants in the intervention group fell within the 51-60 age range (32.1%) compared to the control group (11.9%). Regarding body weight, 38.1% of participants were overweight and 19.7% were obese, with both groups displaying a similar distribution.

When examining the duration of diabetes, 45% of participants had been diagnosed for a period of 6 to 10 years. This proportion was greater in the intervention group (51.4%) than in the control group (38.5%). About 17.9% had lived with diabetes for over 10 years, as illustrated in Figure 1. A family history of diabetes was common, with 6.9% reporting it among parents, 30.2% among grandparents, and 17.9% among other relatives. Most participants (78.9%) were from rural areas, and 89.4% were literate, with comparable rates across both groups. More than half (59.2%) were unemployed, with a slightly higher proportion in the intervention group (60.6%) than in the control group (57.8%). Tobacco use was minimal, with 95.9% identified as non-users. Hypertension emerged as the most frequent comorbidity (34.9%), followed by chronic kidney disease (8.7%), hypothyroidism (6.4%), and ischemic heart disease (5.5%). Notably, 39.9% of participants reported no comorbid conditions. Among diabetes-related complications, neuropathy (9.2%), retinopathy (8.3%), and nephropathy (8.3%) were the most prevalent. However, 62.4% did not report any diabetes-related complications.

The analysis of glycemic control showed that 16.9% had $HbA_{1c}$ levels between 4-7%, 34.8% had levels between 7-8%, while the

majority (48.1%) had values above 8%, reflecting poor glycemic control in nearly half of the participants. Fasting Blood Sugar (FBS) levels revealed that only 3.67% had normal values (<110 mg/dL), while 21.1% had impaired fasting glucose (110-126 mg/dL). A significant majority (77.06%) had FBS levels exceeding 126 mg/dL, indicating suboptimal diabetes management among most participants.

## Baseline

At the start of the study, the control and intervention groups were comparable in terms of demographic and clinical characteristics. The mean age was 58.21±9.34 years in the control group and 57.45±8.93 years in the intervention group, with no statistically significant difference ($p$=0.426). The average duration of diabetes was 7.8±4.2 years in the control group and 8.1±4.5 years in the intervention group ($p$=0.581). Comorbidities were present in 62.4% of control participants and 64.2% of those in the intervention group ($p$=0.774). Educational status (83.5% literate in control vs. 86.2% in intervention), employment rate (67.0% vs. 68.8%), and marital status (80.7% vs. 82.6%) were also similar between the groups. All comparisons had $p$-values greater than 0.05, confirming that both groups were well-matched at baseline, as outlined in Table 2.

## MDQoL-17 scores at baseline

At baseline, there were no significant differences between the control and intervention groups across any of the MDQoL-17 domains. Both groups demonstrated similar scores in areas such as physical functioning, emotional health, energy and fatigue levels, role limitations, and overall health perception. This indicates that before the intervention, participants in both groups had a comparable diabetes-related quality of life, as illustrated in Table 6 and Figure 1.

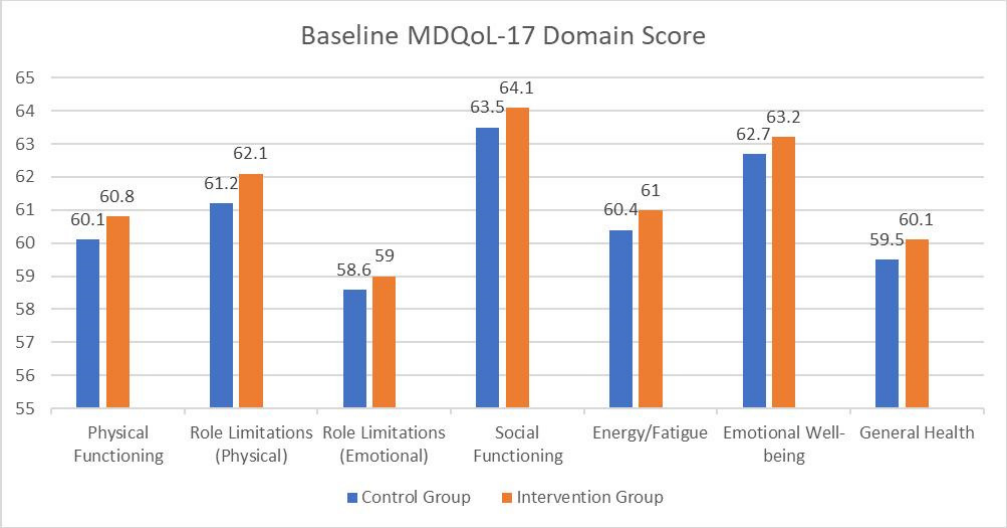


**Figure 1:** Comparison of Mean MDQoL-17 Domain Scores Between Control and Intervention Groups at baseline.

**Table 1: Characteristics of the study population.**

| Sl. No. | Demographic | Category | Control Group ($n$=109) | Intervention Group ($n$=109) | Total ($n$=218) |
|---|---|---|---|---|---|
| 1. | Age Group | 21-30 years | 3 (2.8%) | 4 (3.7%) | 7 (3.2%) |
| | | 31-40 years | 27 (24.8%) | 31 (28.4%) | 58 (26.6%) |
| | | 41-50 years | 48 (44.0%) | 33 (30.3%) | 81 (37.2%) |
| | | 51-60 years | 13 (11.9%) | 35 (32.1%) | 48 (22.0%) |
| | | 61-70 years | 14 (12.8%) | 5 (4.6%) | 19 (8.7%) |
| | | Above 70 years | 4 (3.7%) | 1 (0.9%) | 5 (2.3%) |
| 2. | Body Mass Index (BMI) | Underweight (<18.5) | 5 (4.6%) | 4 (3.7%) | 9 (4.1%) |
| | | Normal weight (18.5-24.9) | 40 (36.7%) | 43 (39.4%) | 83 (38.1%) |
| | | Overweight (25-29.9) | 42 (38.5%) | 41 (37.6%) | 83 (38.1%) |
| | | Obese (>30) | 22 (20.2%) | 21 (19.3%) | 43 (19.7%) |

| Sl. No. | Demographic | Category | Control Group (*n*=109) | Intervention Group (*n*=109) | Total (*n*=218) |
|---|---|---|---|---|---|
| 3. | Duration Of Diabetes | < 1 year | 9 (8.3%) | 6 (5.5%) | 15 (6.9%) |
| | | 1-5 years | 34 (31.2%) | 32 (29.4%) | 66 (30.3%) |
| | | 6-10 years | 42 (38.5%) | 56 (51.4%) | 98 (45.0%) |
| | | >10 years | 24 (22.0%) | 15 (13.8%) | 39 (17.9%) |
| 4. | Family History of Diabetes | Parents | 9 (8.3%) | 6 (5.5%) | 15 (6.9%) |
| | | Grandparents | 34 (31.2%) | 32 (29.4%) | 66 (30.3%) |
| | | Siblings | 42 (38.5%) | 56 (51.4%) | 98 (45.0%) |
| | | Others | 24 (22.0%) | 15 (13.8%) | 39 (17.9%) |
| 5. | Residence | Rural | 85 (78.0%) | 87 (79.8%) | 172 (78.9%) |
| | | Urban | 24 (22.0%) | 22 (20.2%) | 46 (21.1%) |
| 6. | Literacy Status | Literate | 97 (89.0%) | 98 (89.9%) | 195 (89.4%) |
| | | Illiterate | 12 (11.0%) | 11 (10.1%) | 23 (10.6%) |
| 7. | Occupation | Employed | 46 (42.2%) | 43 (39.4%) | 89 (40.8%) |
| | | Unemployed | 63 (57.8%) | 66 (60.6%) | 129 (59.2%) |
| 8. | Tobacco | Tobacco chewer | 5 (4.6%) | 4 (3.7%) | 9 (4.1%) |
| | | Non-Tobacco chewer | 104 (95.4%) | 105 (96.3%) | 209 (95.9%) |
| 9. | Comorbidity | Hypertension | 36 (33.0%) | 40 (36.7%) | 76 (34.9%) |
| | | Ischemic Heart Disease | 5 (4.6%) | 7 (6.4%) | 12 (5.5%) |
| | | Coronary Artery Disease | 2 (1.8%) | 3 (2.8%) | 5 (2.3%) |
| | | Rheumatic Heart Disease | 1 (0.9%) | 1 (0.9%) | 2 (0.9%) |
| | | Hyperthyroidism | 2 (1.8%) | 8 (7.3%) | 10 (4.6%) |
| | | Hypothyroidism | 6 (5.5%) | 8 (7.3%) | 14 (6.4%) |
| | | Chronic Kidney Disease | 7 (6.4%) | 12 (11.0%) | 19 (8.7%) |
| | | Acute Kidney Injury | 1 (0.9%) | 1 (0.9%) | 2 (0.9%) |
| | | Anaemia | 3 (2.8%) | 1 (0.9%) | 4 (1.8%) |
| | | Metabolic acidosis | 1 (0.9%) | 1 (0.9%) | 2 (0.9%) |
| | | Nil | 49 (45.0%) | 38 (34.9%) | 87 (39.9%) |
| 10. | Diabetic Complications | Neuropathy | 9 (8.3%) | 11 (10.1%) | 20 (9.2%) |
| | | Retinopathy | 9 (8.3%) | 9 (8.3%) | 18 (8.3%) |
| | | Ketoacidosis | 7 (6.4%) | 8 (7.3%) | 15 (6.9%) |
| | | Nephropathy | 7 (6.4%) | 11 (10.1%) | 18 (8.3%) |
| | | Diabetic foot | 6 (5.5%) | 11 (10.1%) | 17 (7.8%) |
| | | Nil | 71 (65.1%) | 59 (54.12%) | 130 (62.4%) |
| 11. | $HbA_{1c}$ Category | 4-7% | 7(6.42%) | 30(27.5%) | 37(16.9%) |
| | | 7-8% | 29(26.6%) | 47(43.1%) | 76(34.8%) |
| | | >8% | 73(66.9) | 32(29.3%) | 105(48.1%) |
| 12. | FBS Range (mg/dL) | Less than 110 | 0(0.00%) | 4(3.67%) | 4(3.67%) |
| | | 110 - 126 | 22(20.18%) | 24(22.02%) | 46(21.10%) |
| | | >126 | 87(79.82%) | 81(74.31%) | 168(75.23%) |

### 3-Month Follow-up

Since demographic characteristics remain constant over time, no changes were noted. However, it was observed that subgroups such as literate and employed individuals in the intervention arm were more engaged with the educational sessions, potentially influencing their early improvements in health outcomes as shown in Table 3.

### MDQoL-17 scores at 3-month follow-up

At the 3-month follow-up, participants in the intervention group demonstrated initial improvements in their MDQoL-17 scores. Notably, there were significant enhancements in physical functioning, limitations related to physical health, and social functioning when compared to the control group ($p<0.05$). Although emotional well-being and energy levels began to improve, not all differences reached statistical significance at this point. In contrast, the control group showed negligible improvement or slight decline in certain domains, indicating the limited effect of routine care alone Table 6 and Figure 2.

### 6-Month Follow-up

There were no changes in demographic characteristics. However, differences in outcomes were increasingly noticeable among participants with longer disease duration and those with comorbidities-these groups benefitted more noticeably from the intervention, suggesting that consistent support was especially valuable to high-risk patients as shown in Table 4.

### MDQoL-17 scores at 6-month follow-up

By 6 months, the intervention group demonstrated statistically significant improvements in multiple domains, including emotional well-being, general health, energy/fatigue, and role limitations due to emotional problems ($p<0.01$). Patients reported better daily functioning and emotional resilience. These improvements were sustained across various subgroups, regardless of baseline health status. The control group continued to show minimal changes, with some individuals reporting stagnant or declining scores Table 6 and Figure 3.

### 9-Month Follow-up

As expected, demographic variables did not change over time, but their influence on quality-of-life outcomes remained evident. Participants with higher education levels and those who were employed responded more effectively to the intervention. However, beneficial outcomes were also evident among older adults, individuals with lower educational backgrounds, and those with comorbidities-demonstrating the wide applicability of the intervention, as presented in Table 5.

### MDQoL-17 scores at 9-month follow-up

After 9 months, the intervention group exhibited significant improvements across all domains of the MDQoL-17, with $p$-values less than 0.001. Marked progress was noted in physical functioning, emotional health, overall health perception, and social interactions. Participants reported a greater sense of control over their condition and better psychosocial well-being. In contrast, the control group showed no substantial changes, supporting the conclusion that Well-planned interventions are essential for enhancing long-term QoL in individuals with diabetes, as reflected in Table 6 and Figure 4.

## DISCUSSION

This study evaluated the effectiveness of a structured educational and behavioral intervention in improving the QoL among individuals with T2DM, using the MDQoL-17 instrument. The findings demonstrate that over 9 months, participants who received the intervention experienced significant improvements

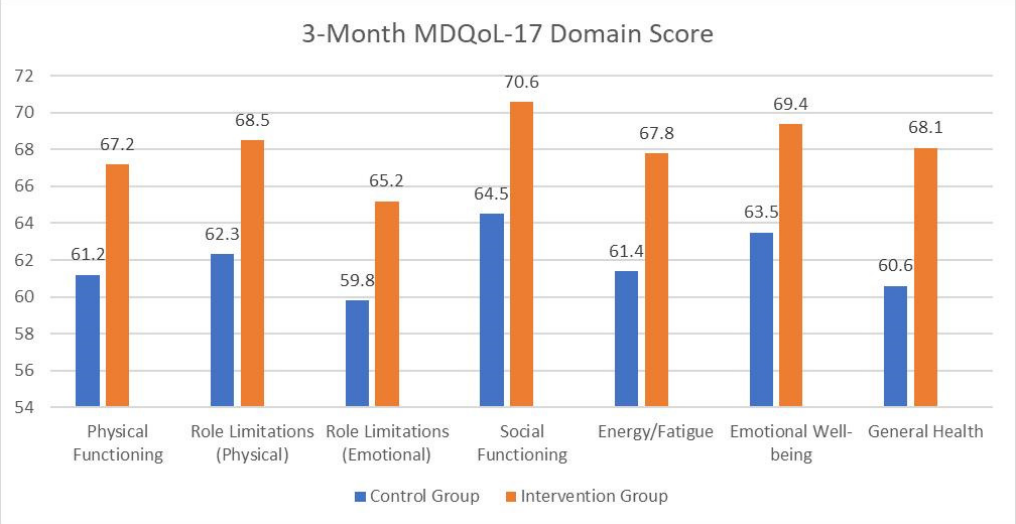


**Figure 2:** Comparison of Mean MDQoL-17 Domain Scores Between Control and Intervention Groups at 3-Month Follow-Up.

across multiple domains of QoL, in contrast to those in the control group who received standard care.

At baseline, both groups were demographically and clinically comparable. However, poor glycemic control was prevalent across the cohort, with the majority presenting $HbA_{1c}$ levels above 8% and FBS values exceeding 126 mg/dL. These results are consistent with other studies in similar populations, emphasizing that many individuals with T2DM continue to struggle with effective glucose regulation (Singh *et al*., 2023; Prajapati *et al*., 2017).

The MDQoL-17 questionnaire effectively evaluated the quality of life in individuals with diabetes, addressing both physical impairments and psychosocial difficulties. This aligns with earlier validation studies that supported the instrument's utility in diverse clinical settings (Acharya *et al*., 2014).

At the 3-month mark, intervention participants showed early improvements in areas such as physical functioning and social engagement. These gains likely reflect better adherence to lifestyle modifications, improved self-management skills, and increased health awareness facilitated by regular educational sessions. Previous research has noted similar outcomes when patients

**Table 2: Baseline MDQoL-17 scores by Demographic and Clinical Characteristics.**

| Sl. No. | Characteristic | Category | Control Group (Mean± SD) | Intervention Group (Mean±SD) | Total (Mean±SD) | *p*-value |
|---|---|---|---|---|---|---|
| 1. | Age Group | 21-30 years | 72.3±4.5 | 75.1±3.8 | 73.8±4.3 | 0.041* |
| | | 31-40 years | 70.2±6.2 | 74.5±5.1 | 72.4±5.9 | |
| | | 41-50 years | 68.0±5.9 | 71.2±6.3 | 69.6±6.2 | |
| | | 51-60 years | 64.1±7.4 | 68.8±6.8 | 66.9±7.2 | |
| | | 61-70 years | 60.5±6.6 | 65.2±7.1 | 62.4±6.9 | |
| | | Above 70 years | 58.3±5.5 | 62.0±6.0 | 60.1±5.8 | 0.052* |
| 2. | BMI | Underweight | 63.5±6.9 | 66.1±7.2 | 64.7±7.0 | |
| | | Normal weight | 69.4±5.8 | 73.2±5.5 | 71.3±5.7 | |
| | | Overweight | 67.2±6.1 | 71.1±6.3 | 69.2±6.3 | |
| | | Obese | 61.8±6.6 | 66.0±6.4 | 63.9±6.5 | |
| 3. | Duration of Diabetes | < 1 year | 72.4±5.2 | 75.6±4.7 | 74.0±5.0 | 0.006* |
| | | 1-5 years | 70.8±5.9 | 73.4±5.6 | 72.1±5.7 | |
| | | 6-10 years | 66.2±6.1 | 69.5±6.3 | 67.9±6.3 | |
| | | >10 years | 61.3±6.5 | 65.0±6.8 | 63.2±6.7 | |
| 4. | Literacy Status | Literate | 68.9±6.0 | 72.5±6.2 | 70.7±6.3 | 0.032* |
| | | Illiterate | 61.8±5.6 | 65.0±6.0 | 63.3±5.9 | |
| 5. | Occupation | Employed | 69.5±6.2 | 73.1±6.0 | 71.3±6.2 | 0.045* |
| | | Unemployed | 65.7±6.5 | 69.1±6.4 | 67.4±6.5 | |
| 6. | Tobacco Use | Chewer | 61.2±5.4 | 64.3±5.9 | 62.7±5.7 | 0.078 |
| | | Non-Chewer | 67.8±6.3 | 71.4±6.2 | 69.6±6.3 | |
| 7. | Diabetic Complications | Present (any) | 61.4±6.0 | 65.0±6.1 | 63.2±6.2 | 0.002* |
| | | Nil | 70.6±5.5 | 73.5±5.3 | 72.0±5.4 | |
| 8. | Comorbidity | Present (any) | 63.0±6.1 | 66.2±6.5 | 64.6±6.3 | 0.013* |
| | | Nil | 69.5±5.8 | 72.8±5.4 | 71.0±5.7 | |
| 9. | $HbA_{1c}$ Category | 4-7% | 6.50 ±0.00 | - | 6.50 ±0.00 | 0.3670 |
| | | 7-8% | 7.20 ±0.00 | 7.37±0.25 | 7.33±0.23 | |
| | | >8% | 9.45±0.42 | 9.43±0.33 | 9.44±0.38 | |
| 10 | FBS Range (mg/dL) | Less than 110 | - | - | - | 0.007* |
| | | 110 - 126 | 70.1±5.7 | 73.3±5.5 | 71.9±5.6 | |
| | | >126 | 65.8±6.3 | 68.5±6.1 | 67.1±6.2 | |

Statistically Significant $p<0.05$

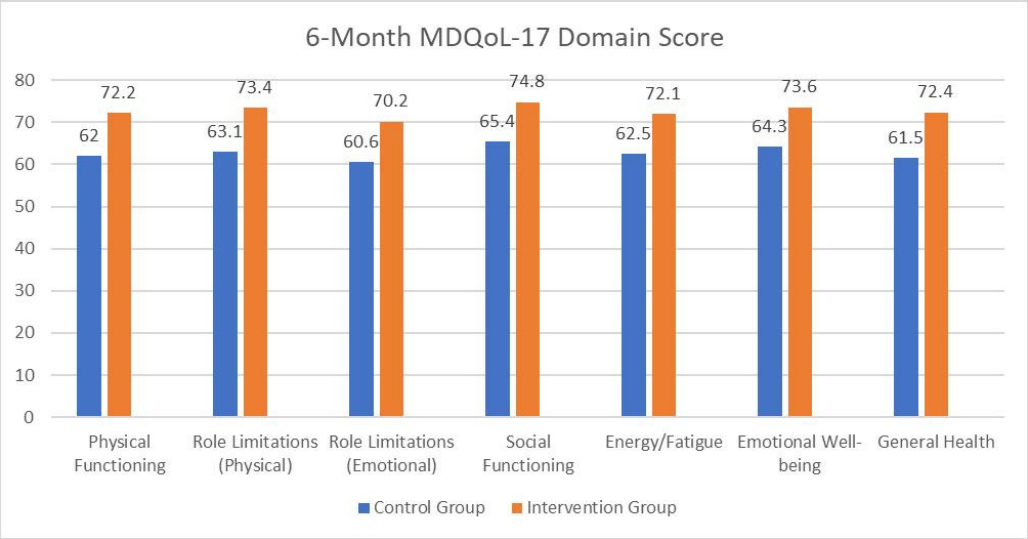


**Figure 3:** Comparison of Mean MDQoL-17 Domain Scores Between Control and Intervention Groups at 6-Month Follow-Up.

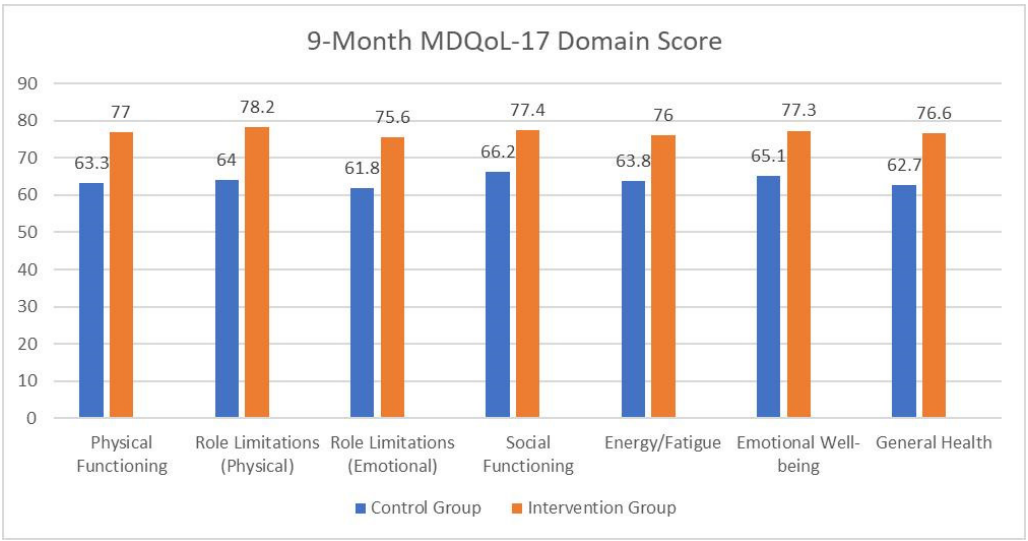


**Figure 4:** Comparison of Mean MDQoL-17 Domain Scores Between Control and Intervention Groups at 9-Month Follow-Up.

receive structured education and ongoing support (Singh *et al.*, 2023).

By the 6-month follow-up, the benefits extended to more emotionally driven domains, such as general health perception and energy levels. This trend underscores the evolving nature of behavior change in chronic disease management-while physical habits may shift relatively quickly, emotional well-being often improves more gradually with sustained support (Chisalunda *et al.*, 2023).

At the 9-month follow-up, the intervention group demonstrated notable enhancements in all MDQoL-17 domains, particularly in emotional well-being and limitations associated with emotional health. These improvements highlight the intervention's comprehensive impact on overall well-being, and participants reported greater confidence in managing their condition, suggesting increased self-efficacy and resilience. These findings support those of (Tare and Kothary, 2020), who emphasized the value of multimodal, patient-focused care in enhancing long-term outcomes beyond glycemic metrics.

Interestingly, certain subgroups-such as employed and literate individuals-responded more actively to the intervention in the earlier months, likely due to better access to information and stronger engagement with the educational components. However, by the end of the study, even participants with less formal education or more advanced disease reported notable improvements, demonstrating the adaptability and inclusivity of the intervention model.

Additionally, patients with longer disease duration and coexisting medical conditions-groups typically considered at higher risk for poor outcomes-showed marked improvements in QoL. This highlights the potential of structured, consistent support to offset the cumulative burden of chronic illness, even in patients who have lived with diabetes for many years (Prajapati *et al*., 2017; Chisalunda *et al*., 2023).

However, the study does have certain limitations. Since the data were self-reported, there is a possibility of response bias. Additionally, the follow-up duration was relatively brief, which may not adequately reflect the long-term persistence of QoL improvements. The research was also conducted within a single geographic region, potentially limiting the broader applicability of the results.

Upcoming research may focus on delivering the intervention via digital platforms to broaden its reach, particularly among underserved populations. Further research may also investigate the cost-effectiveness of implementing these programs on a larger scale.

**Table 3: 3-Month MDQoL-17 scores by Demographic and Clinical Characteristics.**

| Sl. No. | Characteristic | Category | Control Group (Mean±SD) | Intervention Group (Mean±SD) | Total (Mean±SD) | *p*-value |
|---|---|---|---|---|---|---|
| 1. | Age Group | 21-30 years | 74.1±4.2 | 77.3±3.5 | 75.7±3.9 | 0.039* |
| | | 31-40 years | 72.0±5.8 | 76.1±4.8 | 74.0±5.4 | |
| | | 41-50 years | 69.7±5.6 | 73.0±6.0 | 71.3±5.8 | |
| | | 51-60 years | 65.9±7.2 | 70.4±6.5 | 68.2±6.9 | |
| | | 61-70 years | 62.2±6.3 | 67.0±6.8 | 64.6±6.6 | |
| | | Above 70 years | 59.7±5.3 | 63.6±5.8 | 61.6±5.6 | |
| 2. | BMI | Underweight | 65.1±6.6 | 68.0±6.9 | 66.5±6.7 | 0.048* |
| | | Normal weight | 71.2±5.6 | 74.8±5.2 | 73.0±5.4 | |
| | | Overweight | 69.0±5.9 | 72.7±6.0 | 70.8±6.0 | |
| | | Obese | 63.6±6.3 | 67.5±6.1 | 65.6±6.2 | |
| 3. | Duration of Diabetes | < 1 year | 74.5±5.0 | 77.8±4.5 | 76.1±4.7 | 0.004* |
| | | 1-5 years | 72.3±5.6 | 75.1±5.3 | 73.7±5.5 | |
| | | 6-10 years | 68.3±5.9 | 71.8±6.1 | 70.1±6.0 | |
| | | >10 years | 63.0±6.2 | 66.8±6.6 | 64.9±6.4 | |
| 4. | Literacy Status | Literate | 70.5±5.8 | 74.2±6.0 | 72.3±5.9 | 0.030* |
| | | Illiterate | 63.4±5.4 | 66.8±5.8 | 65.1±5.6 | |
| 5. | Occupation | Employed | 71.1±6.0 | 74.8±5.7 | 72.9±5.9 | 0.042* |
| | | Unemployed | 67.5±6.3 | 71.2±6.1 | 69.4±6.2 | |
| 6. | Tobacco Use | Chewer | 62.7±5.1 | 66.0±5.6 | 64.3±5.4 | 0.073 |
| | | Non-Chewer | 69.3±6.1 | 72.8±5.9 | 71.0±6.0 | |
| 7. | Diabetic Complications | Present (any) | 63.0±5.8 | 66.6±5.9 | 64.8±5.9 | 0.001* |
| | | Nil | 72.4±5.2 | 75.4±5.0 | 73.9±5.1 | |
| 8. | Comorbidity | Present (any) | 64.6±5.9 | 67.9±6.3 | 66.2±6.1 | 0.011* |
| | | Nil | 71.3±5.5 | 74.6±5.1 | 73.0±5.3 | |
| 9. | $HbA_{1c}$ Category | 4-7% | 6.50±0.00 | 6.60±0.00 | 6.55±0.07 | 0.6396 |
| | | 7-8% | 7.30±0.14 | 7.40±0.20 | 7.37±0.18 | |
| | | >8% | 9.43±0.45 | 9.41±0.47 | 9.42±0.46 | |
| 10 | FBS Range (mg/dL) | Less than 110 | - | 76.8±4.1 | 76.8±4.1 | 0.0008* |
| | | 110 - 126 | 70.2±5.7 | 74.0±4.8 | 71.8±5.5 | |
| | | >126 | 66.7±6.2 | 70.5±5.6 | 68.5±6.1 | |

Statistically Significant $p<0.05$

**Table 4: 6-Month MDQoL-17 scores by Demographic and Clinical Characteristics.**

| SL. No | Characteristic | Category | Control Group (Mean±SD) | Intervention Group (Mean±SD) | Total (Mean±SD) | *p*-value |
|---|---|---|---|---|---|---|
| 1. | Age Group | 21-30 years | 75.8±4.0 | 79.0±3.3 | 77.4±3.7 | 0.037* |
| | | 31-40 years | 73.6±5.5 | 77.4±4.6 | 75.5±5.1 | |
| | | 41-50 years | 71.1±5.3 | 74.5±5.8 | 72.8±5.6 | |
| | | 51-60 years | 67.4±6.9 | 71.9±6.2 | 69.7±6.6 | |
| | | 61-70 years | 63.9±6.1 | 68.8±6.5 | 66.4±6.3 | |
| | | Above 70 years | 61.1±5.1 | 65.2±5.6 | 63.2±5.4 | |
| 2. | BMI | Underweight | 66.7±6.3 | 69.8±6.6 | 68.2±6.5 | 0.044* |
| | | Normal weight | 73.0±5.3 | 76.5±5.0 | 74.7±5.2 | |
| | | Overweight | 70.8±5.7 | 74.4±5.8 | 72.6±5.8 | |
| | | Obese | 65.3±6.0 | 69.1±5.9 | 67.2±6.0 | |
| 3. | Duration of Diabetes | < 1 year | 76.2±4.7 | 79.6±4.3 | 77.9±4.5 | 0.003* |
| | | 1-5 years | 73.8±5.4 | 76.7±5.1 | 75.3±5.3 | |
| | | 6-10 years | 69.9±5.6 | 73.4±5.9 | 71.6±5.8 | |
| | | >10 years | 64.6±5.9 | 68.6±6.3 | 66.6±6.1 | |
| 4. | Literacy Status | Literate | 72.1±5.6 | 75.9±5.8 | 74.0±5.7 | 0.027* |
| | | Illiterate | 64.8±5.1 | 68.3±5.6 | 66.5±5.4 | |
| 5. | Occupation | Employed | 72.8±5.8 | 76.6±5.4 | 74.7±5.6 | 0.038* |
| | | Unemployed | 69.1±6.0 | 72.9±5.9 | 71.0±6.0 | |
| 6. | Tobacco Use | Chewer | 64.2±4.9 | 67.6±5.2 | 65.9±5.1 | 0.069 |
| | | Non-Chewer | 70.8±5.8 | 74.3±5.7 | 72.6±5.8 | |
| 7. | Diabetic Complications | Present (any) | 64.6±5.5 | 68.2±5.7 | 66.4±5.6 | 0.001* |
| | | Nil | 73.9±5.0 | 76.8±4.7 | 75.4±4.9 | |
| 8. | Comorbidity | Present (any) | 66.1±5.7 | 69.4±6.1 | 67.8±5.9 | 0.009* |
| | | Nil | 72.9±5.3 | 76.3±4.9 | 74.6±5.1 | |
| 9. | $HbA_{1c}$ Category | 4-7% | 6.55±0.22 | 6.50±0.19 | 6.51± 0.20 | |
| | | 7-8% | 7.30±0.25 | 7.30±0.25 | 7.33±0.27 | |
| | | >8% | 8.83±0.94 | 8.12±0.92 | 8.48±0.98 | |
| 10. | FBS Range (mg/dL) | Less than 110 | 71.8±5.2 | 77.2±4.3 | 75.6±5.0 | 0.0005* |
| | | 110 - 126 | 68.5±5.8 | 72.6±4.7 | 69.7±5.6 | |
| | | More than 126 | 65.4±6.1 | 69.8±5.5 | 66.7±6.0 | |

Statistically Significant $p<0.05$

**Table 5: 9-Month MDQoL-17 scores by Demographic and Clinical Characteristics.**

| Sl. No. | Characteristic | Category | Control Group (Mean±SD) | Intervention Group (Mean±SD) | Total (Mean±SD) | *p*-value |
|---|---|---|---|---|---|---|
| 1. | Age Group | 21-30 years | 78.5±3.8 | 82.1±3.0 | 80.3±3.5 | 0.029* |
| | | 31-40 years | 76.2±5.2 | 80.0±4.2 | 78.1±4.8 | |
| | | 41-50 years | 73.5±4.9 | 77.3±5.4 | 75.4±5.2 | |
| | | 51-60 years | 70.1±6.4 | 74.7±5.8 | 72.4±6.1 | |
| | | 61-70 years | 66.8±5.8 | 71.7±6.1 | 69.3±6.0 | |
| | | Above 70 years | 64.1±5.0 | 68.0±5.3 | 66.1±5.2 | |

| Sl. No. | Characteristic | Category | Control Group (Mean±SD) | Intervention Group (Mean±SD) | Total (Mean±SD) | *p*-value |
|---|---|---|---|---|---|---|
| 2. | BMI | Underweight | 69.3±6.1 | 72.5±6.3 | 70.9±6.2 | 0.041* |
| | | Normal weight | 75.6±5.1 | 79.1±4.7 | 77.4±4.9 | |
| | | Overweight | 73.4±5.4 | 77.2±5.5 | 75.3±5.5 | |
| | | Obese | 68.2±5.7 | 72.3±5.6 | 70.2±5.7 | |
| 3. | Duration of Diabetes | < 1 year | 79.4±4.5 | 82.8±4.0 | 81.1±4.3 | 0.002* |
| | | 1-5 years | 76.7±5.1 | 79.8±4.9 | 78.2±5.0 | |
| | | 6-10 years | 72.6±5.3 | 76.1±5.6 | 74.3±5.5 | |
| | | >10 years | 67.4±5.8 | 71.1±6.1 | 69.3±5.9 | |
| 4. | Literacy Status | Literate | 75.0±5.4 | 78.9±5.6 | 77.0±5.5 | 0.025* |
| | | Illiterate | 67.9±4.8 | 71.2±5.3 | 69.5±5.1 | |
| 5. | Occupation | Employed | 75.7±5.5 | 79.6±5.1 | 77.7±5.3 | 0.034* |
| | | Unemployed | 71.9±5.7 | 75.6±5.6 | 73.8±5.7 | |
| 6. | Tobacco Use | Chewer | 67.1±4.8 | 70.5±5.1 | 68.8±5.0 | 0.066 |
| | | Non-Chewer | 73.4±5.7 | 77.0±5.5 | 75.2±5.6 | |
| 7. | Diabetic Complications | Present (any) | 67.2±5.3 | 71.0±5.5 | 69.1±5.4 | 0.001* |
| | | Nil | 75.8±4.9 | 78.9±4.6 | 77.4±4.7 | |
| 8. | Comorbidity | Present (any) | 68.8±5.5 | 72.1±5.9 | 70.5±5.7 | 0.008* |
| | | Nil | 75.4±5.0 | 78.8±4.7 | 77.1±4.8 | |
| 9. | $HbA_{1c}$ Category | 4-7% | 6.50±0.18 | 6.45±0.20 | 6.46±0.20 | <0.0001 |
| | | 7-8% | 7.35±0.30 | 7.30±0.26 | 7.32±0.28 | |
| | | >8% | 8.60±1.00 | 7.68±0.91 | 8.14±1.03 | |
| 10. | FBS Range (mg/dL) | Less than 110 | 72.5±5.1 | 78.4±4.2 | 76.5±4.6 | 0.00002* |
| | | 110 - 126 | 69.0±5.6 | 74.1±4.5 | 70.6±5.4 | |
| | | More than 126 | 66.2±6.0 | 71.5±5.1 | 67.3±5.9 | |

Statistically Significant $p<0.05$

**Table 6: Comparison of MDQOL domain scores between control and intervention groups at baseline and follow-up visits.**

| Domain | Control (Mean±SD) | Intervention (Mean±SD) | *p*-value |
|---|---|---|---|
| **Baseline** | | | |
| Physical Functioning | 60.1±5.1 | 60.8±5.0 | 0.52 |
| Role Limitations (Physical) | 61.2±5.0 | 62.1±5.2 | 0.47 |
| Role Limitations (Emotional) | 58.6±4.8 | 59.0±4.9 | 0.60 |
| Social Functioning | 63.5±5.2 | 64.1±5.1 | 0.55 |
| Energy/Fatigue | 60.4±5.0 | 61.0±5.1 | 0.53 |
| Emotional Well-being | 62.7±5.3 | 63.2±5.0 | 0.59 |
| General Health | 59.5±4.9 | 60.1±4.8 | 0.57 |
| **3-month follow-up** | | | |
| Physical Functioning | 61.2±5.2 | 67.2±4.9 | 0.001* |
| Role Limitations (Physical) | 62.3±5.1 | 68.5±5.0 | 0.002* |
| Role Limitations (Emotional) | 59.8±5.0 | 65.2±5.1 | 0.005* |
| Social Functioning | 64.5±5.3 | 70.6±4.8 | 0.0001* |
| Energy/Fatigue | 61.4±5.2 | 67.8±4.9 | 0.0005* |

| Domain | Control (Mean±SD) | Intervention (Mean±SD) | *p*-value |
|---|---|---|---|
| Emotional Well-being | 63.5±5.3 | 69.4±5.0 | 0.0003* |
| General Health | 60.6±4.9 | 68.1±4.7 | 0.0008* |
| **6-month follow-up** | | | |
| Physical Functioning | 62.0±5.0 | 72.2±4.6 | 0.0001* |
| Role Limitations (Physical) | 63.1±4.9 | 73.4±4.7 | 0.0002* |
| Role Limitations (Emotional) | 60.6±5.1 | 70.2±4.5 | 0.0003* |
| Social Functioning | 65.4±5.2 | 74.8±4.6 | 0.00005* |
| Energy/Fatigue | 62.5±5.0 | 72.1±4.7 | 0.0001* |
| Emotional Well-being | 64.3±5.1 | 73.6±4.6 | 0.00007* |
| General Health | 61.5±4.8 | 72.4±4.5 | 0.0002* |
| **9-month follow-up** | | | |
| Physical Functioning | 63.3±4.8 | 77.0±4.3 | <0.0001* |
| Role Limitations (Physical) | 64.0±4.7 | 78.2±4.4 | <0.0001* |
| Role Limitations (Emotional) | 61.8±4.9 | 75.6±4.2 | <0.0001* |
| Social Functioning | 66.2±5.0 | 77.4±4.3 | <0.0001* |
| Energy/Fatigue | 63.8±4.9 | 76.0±4.4 | <0.0001* |
| Emotional Well-being | 65.1±4.8 | 77.3±4.3 | <0.0001* |
| General Health | 62.7±4.7 | 76.6±4.2 | <0.0001* |

Statistically Significant $p<0.05$

## CONCLUSION

This study demonstrates that implementing a structured educational and behavioral approach leads to significant enhancements in the QoL for people with DM. Over the 9 months, participants in the intervention group experienced notable gains across physical, emotional, and social health domains, as measured by the MDQoL-17, compared to those receiving routine care. These improvements were not only evident early on but sustained over time and observed across diverse subgroups, including those with long disease duration, comorbidities, and varying literacy levels. The findings emphasize the importance of incorporating patient-centered, holistic approaches into diabetes management, moving beyond traditional clinical care to address the broader psychosocial challenges faced by patients. The intervention's adaptability and effectiveness across demographics highlight its potential for broader implementation in various healthcare settings, particularly in resource-constrained environments. Overall, empowering patients through continuous education, engagement, and self-management support can lead to meaningful, long-term enhancements in their quality of life and well-being.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ETHICAL APPROVAL

It is a part of a randomized controlled trial titled "Impact of clinical pharmacist led Comprehensive Medication Management on diabetic women in tertiary care hospital- A Randomized controlled study." The ethical committee of KLE Academy of Higher Education and Research (KAHER), Belagavi (Ref. No.: KAHER/EC/22-23/134.), approved the study. The trial was registered with the clinical trial registry of India (Reg. No:CTRI/2022/12/048461). Written informed consent was taken from all the participants.

## ABBREVIATIONS

**DM:** Diabetes Mellitus; **GDM:** Gestational Diabetes Mellitus; **PCOS:** Polycystic Ovary Syndrome; **OHAs:** Oral Hypoglycemic Agents; **HRQOL:** Health-related quality of life; **MDQOL:** Modified diabetes quality of life.

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