

IMPACT OF PHARMACIST-LED EDUCATIONAL INTERVENTION ON GLYCAEMIC CONTROL, ANTHROPOMETRIC PARAMETERS AND HEALTH-RELATED QUALITY OF LIFE IN OBESE PATIENTS WITH TYPE 2 DIABETES MELLITUS: A PROSPECTIVE SINGLE-ARM INTERVENTIONAL STUDY

Shrishti S Karoshi¹, Anushree Deshpande^{1*}, Vishwa Rajkumar Byakod¹

¹ Dept. of Pharmacy Practice, KLE College of Pharmacy, Belagavi, KLE Academy for Higher Education and Research (KAHER), Belagavi, Karnataka, India.

Author for Correspondence:

Anushree Deshpande*

Department of Pharmacy Practice

KLE College of Pharmacy, Belagavi, KLE Academy for Higher Education and Research (KAHER) Belagavi, Karnataka, India.

Email Id: anushreedeshpande@klepharm.edu

Contact no: +918792998483

ORCID ID: 0000-0002-4655-1807

ABSTRACT

Background: India bears a substantial burden of type 2 diabetes mellitus (T2DM), with obesity-related cardiometabolic risk occurring at lower BMI thresholds in South Asians. Despite robust evidence supporting structured patient education, its integration into routine outpatient diabetes care remains limited. Clinical pharmacists are well-placed to deliver this through patient information leaflets (PILs).

Objective: To evaluate the impact of a pharmacist-led educational intervention on glycaemic control, anthropometric parameters and health-related quality of life among obese adults with type 2 diabetes mellitus.

Methods: A prospective single-arm interventional study was conducted at a tertiary care teaching hospital from September 2025 to April 2026. 102 obese T2DM patients (BMI ≥ 25 kg/m²) received pharmacist-delivered counselling alongside a multilingual PIL developed from current diabetes management guidelines at baseline, one month, and four months, addressing diet, physical activity, glucose self-monitoring, medication adherence, and psychological wellbeing. Glycated Haemoglobin (HbA1c) was measured at baseline and 4 months; fasting blood sugar (FBS), postprandial blood sugar (PPBS), body weight, BMI, and the India-specific EuroQol EQ-5D-5L utility index were recorded at all three timepoints. Repeated-measures ANOVA with Bonferroni-adjusted pairwise comparisons was used for statistical analysis; significance was defined as $p < 0.05$.

Results: Mean FBS declined by 26.01 mg/dL (130.76 ± 19.07 to 104.75 ± 15.88 mg/dL; $p < 0.001$) and HbA1c by 0.28 percentage points ($8.01 \pm 1.66\%$ to $7.73 \pm 1.43\%$; $p = 0.004$) at four months. BMI fell by 0.87 kg/m² (30.82 ± 4.85 to 29.95 ± 4.76 kg/m²; $p = 0.002$). The primary outcome EQ-5D-5L utility index rose from 0.883 ± 0.234 to 0.947 ± 0.099 ($p < 0.001$), with greatest improvements observed in pain/discomfort and anxiety/depression. Retention was 100% across both follow-up intervals.

Conclusion: The educational intervention produced modest but significant improvements in glycaemic control, body composition and health-related quality of life (HRQoL) in obese T2DM patients over four months. Its feasibility without pharmacotherapy modification supports implementation in resource-constrained outpatient settings.

KEYWORDS

Diabetes Mellitus, Type 2, Obesity, Pharmaceutical Services, Patient Education, Quality of Life, Glycaemic Control

How to cite this article: Karoshi SS, Deshpande A, Byakod VR. Impact of pharmacist-led educational intervention on glycaemic control, anthropometric parameters and health-related quality of life in obese patients

INTRODUCTION

Diabetes mellitus type 2 has become one of the defining health challenges of the twenty-first century. The International Diabetes Federation estimated 537 million adults worldwide were living with this condition in 2021, with projections reaching 643 million by 2030 [1]. India bears a particularly heavy share of this burden — the ICMR-INDIAB-17 national survey identified over 101 million adults with T2DM across the country, placing extraordinary strain on an already resource-limited healthcare system [2]. What sharpens India's challenge is a well-recognised phenotypic pattern: cardiometabolic risk in South Asians accumulates at BMI thresholds substantially lower than those seen in Western populations, owing to a tendency toward visceral adiposity even at modest body weights [3, 4].

The relationship between obesity and T2DM is closely intertwined. Excess visceral fat releases adipokines and free fatty acids that disrupt insulin receptor signalling and progressively exhaust pancreatic beta-cell function [5, 6]. The resulting hyperglycaemia drives a range of microvascular and macrovascular complications [7]. Even a 5–7% reduction in body weight has been shown to improve glycaemic parameters and cardiovascular risk meaningfully, and losses exceeding 10% may bring about remission in some patients [8]. Turning this knowledge into practice, however, remains difficult in real-world outpatient settings. An endocrinology appointment typically spans ten to fifteen minutes — sufficient to review medications, but rarely enough for the kind of structured, patient-centred behavioural counselling that sustained self-management depends on [9].

The impact of obesity in T2DM extends beyond metabolic dysregulation alone and substantially affects patients' physical functioning, psychological wellbeing, and overall quality of life. Obese individuals with T2DM frequently experience greater treatment burden, reduced mobility, musculoskeletal discomfort, and increased prevalence of anxiety and depressive symptoms compared with their non-obese counterparts [12,13]. Excess adiposity has also been associated with poorer glycaemic control, greater insulin resistance, and increased risk of cardiovascular complications, making weight management a central component of contemporary diabetes care [6,8]. Despite this, sustainable lifestyle modification remains difficult to achieve in routine clinical practice because

patients often require ongoing behavioural support beyond standard medical consultations. Consequently, obese individuals with T2DM represent a particularly important population for educational interventions aimed at improving self-management behaviours. Demonstrating improvements in both clinical outcomes and health-related quality of life within this high-risk group may provide evidence for practical strategies that address the dual burden of obesity and diabetes simultaneously [8,12,22].

Moreover, obesity may adversely influence treatment adherence and self-management by limiting physical activity, increasing fatigue, and contributing to negative health perceptions. These factors can create a cycle in which poor metabolic control further exacerbates obesity-related complications. Consequently, interventions that simultaneously target lifestyle behaviours, weight management, and patient engagement may be particularly valuable in obese individuals with T2DM, a population that often requires more intensive and sustained support to achieve therapeutic goals [14,22].

Clinical pharmacists occupy a natural position to fill this gap. Their therapeutic knowledge, frequency of contact with patients, and ability to deliver organised counselling make them a practical extension of the diabetes care team. Published systematic reviews have consistently shown that pharmacist-led programmes reduce HbA1c and improve medication adherence in T2DM [10, 11]. Within this institution, pharmacist-delivered structured education for women with T2DM improved knowledge, attitudes, and self-care practices significantly over standard care [17, 24]. Similar findings have been reported elsewhere, with diabetes self-care behaviours, healthy lifestyle practices, and social support showing significant associations with improved glycaemic outcomes among patients with T2DM [25]. A recent national systematic review found diabetes self-care practices remain suboptimal across multiple Indian regions, pointing to persistent educational need irrespective of patient background [29].

Alongside biomarkers, HRQoL is increasingly viewed as a meaningful clinical outcome. The EQ-5D-5L instrument captures five health domains — mobility, self-care, usual activities, pain/discomfort, and anxiety/depression — and converts these into a single utility index anchored at 0 (equivalent to death) and 1 (perfect health) using population-specific preference weights [12-13].

Pain/discomfort and anxiety/depression are consistently the most affected domains in T2DM [12], and untreated psychological distress further undermines glycaemic control by negatively affecting motivation for self-care [14]. However, evidence regarding pharmacist-led educational interventions specifically targeting obese individuals with T2DM and evaluating both clinical and utility-based HRQoL outcomes remains limited in the Indian setting. This study examined whether a pharmacist-led educational intervention could produce measurable gains across glycaemic, anthropometric, and HRQoL outcomes in obese T2DM patients attending an outpatient endocrinology clinic in South India.

MATERIALS AND METHODS

Study Design, Setting, and Ethics

A prospective single-arm interventional study was conducted at the outpatient department of Endocrinology of a Tertiary care teaching hospital. The study was conducted over a period of 9 months including Recruitment period: September 2025–December 2025 and Follow-up completion period: April 2026. Ethical approval was obtained from the Institutional Ethics Committee, KLE College of Pharmacy, Belagavi (IEC Ref. No. KLECOPBGMEC/D005-2025) prior to commencement. Written informed consent was obtained from all the participants in their preferred language. The multilingual PIL was developed from current diabetes management guidelines and reviewed by clinical pharmacy and endocrinology experts for content accuracy prior to use.

Participants

As this was an exploratory real-world study, all eligible patients presenting during the recruitment period were consecutively enrolled (n=102). Inclusion criteria: age ≥ 18 years, confirmed T2DM diagnosis, BMI ≥ 25 kg/m², and written informed consent. Patients with stabilised hypertension or thyroid disorders were included. Exclusion criteria: type 1 diabetes, pregnancy or lactation, severe comorbidities or systemic corticosteroid therapy, concurrent participation in another trial, and use of complementary medicine.

Intervention, Outcomes, and Follow-Up

Participants received 15-minute one-to-one pharmacist-led counselling at baseline, 1 month, and 4 months. The intervention was delivered by the clinical pharmacist using a standardized counselling framework and a multilingual patient information leaflet (PIL) developed from current diabetes management guidelines. The PIL covered dietary

modification, physical activity, self-monitoring of blood glucose, medication adherence, weight management, and psychological well-being [15]. Reinforcement counselling followed the same structured format at each follow-up visit. No changes were made to prescribed pharmacotherapy.

Clinical outcomes included HbA1c, FBS, PPBS, body weight, and BMI, obtained from hospital records. HbA1c was assessed at baseline and 4 months, while other parameters were recorded at all visits. HRQoL was evaluated using the EQ-5D-5L, and utility index scores were calculated using the India-specific value set [16].

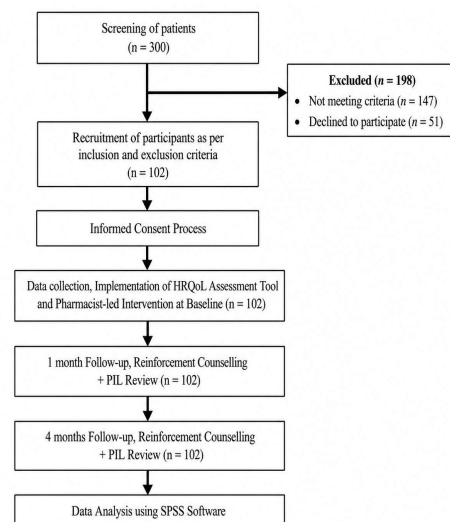
Follow-up assessments were conducted at 1 month and 4 months. Multiple telephonic reminders were provided before scheduled visits, resulting in 100% participant retention and completion of all follow-up assessments.

Statistical Analysis

Data were analysed using IBM SPSS Statistics version 20.0. Continuous variables were expressed as mean $\pm$ standard deviation (SD), while categorical variables were presented as frequencies and percentages. Repeated Measures ANOVA followed by Bonferroni-adjusted pairwise comparisons were performed to identify significant differences between time points. For HbA1c, comparisons were made only between baseline and 4 months. A p-value <0.05 was considered statistically significant.

RESULTS

Figure 1. Participant flow diagram



Participant Flow

All 102 enrolled patients completed assessments at 1 month and 4 months, giving a 100% follow-up rate. The participant flow is illustrated in Figure 1.

Table 1 Sociodemographic and Disease Characteristics of Participants (n = 102)

Variable	Category	Frequency of patients, n (%)
Age (years)	≤40	20 (19.6)
	41–60	52 (51.0)
	61–80	29 (28.4)
	>80	1 (1.0)
Gender	Female	74 (72.5)
	Male	28 (27.5)
Occupation	Homemaker	59 (57.8)
	Service	24 (23.5)
	Retired	12 (11.8)
	Self-employed	7 (6.9)
Caffeine Consumption	Yes	89 (87.3)
Alcohol Consumption	Yes	11 (10.8)
Smoking	Yes	4 (3.9)
T2DM Duration	<1 year	22 (21.6)
	1–5 years	28 (27.5)
	6–10 years	27 (26.5)
	11–15 years	13 (12.7)
Type of Treatment	OHA	77 (75.5)
	OHA + Insulin	25 (24.5)
Comorbidities	Hypertension	49 (48.0)
	Hypothyroidism	19 (18.6)
	IHD	4 (3.9)
	Diabetic Foot	3 (2.9)
	Hyperthyroidism	3 (2.9)
	Goitre	1 (1.0)
	IBS	1 (1.0)
	COPD	1 (1.0)
	Bronchial Asthma	1 (1.0)

All 102 participants completed both follow-up visits (100% retention); no comparison of completers versus those lost to follow-up was required.

Baseline Characteristics

Of the 102 patients enrolled as shown in Table 1, the majority were aged 41–60 years (51.0%), followed by those in the 61–80 age group (28.4%). Women constituted 72.5% of the cohort and homemakers formed the largest occupational group (57.8%). Caffeine consumption was reported by 87.3% of participants, while alcohol use and smoking were infrequent (10.8% and 3.9%, respectively). Regarding diabetes duration, 21.6% had been diagnosed for less than one year, while the remaining 78.4% had lived with T2DM for one year or more, with 27.5% in the 1–5year range and 26.5% in the 6–10year range. Hypertension was the most prevalent comorbidity (48.0%), followed by hypothyroidism (18.6%), with IHD, diabetic foot, and hyperthyroidism each present in smaller proportions; as several patients carried more than one concurrent condition, comorbidity percentages are non-mutually exclusive. Majority of the patients (75.5%) were managed on oral hypoglycaemic agents alone, with the remaining 24.5% on combination OHA-insulin regimens.

Table 2. EQ-5D-5L Health States and Utility Index Across Study Visits (n = 102)

Variable	Category	Baseline n (%)	1 Month Follow-up n (%)	4 Month Follow-up n (%)
Mobility	No problem	75 (73.5)	81 (79.4)	85 (83.3)
	Slight problem	17 (16.7)	11 (10.8)	11 (10.8)
	Moderate Problem	7 (6.9)	8 (7.8)	6 (5.9)
	Severe Problem	2 (2.0)	1 (1.0)	0 (0)
	Extreme Problem	1 (1.0)	1 (1.0)	0 (0)
Self-care	No problem	97 (95.1)	98 (96.1)	99 (97.1)
	Slight problem	2 (2.0)	1 (1.0)	1 (1.0)
	Moderate Problem	2 (2.0)	3 (2.9)	2 (2.0)

	Severe Problem	1 (1.0)	0 (0)	0 (0)
	Extreme Problem	0 (0)	0 (0)	0 (0)
Usual Activities	No problem	90 (88.2)	92 (90.2)	93 (91.2)
	Slight problem	9 (8.8)	7 (6.9)	7 (6.9)
	Moderate Problem	1 (1.0)	1 (1.0)	1 (1.0)
	Severe Problem	1 (1.0)	1 (1.0)	0 (0)
	Extreme Problem	1 (1.0)	1 (1.0)	1 (1.0)
Pain or Discomfort	No problem	44 (43.1)	48 (47.1)	59 (57.8)
	Slight problem	34 (33.3)	34 (33.3)	33 (32.4)
	Moderate Problem	17 (16.7)	15 (14.7)	10 (9.8)
	Severe Problem	5 (4.9)	4 (3.9)	0 (0)
	Extreme Problem	2 (2.0)	1 (1.0)	0 (0)
Anxiety or Depression	No problem	72 (70.6)	78 (76.5)	89 (87.3)
	Slight problem	24 (23.5)	20 (19.6)	12 (11.8)
	Moderate Problem	6 (5.9)	4 (3.9)	1 (1.0)
	Severe Problem	0 (0)	0 (0)	0 (0)
	Extreme Problem	0 (0)	0 (0)	0 (0)

EQ-5D Utility Index	Perfect Health	34 (33.3)	40 (39.2)	51 (50.0)
	Health State better than death	66 (65.5)	60 (58.8)	51 (50.0)
	Health State worse than death	2 (2.0)	2 (2.0)	0 (0)

EQ-5D-5L Scores and Utility Index recorded at all timepoints

Distribution of responses across EQ-5D-5L domains is shown in Table 2. Improvements were observed primarily in mobility, pain/discomfort, and anxiety/depression over the study period, whereas self-care and usual activities remained largely unchanged. These domain-level changes were accompanied by an increase in the mean EQ-5D utility index from 0.88 ± 0.23 at baseline to 0.94 ± 0.09 at 4 months, indicating an overall improvement in health-related quality of life.

Table 3. Estimated Mean Difference (Bonferroni-adjusted) (95% CI)

Parameter	Comparison	Estimated Mean Difference (95% CI)	p-value
HbA1c	Baseline vs 4 Months	0.147 (0.038 to 0.256)	0.004 *
	Baseline vs 1Month	0.598 (0.318 to 0.878)	<0.001 *
FBS	Baseline vs 4 Months	0.951 (0.670 to 1.231)	<0.001 *
	1 Month vs 4 Months	0.353 (0.126 to 0.580)	0.001 *
	Baseline vs 1Month	0.314 (-0.037 to 0.665)	0.095
PPBS	Baseline vs 4Months	0.490 (0.138 to 0.842)	0.003 *
	1 Month vs 4 Months	0.176 (-0.108 to 0.461)	0.403
	Baseline vs 1Month	0.314 (-0.037 to 0.665)	0.095

Body Weight	Baseline vs 1 Month	0.020 (-0.039 to 0.078)	1.000
	Baseline vs 4 Months	0.078 (0.005 to 0.152)	0.032 *
	1 Month vs 4 Months	0.059 (-0.008 to 0.125)	0.100
BMI	Baseline vs 1 Month	0.039 (-0.008 to 0.086)	0.135
	Baseline vs 4 Months	0.108 (0.033 to 0.183)	0.002 *
	1 Month vs 4 Months	0.069 (0.007 to 0.130)	0.023 *
Mobility	Baseline vs 1 Month	0.069 (-0.001 to 0.139)	0.057
	Baseline vs 4 Months	0.176 (0.067 to 0.286)	<0.001 *
	1 Month vs 4 Months	0.108 (0.025 to 0.190)	0.006 *
Self-care	Baseline vs 1 Month	0.020 (-0.014 to 0.053)	0.475
	Baseline vs 4 Months	0.039 (-0.008 to 0.086)	0.135
	1 Month vs 4 Months	0.020 (-0.014 to 0.053)	0.475
Usual Activities	Baseline vs 1 Month	0.020 (-0.014 to 0.053)	0.475
	Baseline vs 4 Months	0.049 (-0.003 to 0.101)	0.074
	1 Month vs 4 Months	0.029 (-0.012 to 0.070)	0.250
Pain/Discomfort	Baseline vs 1 Month	0.108 (0.033 to 0.183)	0.002 *
	Baseline vs 4 Months	0.373 (0.233 to 0.512)	<0.001 *

	1 Month vs 4 Months	0.265 (0.134 to 0.396)	<0.001 *
Anxiety/Depression	Baseline vs 1 Month	0.078 (0.005 to 0.152)	0.032 *
	Baseline vs 4 Months	0.216 (0.105 to 0.326)	<0.001 *
	1 Month vs 4 Months	0.137 (0.047 to 0.227)	0.001 *
EQ-5D Utility Index	Baseline vs 1 Month	0.059 (0.012 to 0.105)	0.014 *
	Baseline vs 4 Months	0.186 (0.109 to 0.263)	<0.001 *
	1 Month vs 4 Months	0.127 (0.056 to 0.199)	0.001 *

Comparison of Clinical and Patient-Reported Outcomes Across Follow-up Period

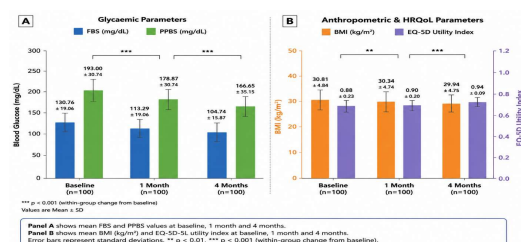
Pairwise comparisons are presented in Table 3. HbA1c demonstrated a significant reduction between baseline and 4 months ($p = 0.004$). Significant improvements were observed in FBS across all follow-up comparisons (all $p \leq 0.001$), whereas PPBS showed a significant reduction only at 4 months compared with baseline ($p = 0.003$). BMI decreased significantly between baseline and 4 months ($p = 0.002$) and between 1 and 4 months ($p = 0.023$). Among HRQoL measures, significant improvements were observed in mobility, pain/discomfort, anxiety/depression, and EQ-5D utility index, while self-care and usual activities did not show statistically significant changes.

Table 4. Longitudinal Changes in Clinical and HRQoL Parameters

Variable	Baseline (Mean $\pm$ SD)	1 month (Mean $\pm$ SD)	4 months (Mean $\pm$ SD)
HbA1c	8.01 $\pm$ 1.65	-	7.73 $\pm$ 1.43
FBS	130.76 $\pm$ 19.06	113.29 $\pm$ 19.06	104.74 $\pm$ 15.87
PPBS	193.00 $\pm$ 30.74	178.87 $\pm$ 30.74	166.65 $\pm$ 35.15
Body Weight	74.03 $\pm$ 12.89	72.87 $\pm$ 12.63	71.88 $\pm$ 12.58
BMI	30.81 $\pm$ 4.84	30.34 $\pm$ 4.74	29.94 $\pm$ 4.75

EQ-5D Utility Index	0.88 ± 0.23	0.90 ± 0.20	0.94 ± 0.09
----------------------------	-------------	-------------	-------------

Figure 2. Changes in Clinical and patient-reported outcomes over time



Longitudinal Changes in Clinical and Quality of Life Outcomes

Changes in clinical outcomes across the study period are presented in Table 4 and illustrated in Figure 2. Mean HbA1c declined from $8.01 \pm 1.65\%$ at baseline to $7.73 \pm 1.43\%$ at four months. FBS fell progressively from 130.76 ± 19.06 mg/dL at baseline to 104.74 ± 15.87 mg/dL at four months, passing through 113.29 ± 19.06 mg/dL at one month, while PPBS declined from 193.00 ± 30.74 to 166.65 ± 35.15 mg/dL over the same period. Body weight and BMI reduced steadily from 74.03 ± 12.89 kg and 30.81 ± 4.84 kg/m² at baseline to 71.88 ± 12.58 kg and 29.94 ± 4.75 kg/m² at four months. The EQ-5D utility index improved from 0.88 ± 0.23 to 0.94 ± 0.09 , reflecting a gradual gain in overall health-related quality of life across the intervention period.

DISCUSSION

Over the nine-months study period, the pharmacist-led educational intervention was associated with improvements in glycaemic control, anthropometric measures, and health-related quality of life among obese patients with T2DM. However, because the study lacked a control group, the observed changes cannot be attributed exclusively to the intervention and may partly reflect increased healthcare contact, patient motivation, or natural disease variation. Nevertheless, the consistent positive trends across both clinical and patient-reported outcomes suggest a beneficial role for structured pharmacist-led education in routine diabetes care [10,11].

A notable finding was the improvement in HRQoL. The EQ-5D-5L utility index increased from 0.883 ± 0.234 at baseline to 0.947 ± 0.099 at four months ($p < 0.001$), representing a gain of 0.064 utility units. This magnitude of change is generally considered clinically meaningful in chronic disease populations and indicates a perceptible improvement in overall

health status [12]. Utility scores are also important from a health economics perspective because they are used to estimate quality-adjusted life years (QALYs) in cost-effectiveness analyses. Although no economic evaluation was performed, the observed improvement suggests benefits beyond glycaemic control alone. Furthermore, the proportion of patients reporting perfect health increased from 33.3% to 50.0%, while no participant remained in a health state worse than death at study completion.

Among glycaemic parameters, FBS demonstrated the greatest improvement, with the proportion of patients having values >140 mg/dL decreasing from 33.3% to 2.9% by four months. This rapid response may reflect improved dietary practices and medication adherence reinforced through repeated counselling and use of the PIL. HbA1c decreased by 0.28 percentage points ($p=0.004$), indicating a modest but statistically significant improvement. Although the reduction in HbA1c was modest, its clinical significance should be considered in the context of the intervention. The educational programme was implemented without pharmacotherapy modification and under routine outpatient conditions rather than a controlled experimental setting. Behavioural interventions typically produce more gradual changes than medication-based approaches because they depend on sustained patient engagement and lifestyle adaptation. Therefore, the observed improvement may still represent meaningful progress, particularly in patients with established T2DM and obesity [10,11,20]

PPBS did not improve significantly at one month but showed significant reduction by four months ($p=0.003$). This delayed response is expected because postprandial glucose is strongly influenced by long-term dietary habits rather than short-term behavioural changes. The sustained availability of the take-home PIL may have supported gradual adoption of healthier eating practices, resulting in measurable improvement over time [21].

The intervention also produced a significant reduction in BMI (0.87 kg/m²; $p=0.002$) without any modification of prescribed pharmacotherapy. While the absolute reduction appears modest, it is clinically meaningful in the context of a four-month behavioural intervention and corresponds to a sustained downward trend in body weight across follow-up visits. In South Asian populations, where cardiometabolic risk develops at lower BMI thresholds than in Western populations [3,4], even small reductions in body weight may contribute to improvements in insulin sensitivity, glycaemic control, and cardiovascular risk. Current RSSDI guidelines emphasize weight management as a

central therapeutic goal in T2DM and recognize pharmacists as important contributors to multidisciplinary diabetes care [22].

Improvements in HRQoL were primarily driven by changes in the pain/discomfort and anxiety/depression domains. Pain/discomfort showed the earliest and largest improvement, with significant change evident by one month and sustained through four months ($p < 0.001$). Reduced musculoskeletal stress associated with weight loss, better glycaemic control, and increased physical activity may collectively explain this benefit [6,7]. Similar improvements have been reported following educational interventions in both Indian and Nigerian populations [23,26].

Anxiety/depression also improved consistently across all follow-up intervals, with the proportion of participants reporting no psychological problems increasing from 70.6% to 87.3%. The gradual nature of this improvement suggests progressive strengthening of patients' confidence and ability to manage their condition rather than a short-term counselling effect. Providing clear, practical information through structured education may reduce uncertainty and enhance self-efficacy, leading to improved psychological well-being. Comparable findings have been observed in Indian diabetes self-management education studies [23]. In addition, previous randomized studies conducted by the present research group demonstrated improvements in quality of life, knowledge, and self-management behaviours following pharmacist-led educational interventions [17,24].

In contrast, the self-care and usual activities domains did not show statistically significant improvement. This likely reflects a ceiling effect rather than lack of intervention benefit, as most participants reported no problems in these domains at baseline. Such limitations of the EQ-5D-5L have been documented in relatively independent outpatient populations [12]. Despite this, the composite utility index remained sensitive to change, supporting its suitability as the primary HRQoL outcome measure.

The role of the clinical pharmacist extended beyond distribution of educational material. Structured counselling sessions provided opportunities to address medication-related concerns, reinforce lifestyle goals, and support self-management behaviours. Regular patient interaction represents a unique advantage of pharmacists within the healthcare system and has been associated with improved adherence and diabetes outcomes across diverse settings [10,11,18,28]. Reinforcement of key topics such as medication timing, missed-dose management, and hypoglycaemia recognition likely

contributed to the improvements observed in this study. The RSSDI guidelines similarly advocate greater integration of pharmacists into diabetes care delivery models [22].

The practical feasibility of the intervention is also noteworthy. The educational programme required minimal additional resources, involved short counselling sessions integrated into routine care, and did not increase physician workload or necessitate changes in prescribed therapy. These characteristics may facilitate implementation in resource-constrained healthcare settings where diabetes burden is high and access to extended physician counselling is limited [22].

Finally, complete retention of all 102 participants throughout the study highlights the feasibility of telephonic follow-up in this setting. Remote assessment minimized travel-related barriers and allowed flexible scheduling, which may have been particularly beneficial for the predominantly homemaker population included in the study [27].

STRENGTHS AND LIMITATIONS

The strengths of this study include its real-world outpatient setting with 100% participant retention, use of the India-specific EQ-5D-5L value set for utility index computation [16], and a multidimensional outcome framework spanning glycaemic, anthropometric, and quality-of-life measures simultaneously — all without requiring changes to prescribed pharmacotherapy or additional physician time. The principal limitations are the absence of a concurrent control group and the exploratory design without formal sample size calculation, which mean the observed improvements cannot be causally attributed to the PIL intervention. The single-centre recruitment of a predominantly female cohort and a four-month follow-up window limit both generalisability and assessment of long-term durability. Potential social desirability bias associated with self-reported HRQoL assessments. Multicentre randomised trials with longer follow-up and larger diverse samples are needed to establish causal efficacy and confirm whether these gains are sustained.

CONCLUSION

A pharmacist-led educational intervention produced modest but statistically significant improvements in glycaemic control, body composition, and health-related quality of life in 102 obese T2DM patients over four months. Mean FBS fell by 26.01 mg/dL, HbA1c by 0.28 percentage points, BMI by 0.87 kg/m², and the EQ-5D-5L utility index rose by 0.064 units. The largest quality-of-life gains occurred in pain/discomfort and anxiety/depression. All 102 participants were retained throughout. The approach

required no pharmacotherapy modification and no additional physician workload, making it practically scalable in resource-constrained outpatient settings. These findings support embedding structured pharmacist-led education into routine T2DM care in India, with future randomised multi-centre trials needed to confirm durability.

DECLARATIONS

Conflict of Interest: The authors declare no conflicts of interest.

Funding: This study received no external funding.

Ethics Approval: The research was approved by the Institutional Ethics Committee of KLE College of Pharmacy Belagavi, KLECOPBGMEC/D005-2025, and certifies that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Written informed consent was obtained from the participants.

Data Availability: Data are available from the corresponding author on reasonable request.

Author Contributions: SSK: patient enrolment, data collection, questionnaire administration, and manuscript preparation. AD: study design, supervision, and critical revision. VB: statistical analysis and data verification.

Acknowledgement: The authors sincerely thank the Principal of Jawaharlal Nehru Medical College, Medical Superintendent of KLE's Dr Prabhakar Kore Charitable Hospital Belagavi, MD, and Head of Department of Endocrinology and General Medicine of KLE's Dr Prabhakar Kore Hospital and MRC Belagavi, Principal of KLE College of Pharmacy Belagavi for allowing us to conduct the project in this wonderful facility.

REFERENCES

- Magliano DJ, Boyko EJ; IDF Diabetes Atlas 10th edition scientific committee. IDF Diabetes Atlas. 10th ed. Brussels: International Diabetes Federation; 2021.
- Anjana RM, Unnikrishnan R, Deepa M, Pradeepa R, Tandon N, Das AK, et al. Metabolic non-communicable disease health report of India: the ICMR-INDIAB national cross-sectional study (ICMR-INDIAB-17). *Lancet Diabetes Endocrinol.* 2023;11(7):474–89.
- Pradeepa R, Mohan V. Epidemiology of type 2 diabetes in India. *Indian J Ophthalmol.* 2021;69(11):2932–8.
- Bays HE, Shrestha A, Niranjana V, Khanna M, Kambhamettu L. Obesity pillars roundtable: obesity and South Asians. *Obes Pillars.* 2022;1:100006.
- Smith KB, Smith MS. Obesity statistics. *Prim Care.* 2022;49(1):1–15.
- Biondi G, Marrano N, Borrelli A, Rella M, Palma G, Calderoni I, et al. Adipose tissue secretion pattern influences β -cell wellness in the transition from obesity to type 2 diabetes. *Int J Mol Sci.* 2022;23(10):5522.
- Zhao Q, Liao Z, Li X, Liu Y, Zhang L. Vascular complications of diabetes: a narrative review. *Medicine (Baltimore).* 2023;102(40):e35285.
- ElSayed NA, McCoy RG, Aleppo G, Balapattabi K, Beverly EA, Briggs Early K, et al. Obesity and weight management for the prevention and treatment of type 2 diabetes: Standards of Care in Diabetes–2025. *Diabetes Care.* 2025;48(Suppl 1).
- Pantalone KM, Kattan MW, Yu C, Wells BJ, Chagin KM, Sakurada B, et al. Predicting clinical inertia in type 2 diabetes: assessment of primary care physicians and their patients. *Front Endocrinol (Lausanne).* 2022;13:871423.
- Coutureau C, Slimano F, Mongaret C, Kanagaratnam L. Impact of pharmacist-led interventions in primary care for adults with type 2 diabetes on HbA1c levels: a systematic review and meta-analysis. *Int J Environ Res Public Health.* 2022;19(6):3156.
- Alabkal RM, Medlinskiene K, Silcock J, Graham A. Impact of pharmacist-led interventions to improve clinical outcomes for adults with type 2 diabetes at risk of cardiovascular disease: a systematic review and meta-analysis. *J Pharm Pract.* 2023;36(4):888–99.
- Afshari S, Ameri H, Baharinya S, Arab-Zozani M, Mojahedian MM. Assessment of the properties of the EQ-5D-5L in patients with type 2 diabetes mellitus: a systematic review and meta-analysis. *Expert Rev Pharmacoecon Outcomes Res.* 2022;22(2):351–64.

13. Abedini MR, Bijari B, Miri Z, Shakhs Emampour F, Abbasi A. The quality of life of patients with type 2 diabetes using EQ-5D-5L in Birjand. *Health Qual Life Outcomes*. 2020;18(1):18.
14. Gonzalez JS, Tanenbaum ML, Commissariat PV. Psychosocial factors in medication adherence and diabetes self-management: implications for research and practice. *Am Psychol*. 2021;76(6):1015–28.
15. Anyanwu PE, Yates T, Doal S, Brooks A, Donaldson J, Khunti K, et al. Physical activity guidelines for adults with type 2 diabetes: a systematic review. *Diabetes Res Clin Pract*. 2025;220:111982.
16. Rao KD, Sundararaman T, Bhatnagar A, et al. India-specific value set for EQ-5D-5L: a study of the general population of India. *Pharmacoeconomics*. 2022;40(4):429–41.
17. Deshpande A, Ganachari M. Effect of a pharmacist-led educational program on female diabetic patients: a hospital-based randomized controlled study. *Diabetes Research and Clinical Practice*. 2025 Dec 1;230.
18. Bukhsh A, Khan TM, Phisalprapa P, Duangjai A, Saokaew S, Nawaz MS, et al. Impact of pharmacist-led diabetes self-care education on patients with type 2 diabetes in Pakistan: a randomized controlled trial. *Front Pharmacol*. 2022;13:754999.
19. Mishra AK, Choudhary MK, Kumar C, Kishor A, Kumari A, Mishra AK. Assessment of health-related quality of life and its determinants in type 2 diabetes mellitus patients: a cross-sectional study. *Cureus*. 2024;16(8):e65923.
20. Huang L, Zhang L. A meta-analysis of the impact of pharmacist interventions on clinical outcomes in patients with type 2 diabetes. *Res Social Adm Pharm*. 2024;20(3):289–298.
21. Al Assaf S, Zelko R, Hanko B. The effect of interventions led by community pharmacists in primary care for adults with type 2 diabetes on therapeutic adherence and HbA1c levels: a systematic review. *Int J Environ Res Public Health*. 2022;19(10):6188.
22. Bajaj S; RSSDI Clinical Practice Recommendations Working Group. RSSDI clinical practice recommendations for the management of type 2 diabetes mellitus 2022. *Int J Diabetes Dev Ctries*. 2023;43(Suppl 2):1–143.
23. Anjali M, Khapre M, Kant R, Kumar S, Pandey P. Effectiveness of diabetes self-management education on distress and HbA1c among Indian type 2 diabetes mellitus patients: a randomized controlled trial. *Indian J Community Med*. 2023;48(5):702–8.
24. Deshpande AS, Ganachari MS. Impact of an educational intervention on knowledge, attitude, and practice among women diabetic patients: a prospective randomized controlled study. *Int J Pharm Investig*. 2025;16(1):143–154. doi:10.5530/ijpi.20260494.
25. Chen WJ, Lin LY. The impact of diabetes self-care, healthy lifestyle, social support, and demographic variables on HbA1c outcomes in patients with type 2 diabetes. *Clin Med Insights Endocrinol Diabetes*. 2025;18:11795514251331907.
26. Okafor CN, Akosile CO, Nkechi CE, Okonkwo UP, Nwankwo CM, Okoronkwo IL, et al. Effect of educational intervention programme on the health-related quality of life of individuals with type 2 diabetes mellitus in South-East Nigeria. *BMC Endocr Disord*. 2023;23(1):74.
27. Chittooru CS, Ananda KG, Panati D, Chaudhuri S, Prahalad H. Self-care practices and its determinants among diabetic population in rural Andhra Pradesh, India. *Clin Epidemiol Glob Health*. 2022;16:101102.
28. Lim PC, Tan HH, Mohd Noor NA, Shahabudin S, Saleem M, Ng YC, et al. The impact of pharmacist interventions, follow-up frequency and default on glycemic control in Diabetes Medication Therapy Adherence Clinic program: a multicenter study in Malaysia. *J Pharm Policy Pract*. 2023;16(1):83.
29. Chaudhuri S, Agiwal V, Chandrasekhar C, Babu MP, Yalamanchili P, et al. Self-care practices in diabetes among populations in India: a systematic review and meta-analysis. *Discover Public Health*. 2025;22:315.
30. Bajaj HS, Bhattacharyya OK, Bhupathiraju SN, Bhatt DL. Pharmacist-led collaborative interventions in South Asian patients with type 2 diabetes: a narrative synthesis. *Can J Diabetes*. 2023;47(4):319–27.

Figure Legends

Figure 1. Participant flow diagram showing patient enrolment, follow-up, and analysis.

Figure 2. Longitudinal changes in clinical and health-related quality-of-life outcomes following pharmacist-led educational intervention. Panel A shows mean fasting blood sugar (FBS) and postprandial blood sugar (PPBS) values across baseline, 1-month, and 4-month follow-up visits. Panel B shows mean body mass index (BMI) and EQ-5D-5L utility index across the same follow-up period. Error bars represent standard deviations.