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Original Article

A Randomized Controlled Trial Assessing the Effects of a Pharmacist-Led Educational Pharmaceutical Care Program on Clinical and Self-Management Outcomes in Type 2 Diabetes Mellitus Patients in Gujarat, India

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ABSTRACT

Objectives: The objective of the pharmacist-led educational Pharmaceutical Care Intervention Program (PLEPCIP) was to evaluate its effect on glycemic control, as measured by HbA_{1c} levels, in patients with type 2 diabetes. Secondary outcomes included changes in blood pressure, lipid profile, body weight, medication adherence (assessed using the MMAS-4 scale), and self-management behaviors such as physical activity and dietary practices. **Materials and Methods:** Study was a prospective and longitudinal randomized controlled trial conducted in patients with type 2 diabetes at the OPD of a private diabetic hospital. A total of 280 patients enrolled; of these, *n*=139 patients were randomized to the Control Group (CG) and *n*=141 to the Interventional Group (IG). The duration of the present study was 16 months with 4 follow-up discussion sessions. Study outcome was measured at multiple visits, including baseline week 0 and follow-up weeks 16, 32, 48, and 64. **Results:** Patients in the intervention group demonstrated a statistically significant reduction in glycated hemoglobin (HbA_{1C}) levels compared to the control group (mean reduction: 1.1% vs. 0.03%; $p<0.001$). Additionally, the intervention group exhibited significant improvements in Body Mass Index (BMI; $p=0.049$), systolic blood pressure (SBP; $p=0.015$), and Diastolic Blood Pressure (DBP; $p=0.030$). Triglyceride concentrations also decreased significantly within the intervention cohort ($p=0.003$). Furthermore, participants in the intervention group reported enhanced self-management behaviors, characterized by increased engagement in physical activity and adherence to a balanced dietary regimen. Medication adherence, as assessed by the Morisky Medication Adherence Scale, showed significant improvement ($p<0.001$), indicating better compliance with prescribed therapeutic protocols. **Conclusion:** A greater reduction in the HbA_{1C} with overall metabolic outcomes was significantly associated with the clinical pharmacist-led educational Pharmaceutical Care Intervention Program (PLEPCIP) in type 2 diabetes mellitus patients.

Keywords: Structured Pharmaceutical Care Program, Education Intervention, Type-2 Diabetes Mellitus, longitudinal study.

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INTRODUCTION

Globally, Diabetes Mellitus (DM) is a chronic, metabolic health issue. Type 2 diabetes, end up in both macrovascular and microvascular issues, which raise morbidity and mortality.[1] India faces a diabetes crisis with 77 million cases, 25 million at risk, and over 50% undiagnosed.[2] In Gujarat, prevalence rate of diabetes is 7.1% and pre diabetics population is 10.2%.[3,4] The urban area's BMI-based obesity prevalence is 40%, and in rural areas is 47.4%.[5] Global research supports pharmacist-led approaches in low-income nations can improve clinical and patient-reported outcomes for individuals with type 2 diabetes.[6,7] Individual who practices of blood glucose testing, diet control, physical activity with regular medication can achieve best glycaemic control in Type-2 DM patients.[8,9] Previous studies have demonstrated that educational interventions significantly enhance glycaemic control, clinical outcomes, lifestyle behaviors, and psychosocial well-being, while also improving treatment adherence among patients with type 2 diabetes mellitus.[10-14] In Gujarat, pharmacists mainly handle medicine dispensing and storage guidance, with minimal role in disease management. Research on interventional

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structured educational care programs by hospital-based clinical pharmacists remain unexplored. The primary objective of the present study was to evaluate the effectiveness of pharmacist-led educational interventions on glycaemic control, as measured by glycosylated Haemoglobin (HbA_{1C}), in patients with type 2 diabetes mellitus. Secondary outcomes included assessments of medication adherence, blood pressure (systolic and diastolic), lipid profile, Body Mass Index (BMI), and glycaemic parameters-Random Blood Sugar (RBS), Fasting Blood Sugar (FBS), and Postprandial Blood Sugar (PPBS). Additionally, the study examined changes in patients' lifestyle behaviors, specifically dietary patterns and physical activity levels.

MATERIALS AND METHODS

Study was a prospective and longitudinal, randomized (Adaptive randomization, such as minimization), Interventional (Specify - Educational Intervention), Parallel Group Trial conducted with 280 patients visited at Saarathi Institute of Diabetes Sciences, private health care hospital situated in Anand district. Study population were taken from age 18-75 years. Study was conducted during March 2023 to June 2024 with 16 months of follow up from the baseline counselling week 0, 16, 32, 48 and 64 counselling. Clinical pharmacists provide 2-hr per day counselling on weekdays at the diabetic hospital. Approval of current study was obtained from institutional ethics committee (IEC-2), Bhaikaka University, Karmsad, Anand, Gujarat (approval no: IEC/BU/2023/EX.16/93/2023). The sample size was calculated based on an anticipated[15] mean reduction in HbA_{1C} of 1.7%, with a standard deviation of 4%, using a 5% significance level and 90% power. Accounting for a 20% dropout rate, the final sample size was set at 290 patients.

Study Criteria and Recruitment

Study criteria were decided for inclusion of patient recruitment in the study. Patients who were attending outpatient's diabetic clinic with Type-II diabetes mellitus (presence or absence of complications) with HbA_{1C} more than 7% and received oral hypoglycaemic and/or insulin therapy were included in the study. Patients who provide written informed consent were randomized in the study. If patients were younger than 18 years (As they are legally considered dependents), Pregnant Women and Participants who has not completed all the research procedures were excluded from the study. Total 290 eligible patients enrolled and randomized in to interventional group (n=145) and control group (n=145). Due to loss of follow up, contact, and interest, total (n=280) patients, control group (n=139) and interventional group (n=141) has completed (Figure 1).

Detailed of Interventions

After randomization, the research clinical pharmacist gathered baseline data for both groups through questionnaires, lab reports, hospital records, patient interviews, and caregiver input. The program assessed patient's demographics, clinical measures and medication adherence at baseline, 16, 32, 48, and 64 weeks. All assessments were completed during baseline and follow up visit and data were collected from the patients by clinical pharmacist. Control group patients received usual care provided by the doctor. Usual care includes appointments with doctor every 4-8 weeks to renew their medicines prescriptions throughout study.

Laboratory Measures

All blood samples were analyzed in a laboratory situated in the basement of the hospital. For the tests, 7-8 mL of blood were collected following an 8-hr fasting period. The investigations included HbA_{1C}, random and postprandial blood glucose levels, lipid profile like LDL, TGs and cholesterol. Additionally, serum creatinine and urea levels were measured.

Clinical Measure

Blood pressure measurements were taken by staff of hospital. Average systolic and diastolic blood pressure measurements were calculated for each participant. Weight measured using a weighing machine (iScale Chargeable Digital Weighing Machine/ Electronic) and height measured with height scale (PRESTIGE Plastic Height Measuring Scale (Stadiometer) For Adults & Children). Body Mass Index (BMI) was measured using the formula weight (kg)/height (m^2) with accordance to the World Health Organization's standards.[16]

Research Intervention

Along with conventional diabetes treatment, Intervention group's study participants were given a 16-month PLEPCIP according to Albert Bandura's theory of self-efficacy[17] and self-regulatory behaviour.[18] The seven crucial practices of self-wellness for optimal and effective diabetic self-regulation were established by the American Association of Diabetic Educators (AADE).[19] The core elements of our strategy include self-care behaviors, such as eating a nutritious diet, exercising, checking blood sugar levels, taking medicine on a regular basis, having a problem-solving mindset, lowering risk, and practicing all health interventions positively. Intervention group participants received 1. Pharmaceutical care program booklet includes brief guidance conducting self-regulatory behavior. 2. Attended five follow up discussion and counselling sessions 3. Received follow up telephone calls/ Home visit every 4 months. The intervention was initially developed and assessed in a pilot study involving twenty patients with type-2 diabetes mellitus.

Pharmaceutical care program book

The illustrative Book consisted of eight sections:

1. Diabetic Information Booklet (DIB) 2. Self-Regulating Blood Sugar Techniques (SRBST) 3. Demonstration of Diabetes Related Test (DODRT) 4. Diabetes Care Plan (DCP) 5. Patient

Information Leaflet about Diabetic Complication and Resolving Information (PILSDCRI) 6. Physical Exercise (PE) 7. Diabetes Diet Chart (DDC) 8. Insulin Information Booklet (IIB). The booklet was prepared in English and local language-Gujarati. The Booklet was developed with all DM information presented in easy way, illustrative with all pictorial diagrams (prepared by clinical pharmacist). Booklet prepared in such a way that it represents all self-regulatory behaviors and encourage practice of the same. Participants in the interventional group received booklet at baseline visit. Performance parameters of the booklet were aligned with Pharmaceutical Care Plan Intervention Form (PCPIF). PCPIF was comprehensive document containing data of all the planned visit of the patients follow up started with baseline visit to last visit-5. PCPI form has PCPI No, visit no, PCPI Type (Home/Clinic/Phone), PCPI Theme, PCPI Minutes, parameter like BMI, Blood glucose, BP, HbA_{1C}, lipid parameter etc. It includes de-addiction/cessation counselling, self-monitoring counselling/education parameters, diabetes test understanding and monitoring parameters, daily activity discussion, diabetes disease awareness, complication awareness, visit to dietician, visit to nephrologist, cardiologist, ophthalmologist etc with Morisky Medication Taking Adherence Scale-MMAS (4-item) score of all visits.

Follow up discussion and counselling session

Patients in the intervention group consulted a pharmacist in person five times in consecutive months at 4-month intervals to discuss their medication and self-management plans. Discussion was carried out by clinical pharmacist on control of BMI-through weight management with balanced diet and physical exercise, effective implementation of action plan, regulation of stress, managing good habits and balance life style for effective blood sugar control. Discussion session lasted for 100-110 min. Counselling session on physical exercise involved cycling, yoga, meditation, running, dancing. Pharmacist motivated participants for long walk with friend, involved family participation in exercise, take good care of foot, also explained diabetes leg exercise for peripheral neuropathy. Discussion was also carried out on medication adherence with help of doctor. All participants and family members were given a clinical pharmacist's phone number at the end of the group session, and they were encouraged to take support if needed.

Received monitoring telephone / Home visit every 4 months

Prior to each four-monthly discussion session, interventional participants received a reminder via telephonic call to attend the session. Following the completion of the discussion, a follow-up phone call was made 60 days later to assess self-regulatory behaviors and reinforce motivation for continued adherence, aiming to enhance therapeutic outcomes. During each follow-up visit, patients in the interventional group were assessed for clinical parameters and improvements in management practices, as outlined in the PCPI form. Responses to all queried parameters were carefully documented in the PCPIF at every visit. The duration of each follow-up phone call was ten to 12 min. Asking meaningful inquiries, offering positive confirmation, actively absorbing, recapping conversations, demonstrating empathy, boosting self-confidence with adaption of improved behaviors were some of the strategies used during phone talks to foster the essence of Supportive Counselling (SC).[20]

Patient's demographic data collection form

Demographic data included patient details, medical history, lab tests (e.g., HbA_{1C}, lipid profile, RBS, FBS), and lifestyle history. HbA_{1C} values taken from lab test performed at Hospital set up and Blood pressure measurements were taken by trained staff of hospital at each visit for the intervention group participants. The data were collected for the interventional and control groups at baseline and at every follow up visit.

Morisky medication -Taking adherence Questionnaire (MMAS-4)

Additionally, the four-item MMAS questionnaire was given to patients in both groups: The published version of the Morisky Medication Adherence Scale-4, consist of 4 questions were used to create this form. Both the Gujarati and English versions of this questionnaire were available. A scale of 0 to 4 was used to rank the results, with 0 denoting non-adherence and 4 denoting adherences. If a patient answered "no" to each of the four questions, they were considered to be medication adherent. On the other hand, a patient became non-adherent if they answered "yes" to any question.

Outcome measures

The change in HbA_{1C} levels was the primary outcome measure. Among the secondary results were changes in RBS, FBS, PPBS, SBP, DBP, lipid profile, creatinine, urea, BMI, and medication adherence scores over a period of 16 months. The study compared results of baseline visit and every follow up visit for intervention and control groups, with goals set for hypertension (<140/90 mmHg), fasting blood sugar (80 to 130 mg/dL), Random Blood Sugar and Postprandial blood sugar (<140 mg/dL), HbA_{1C} (<7%), triglycerides level (<150 mg/dL), LDL level (<100 mg/dL), HDL level (40 -50 mg/dL), Creatinine (<0.6 to 1.6 mg/dL) and urea (<6 to 24 mg/dL).

Statistical Analysis

Data were collected at baseline and at 4-month intervals up to 16 months. Statistical analyses were performed using SPSS version 27. Descriptive statistics (frequency, percentage, mean, standard deviation, and median) summarized categorical variables. The Shapiro-Wilk test assessed data normality; as distributions were non-normal, non-parametric tests were applied. Categorical

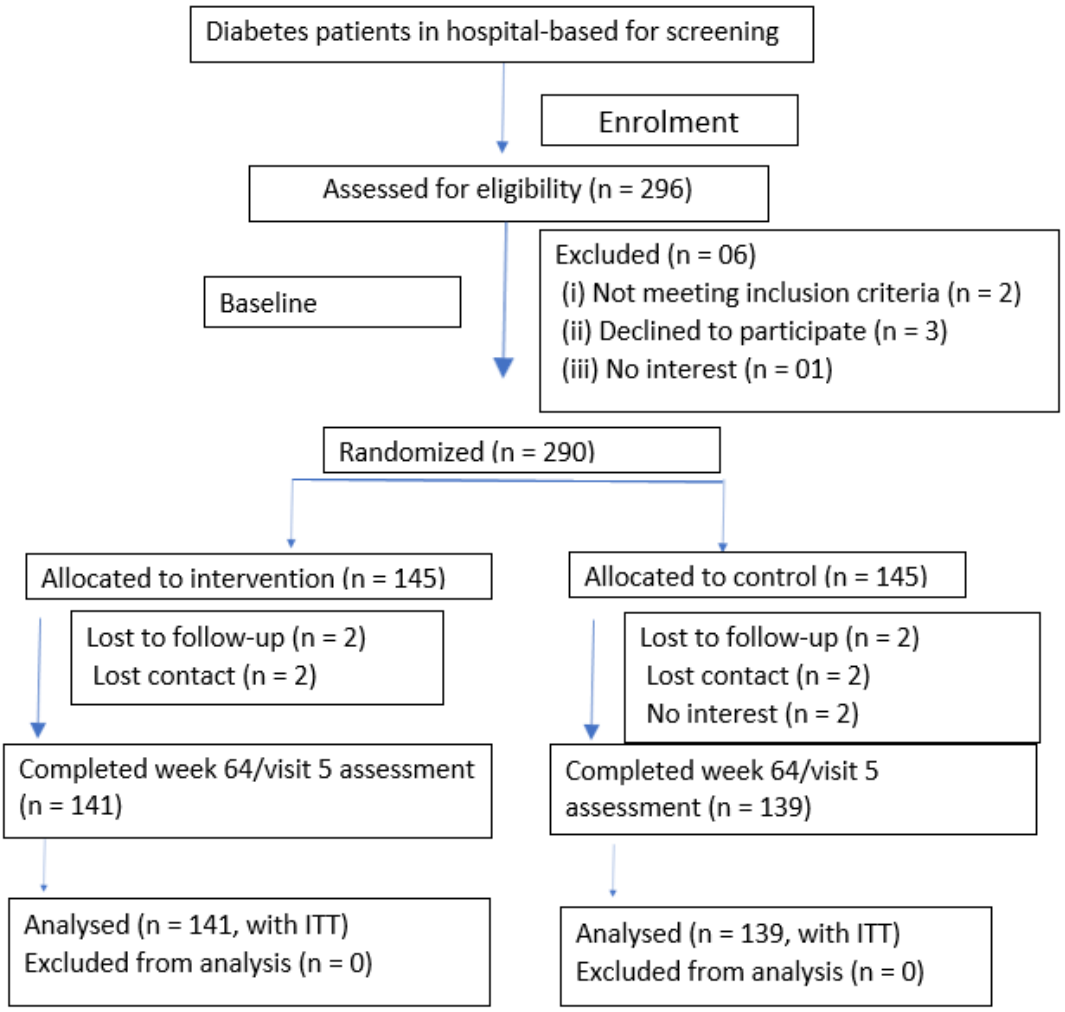

Figure 1: Consort flow chart of study participation.

ITT*: intention to treat

variables were analyzed using the Chi-square and McNemar's tests. Between-group comparisons employed the Mann-Whitney U test, while within-group changes from baseline to study completion were evaluated using the Wilcoxon Signed-Rank test.

RESULTS

A total of 280 eligible patients from the Saarathi Institute of Diabetes Sciences, a private hospital, were enrolled in the study. Of these, *n*=139 control group patients and *n*=141 interventional group patients completed the study, as shown in Figure 1. Study participant characteristics were presented in Table 1. At baseline demographic characteristic of participants remained non-significant.

HbA_{1c}, fasting blood sugar and post prandial blood sugar

At the end of the 16-month trial, the intervention group demonstrated a significantly greater reduction in HbA_{1C} levels compared to the control group (mean change: 1.1% vs. 0.03%; p=0.000). Additionally, a higher proportion of participants in the intervention group achieved the American Diabetes Association (ADA) target of HbA_{1C} <7% (13.47%) compared to the control group (0.72%; p=0.001) presented in Table 2. Significant reductions in Random Blood Sugar (RBS), Fasting Blood Sugar (FBS), and Postprandial Blood Sugar (PPBS) were observed within the intervention group at study completion (mean reductions: 7.32 mg/dL, 7.54 mg/dL, and 11.32 mg/dL, respectively; p=0.000 for RBS and FBS, p=0.006 for PPBS) presented in Table 3. Between-group comparisons also revealed statistically significant differences in RBS, FBS, and PPBS values (p=0.016, p=0.006, and p=0.002, respectively), indicating the positive impact of the educational intervention on glycemic control.

Body mass index

At baseline, a high prevalence of obesity was observed in both groups, including 57% in the intervention group and 53% in the control group. At the end of the trial period, there was a significant difference in body mass index across groups (p=0.002)

and between groups (IG, p=0.049), with interventional group participants showed a substantial decrease in BMI (0.83 Kg/m2) compared to control group (p=0.08) presented in Table 4.

Life style factor: physical exercise, balanced diet

The impact of educational care was evident in improved adherence to physical exercise and a balanced diet. A statistically significant increase was observed in both behaviors between the intervention and control groups (p=0.004 for physical exercise; p=0.038 for balanced diet). Within the intervention group, 40

Table 1: Baseline demographic characteristics, comorbidities, and lifestyle factors of study participants in the intervention and control groups.

Demographics and associated comorbidities	Intervention Group *n*=141	Control Group *n*=139	*p*- Value
Age (μ±σ) Md	54.33(8.83) 56.00	57.60(11.61) 57.00	< 0.018*
Gender, n (%)			
Men	77 (54.60%)	80 (57.6%)	1.00
Women	64 (45.40%)	59 (42.4%)	
Marital Status, n (%)			
Married	121(85.8%)	138(99.3%)	1.00
Single, divorced	20(14.2%)	1(0.7%)	
Religion, n (%)			
Hindu	136(96.5%)	137(98.6%)	1.00
Christian	1(0.7%)	1(0.7%)	
Sikh	1(0.7%)	0(0%)	
Muslim	3(2.1%)	1(0.7%)	
Occupation, n (%)			
Professional	75(53.2%)	68(48.9%)	1.00
Skilled Worker	21(14.9%)	16(11.5%)	1.00
Others	45(31.9%)	55(39.6%)	1.00
Comorbid Condition, n (%)			
Associated comorbidities	121(85.8%)	120(86.3%)	0.833
Heart Disease	13 (9.2%)	5 (3.5%)	< 0.001*
Kidney Disease	31(22%)	23(16.3%)	0.204
Blood Pressure	116(82.3)	110 (79.13%)	0.567
Allergic history	8(5.7%)	12(8.6%)	0.121
Adverse Drug Reaction History	3(2.1%)	5(3.5%)	0.312
Regular eye check-up history, n (%)	59(41.8%)	70(50.3)	0.004*
Nervous system checkup for loss of sensation, n (%) and life style factor:			
Mild sensory neuropathy	133(94.3%)	131(94.2%)	1.00
Severe sensory neuropathy	6(4.3%)	6(4.3%)	1.00
Abnormal	2(1.4%)	2(1.4%)	1.00
Smokers, n (%)	53 (37.6%)	75 (54%)	0.006*
Drinker, n (%)	28 (19.9%)	29(20.9%)	1.00
Prescription medicine users, n (%)	141(100%)	139(100%)	1.00
Duration of disease (μ±σ) Md	6.82(2.95) 7.00	6.86(2.95) 7.00	0.927
BMI (kg/m2), (μ±σ) Md	26.77 (5.20) 25.20	25.81(4.19) 25.16	0.279
Balanced diet, n (%)	108(76.6%)	102(73.4%)	0.535
Exercise, n (%)	81(57.4%)	78(56.1%)	0.327

μ= mean, σ= Standard deviation, Md= median$p$<0.05 = significant value denoted as *

Table 2: Comparative analysis of HbA_{1C} changes between intervention and control groups over the 16-month study period.

HbA_{1C} Range	Intervention Group *n*=141		Control Group *n*=139		Absolute difference between Visit 1 and Visit 5	
	Visit 1 n (%)	Visit 5 n (%)	Visit 1 n (%)	Visit 5 n (%)	ΔN (IG)	ΔN (CG)
≤7 (Good control)	4(2.8)	23(19.3)	3(2.2)	3(2.2)	19	0
7-8 (Optimal control)	59(41.8)	91(64.5)	55(39.6)	55(39.6)	32	0
8-9 (Sub-optimal control)	33(23.4)	24(17.0)	35(25.2)	35(25.9)	9	0
>9 (Uncontrolled)	45(31.9)	3(2.1)	46(33.1)	45(32.4)	42	1
				Mean	26.5	0
				SD	15.78	0
Δ- Absolute Change in Number*	Difference between Baseline and end of study			*p*-value	<0.001	0.932
	Difference between IG and CG at Visit 1			*p*-value	0.953	
	Difference between IG and CG at Visit 5			*p*-value	<0.001	

SD: Standard deviation

patients showed improved physical activity (p=0.000) and 22 adopted a balanced diet (p=0.000). Notably, the control group also demonstrated significant improvements, with 22 patients engaging in regular physical exercise (p=0.000) and 15 adopting a balanced diet (p=0.001), as detailed in Table 4.

Medication adherence

The Morisky medication-taking adherence test showed that 7% of patients in the control group and 45% of intervention patients had very low adherence at baseline detailed in Table 4. The intervention group's medication adherence increased significantly during the study period (p=0.000) compared to control group (p=0.412). Mean (SD) of MMAS score for intervention group at visit 5 was (3.64±0.48) and for control group (2.78±0.74), which showed positive effect of intervention.

DISCUSSION

This study represents the first investigation in Gujarat to evaluate the impact of clinical pharmacy-led educational interventions on clinical outcomes in patients with type 2 diabetes mellitus. The intervention involved personalized self-management education delivered by clinical pharmacists, focusing on medication adherence, lifestyle modifications-including dietary improvements, physical activity, Self-Monitoring of Blood Glucose (SMBG), and smoking cessation-to support patients in achieving glycaemic control. Before interpreting these findings further, it is important to acknowledge the study's limitations. This includes study conducted at a single site over a 16-month period, the findings may lack generalizability. Future research should replicate this intervention across multiple locations with larger sample sizes and extended follow-up durations to enhance external validity. Additionally, long-term clinical outcomes-such as reductions in diabetes-related morbidity and mortality associated with improved HbA_{1C} levels-were not assessed. Participants also received routine counselling and medical services as part of standard care, which, although not directly linked to the study protocol, may have influenced the outcomes. To establish clearer causal relationships between the intervention and observed effects, future studies should adopt a multicentric experimental design with rigorous control of confounding variables.

The intervention group demonstrated a statistically significant reduction in mean glycated hemoglobin (HbA_{1c}) levels, decreasing from 8.65% at baseline to 7.55% at the end of the study period (p=0.000). Furthermore, the proportion of patients achieving the target HbA_{1C} level of <7% increased markedly from 0.71% at baseline to 13.47% post-intervention, underscoring the effectiveness of the pharmacist-led approach in enhancing glycaemic outcomes. Present finding supported with Korcegez *et al.*[21] (2017), showed more reduction in HbA_{1C} in intervention group compared control group (-0.74% vs. -0.04%; p<0.001) in 12 month. Cani *et al.* [22], (2015) showed that significant improved HbA_{1C}, FBS and RBS in the intervention group during 6-month duration (p<0.001). Wishah *et al.*[23], (2015) showed that HbA_{1C} and FBS decreased significantly (p<0.05). Patients in the intervention group demonstrated a statistically significant reduction in Fasting Blood Sugar (FBS) levels by 7.54 mg/dL (p=0.042) and Postprandial Blood Sugar (PPBS) levels by 11.32 mg/dL (p=0.006)

Table 3: Changes in Clinical Parameters of study participants from Baseline to End of Study: Intervention vs. Control Group.

	Intervention Group *n*=141				Control Group *n*=139				b/w Group
Measures	**Visit 1 n (%)**	**Visit 5 n (%)**	**Mean Difference**	***p*-Value**	**Visit 1 n (%)**	**Visit 5 n (%)**	**Mean Difference**	***p*-Value**	***p*-value**
	Mean (± SD) [Median]		**V1-V5**		**Mean (± SD) [Median]**		**V1-V5**		
RBS mg/dL	184.7 (51.22) [174]	177.43 (46.01) [167]	7.32	0.000*	188.01 (47.47) [186]	187.01(46.34) [185]	1	0.780	0.016*
FBS mg/dL	148.33(46.89) [137]	140.79(42.95) [130]	7.54	0.000*	151.81(44.11) [139]	150.98(43.02) [139]	0.83	0.905	0.006*
PPBS mg/dL	201.76(67.34) [200]	190.44(43.76) [190]	11.32	0.006*	208.03(58.77) [201]	207.15(58.13) [200]	0.88	0.702	0.002*
HbA_{1C} %	8.65(1.42) [8.2]	7.55(0.66) [7.4]	1.1	0.000*	8.71(1.43) [8.4]	8.68(1.38) [8.4]	0.03	0.932	0.001*
LDL mg/dL	103(27.36) [100]	100(23.55) [100]	3	0.442	104.7(25.28) [100]	104.69(25.27) [100]	0.01	0.999	0.415
TCH mg/dL	169.67(43.72) [169]	168.86(39.1) [168]	0.81	0.764	170.83(40.71) [168]	170.01(39.92) [168]	0.82	0.800	0.989
TGs mg/dL	178.99(91.16) [154]	172.61(82.03) [150]	6.38	0.003*	180.35(89.51) [154]	180.05(89.01) [154]	0.3	0.958	0.366
HDL mg/dL	45.99(6.38) [48.00]	47.43(4.03) [49]	-1.44	0.075	46.27(5.05) [48]	46.27(5.05) [48]	0	1.000	0.064
SBP mmHg	135(19.81) [135]	133.72(16.15) [133]	1.28	0.015*	136.63(15.36) [135]	136.45(15.07) [135]	0.18	0.957	0.012*
DBP mmHg	80.18(10.89) [80.00]	78.52(8.66) [78]	1.66	0.030*	81.09(8.19) [80]	81.09(8.19) [80]	0	1.000	0.011*
Creatininemg/dL	1.06(0.68) [0.90]	1.06(0.68) [0.9]	0	1.000	1.07(0.68) [0.92]	1.07(0.68) [0.92]	0	1.000	0.892
Urea mg/dL	12.22(10.03) [10.00]	12.12(9.52) [10]	0.1	0.953	11.81(5.21) [10]	11.81(5.21) [10]	0	1.000	0.841

$p<0.05$ = significant value denoted as *

over the study period. Additionally, between-group comparisons revealed significant differences in both FBS (p=0.006) and PPBS (p=0.002), further supporting the efficacy of the intervention in improving glycaemic parameters, these results were similar with Mourão *et al.*[24] PLEPCIP strengthened patient-pharmacist relationships, enhancing diabetes education, self-regulation, and care adherence, leading to improved glycaemic control.

In the present study, patients in the intervention group exhibited a statistically significant reduction in systolic blood pressure (SBP) by 1.28 mmHg (p=0.015) and diastolic blood pressure (DBP) by 1.66 mmHg (p=0.030). These findings contrast with those of Mourão *et al.*[24], who reported a significant decrease in SBP (p=0.013) but no significant change in DBP (p=0.809). Furthermore, between-group comparisons revealed significant reductions in both SBP (p=0.012) and DBP (p=0.011) in the intervention group compared to the control group. These improvements are likely attributable to enhanced medication adherence, which plays a critical role in achieving optimal blood pressure control.

In the current study, Triglyceride (TG) levels decreased significantly (p=0.003), a finding consistent with emerging evidence that links improved glycaemic control and lifestyle modifications to favorable lipid outcomes. Enhanced insulin sensitivity resulting from better blood glucose regulation reduces hepatic triglyceride synthesis, while dietary changes-such as reduced intake of refined carbohydrates and saturated fats-along with increased physical activity and weight loss, contribute to improved lipid metabolism.[25,26] Pharmacological agents, including statins, fibrates, and omega-3 fatty acids like icosapent ethyl, have also demonstrated efficacy in lowering TG levels, particularly in patients with diabetic dyslipidemia.[25]

However, several potential confounders must be considered when interpreting these results. Baseline lipid profiles can influence the magnitude of change observed; patients with higher initial TG levels may show more pronounced reductions. Concurrent use of lipid-lowering medications, adherence variability, and differences in intervention intensity or duration may also affect outcomes. Additionally, healthcare system factors-such as access to care and patient education-can modulate the effectiveness of interventions.

Table 4: Intervention Effects on Lifestyle Factors and Medication Adherence Between Intervention and Control Group.

	Intervention Group *n*=141				Control Group *n*=139				b/w Group
Measures	**Visit 1 n (%)**	**Visit 5 n (%)**	**Mean Difference**	***p*-Value**	**Visit 1 n (%)**	**Visit 5 n (%)**	**Mean Difference**	***p*-Value**	***p*-value**
	Mean (± SD) [Median]		V1-V5		Mean (± SD) [Median]		V1-V5		
BMI Kg/m^2	26.77 (5.20) [25.20]	25.94 (5.03) [24.80]	0.83	0.049	25.81 (4.19) [25.16]	25.73 (4.03) [25.16]	0.08	0.978	0.002
	n (%)				n (%)				
Physical Exercise	81 (57.86%)	121 (85.82%)	40	0.000	78 (56.1%)	100 (71.9%)	22	0.000	0.004
Balanced Diet	108 (77.14%)	130 (92.20%)	22	0.000	102 (73.4%)	117 (84.2%)	15	0.001	0.038
	Morisky Medication -taking Adherence Scale (MMAS-4)								
Very Low Adherent	63 (45%)	0 (0%)	0	<0.001	10 (7%)	9 (6.47%)	1	0.412	0.001
Low Adherent	65 (46%)	0 (0%)	0		64 (46%)	63 (44.2%)	1		
High adherent	13 (9%)	49 (35%)	36		40 (29%)	42 (30.21%)	2		
Very High adherent		92 (65%)	92		25 (18%)	25 (18%)	0		

These variables may explain discrepancies between studies, such as those by Nola *et al.*[27] and Kelly & Rodgers,[28] which reported no significant changes in TG or LDL levels.

At the end of the 16-month trial period, a statistically significant difference in body mass index (BMI) was observed both between groups (p=0.002) and within the intervention group (p=0.049). Participants in the intervention group experienced a mean reduction of 0.83 kg/m² in BMI, indicating the effectiveness of the clinical pharmacy-led intervention in promoting weight management alongside glycaemic control. A multicentric retrospective study You *et al.*, (2015)[29] showed significant reduced in BMI values in the intervention group (29.34-28.92 kg/m2; p=0.03). Study by Al Mazroui *et al.*[30] 2009, showed, higher reduction in BMI Value (-1.05 kg/m2). Over 16 months, pharmacist-led educational care improved patient confidence, medication adherence, and self-management, helping maintain healthy body weight in diabetes treatment.

The study demonstrated a significant improvement in medication adherence within the intervention group, with 65% of participants achieving the highest level of adherence to their diabetes medications (p<0.001). This outcome underscores the effectiveness of the clinical pharmacy-led intervention in promoting consistent and responsible medication-taking behavior among patients with type 2 diabetes. Nascimento *et al.*,[31] (2016) had showed enhanced adherence statistically significant (p<0.05). Jahangard- Rafsanjani *et al.*[32] (2015) demonstrated that, at the conclusion of the 5-month study, medication adherence had greatly enhanced in the intervention group.

CONCLUSION

The pharmacist-led educational care program represented significant improvements in HbA_{1C} and other key metabolic parameters, among outpatients with type-2 diabetes. These findings align with established diabetes management guidelines, which emphasize patient education, adherence support, and lifestyle modification. The observed improvements in HbA_{1C}, medication adherence, BMI, and lipid profiles in the intervention group reflect the effectiveness of guideline-based, pharmacist-led care in enhancing diabetes outcomes. These findings underscore the critical role of pharmacist-driven interventions in optimizing diabetes management. The study supports the broader implementation of such pharmacist-led services across healthcare institutions in Gujarat and throughout India to strengthen chronic disease management and improve patient outcomes.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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ABBREVIATIONS

PLEPCIP: Pharmacist-led educational pharmaceutical care intervention program; **RBS:** Random blood sugar; **FBS:** Fasting blood sugar; **PPBS:** Post prandial blood sugar; **HbA_{1C}:** Glycosylated HB%; **SBP:** Systolic Blood Pressure; **DBP:** Diastolic blood pressure; **IG:** Interventional group; **CG:** Control group; **TG:** Triglyceride level; **TCH:** Total cholesterol; **HDL:** High-density lipoprotein **LDL:** Low-density lipoprotein; **HDL:** High density Lipoprotein **SMBG:** Self-monitoring Blood Glucose.

AUTHOR CONTRIBUTION STATEMENT

Rishita developed study concept and study design with assistance from Dr. Harsha. Rishita was exclusively responsible for data collection. Statistical analysis and data interpretation was performed by Rishita along with guidance from Dr. Harsha. The manuscript was written by Rishita. Dr. Harsha and Rishita revised and prepared final version of manuscript.

SUMMARY

Despite advances in pharmacotherapy, glycaemic control in type 2 diabetes mellitus (T2DM) remains suboptimal. This 16-month study in Gujarat, India evaluated a clinical pharmacist-led educational pharmaceutical care intervention program (PLEPCIP). The 4-month active intervention phase significantly improved HbA_{1C}, blood pressure, lipid profile, BMI, and fasting blood sugar. It also enhanced self-management behaviors such as diet, exercise, foot care, glucose monitoring, and medication adherence among T2DM patients.

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