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Original Article

Pharmacist-Led Comprehensive Medication Management Improves Glycemic Control and Adherence in Women with Type 2 Diabetes: A Randomized Controlled Trial

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ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) is associated with a high prevalence of poor medication adherence, which hinders optimal glycemic control and increases the risk of complications. In this context, evaluating the impact of pharmacist-led Comprehensive Medication Management (CMM) is important to understand its role in improving medication adherence and glycemic outcomes among women with T2DM. **Materials and Methods:** This randomized controlled trial was conducted at a tertiary hospital in Belagavi, India, with 218 women with T2DM assigned to an intervention group (*n*=109) receiving pharmacist counseling plus standard care or a control group (*n*=109) receiving standard care alone. Counseling covered adherence strategies, lifestyle changes, and diabetes education. Outcomes over 9 months included the Item Morisky Medication Adherence Scale to Self-Validated Medication Adherence Scale, glycated Hemoglobin (HbA_{1C}), and Fasting Blood Glucose (FBG). **Results:** Baseline characteristics were comparable. At 9 months, HbA_{1C} ≤8% was achieved by 87.1% of the intervention group versus 40.3% of controls (p<0.001; 95% CI, 33.5%-60.1%). At 9 months, 94.4% of the intervention group achieved FBG ≤126 mg/dL versus 73.3% of controls (p<0.001; 95% CI, 12.5%-29.7%). Mean MA scores improved from 5.73±1.88 to 7.12±1.58 in the intervention group (p<0.001), with minimal change in controls. **Conclusion:** Pharmacist-led CMM significantly improved adherence and glycemic control in women with T2DM. Incorporating pharmacists into routine diabetes care can enhance outcomes and reduce disease burden, particularly in resource-limited settings.

Keywords: Comprehensive Medication Management, Diabetes Mellitus, Fasting Blood Glucose, Medication adherence, Randomized controlled trial.

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INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic and progressive endocrine disorder characterized by hyperglycemia due to impaired insulin secretion, action, or both, leading to abnormal carbohydrate, fat, and protein metabolism (World Health Organization, 2013; Mohan, 2010). Globally, DM affected 425 million people in 2017, with projections of 693 million by 2045 (Voet and Voet, 2000; Benedict *et al.*, 2018). Type 2 Diabetes Mellitus (T2DM) accounts for over 95% of cases.

India, with ~69 million cases in 2015, ranks second worldwide (European Society of Cardiology, 2023). Glycemic control remains suboptimal: only 25-35% of patients meet Fasting Blood Glucose (FBG) targets, and 15-30% achieve glycated hemoglobin (HbA_{1C}) <7%, with even poorer control in rural populations (Unnikrishnan *et al.*, 2016). In 2021, an estimated 74 million were diagnosed and 40 million undiagnosed in India, with 17% reporting microvascular and 3% macrovascular complications, contributing to ~4 million annual deaths (International Diabetes Federation, 2019). Globally, prevalence after age 65 is higher in women, countering the belief that chronic diseases predominantly affect men. By 2025, 192.3 million women and 188 million men are projected to have DM (Roglic, 2009).

Effective DM management focuses on complication prevention, with adherence to Oral Hypoglycemic Agents (OHAs) being crucial (Tipnis and Bajaj, 2011; Aditama *et al.*, 2021). Despite treatment, average HbA_{1C} remains ~8%, often due to poor adherence. Pharmacists, with clinical expertise, can address adherence barriers through interventions such as Comprehensive Medication Management (CMM) a collaborative approach to optimize drug therapy (Cipolle *et al.*, 2012; American College of Clinical Pharmacy, 2018; Butler *et al.*, 2017). Adherence is often evaluated using the 8-item Morisky Medication Adherence Scale (MMAS-8) (McInnis *et al.*, 2014). Common drug therapy

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problems identified include the need for additional medications or dose adjustments to achieve therapeutic goals (American College of Clinical Pharmacy, 2018).

This study aimed to assess the impact of pharmacist-led CMM on medication adherence and glycemic outcomes among women with T2DM.

MATERIALS AND METHODS

Study design and setting

This prospective Randomized Controlled Trial (RCT) was conducted at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, Karnataka, a tertiary care facility serving northern Karnataka. The hospital has dedicated general medicine services, advanced diagnostics, and an in-house pharmacy.

Ethical approval

The Institutional Ethical Committee of KLE Academy of Higher Education and Research, Belagavi, approved the study (Ref. No. KAHER/EC/22-23/134). Written informed consent was obtained from all participants before enrolment.

Study period

The study was conducted over 12 months.

Sample size

A pilot study (n=10) determined standard deviations of 1.02 (intervention) and 1.55 (control) for MA scores. Using the pooled standard deviation in the two-sample means formula:This pooled standard deviation was then applied in the standard formula for comparing two means to estimate the final sample size.

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

Where,

With n= sample size, S=pooled SD, Z_1-α/2=1.96 (5% significance), Z_1-β=1.68 (95% power), and d=0.25, the required sample size was 109 per group (total=218).

The chosen sample size was designed to provide adequate statistical power to identify a significant difference in MA scores between the intervention and control groups. Additionally, it aimed to ensure that the results reached statistical significance, with the p-value set at a threshold of less than 0.05.

Randomization

Participants were randomized to intervention or control groups using computer-generated simple randomization and allocated via Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) managed by an independent researcher.

Participants

Inclusion criteria: Women ≥18 years with T2DM receiving antidiabetic therapy. **Exclusion criteria:** Terminal comorbidities with <9 months life expectancy, untreated hyperthyroidism, acute diabetic emergencies, pregnancy or lactation, refusal to consent, or high risk of loss to follow-up.

Intervention

Both groups received standard diabetes care. The intervention group additionally received structured pharmacist-led counseling on disease understanding, medication use, adherence strategies, lifestyle modification, potential complications, and adverse drug reactions. Counseling was repeated at each follow-up visit over 9 months.

Data collection

Medication adherence was assessed using the Item Morisky Medication Adherence Scale (MMAS-8) TO Self-Validated Medication Adherence Scale, categorizing scores as high (8), medium (6-<8), or low (<6). Glycemic control was evaluated using glycated Hemoglobin (HbA_{1C}) and Fasting Blood Glucose (FBG).

Statistical Analysis

Data were analyzed using SPSS v26.0. Categorical variables (adherence levels, biochemical parameters) were compared using Chi-square tests; mean MA scores were compared using independent t-tests. Changes over time were analyzed using one-way ANOVA and repeated-measures ANOVA. Normality and variance assumptions were tested before applying parametric methods. Significance was set at p<0.05.

RESULTS

Baseline characteristics

At baseline, the demographic and clinical profiles of the control and intervention groups (n=109 each) were comparable (Table 1). Most participants were aged 41-50 years (37.2%), with 45.0% living with diabetes for 6-10 years. Overweight status was common (38.1%), 78.0% reported a family history of diabetes, and 78.9% resided in rural areas. The literacy rate was high (89.4%), and 59.2% were unemployed. Comorbidities and diabetes-related complications were present in 60.1% and 37.6% of participants, respectively. No significant baseline differences were found between groups for demographic or clinical variables.

At baseline, poor glycemic control was observed in both groups, with HbA_{1C}>8% in 98.2% (control) and 97.2% (intervention) (p=0.32) and FBG>126 mg/dL in 84.4% and 80.7%, respectively (p=0.59). No significant changes were seen at 3 months. By 6 months, more intervention participants achieved HbA_{1C}≤8% compared to controls (70.6% vs. 33.0%; p<0.001; 95% CI for

difference, 27.5%-47.7%), and the difference widened at 9 months (87.1% vs. 40.3%; p<0.001; 95% CI, 36.4%-57.3%) (Table 2).

FBG trends showed a temporary advantage in controls at 3 months (36.7% vs. 27.5%; p=0.01; 95% CI, 2.0%-16.4%), which reversed thereafter. At 6 months, target FBG was achieved by 77.0% of the intervention group versus 46.7% of controls (p<0.001; 95% CI, 19.7%-41.0%), and by 9 months in 94.4% versus 73.3% (p<0.001; 95% CI, 12.5%-29.7%) (Table 3). These results strongly suggest that the intervention had a significant and sustained positive effect on glycemic control over time.

Medication adherence

Baseline MA scores were similar between groups. Over 9 months, moderate/high adherence increased to 88.1% in the intervention group versus 67.0% in controls (p<0.001; 95% CI, 11.7%-30.5%) as shown in Table 4. Mean MA scores improved from 5.73±1.88 to 7.12±1.58 in the intervention group (p<0.001) with minimal change in controls (Table 5).

Adherence and glycemic outcomes

At 9 months, participants with moderate/high adherence in the intervention group were more likely to achieve HbA_{1C}≤8% (87.2% vs. 40.4%; p<0.001; 95% CI, 35.0%-58.6%) and FBG ≤126 mg/dL

Table 1: Demographic and Clinical Characteristics at Baseline.

Variables	Category	Control Group (*n*=109)	Intervention Group (*n*=109)	Total (*n*=218)
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%)
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%)
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%)
Family History of Diabetes	Yes	85 (78.0%)	85 (78.0%)	170 (78.0%)
	No	24 (22.0%)	24 (22.0%)	48 (22.0%)
Residence	Rural	85 (78.0%)	87 (79.8%)	172 (78.9%)
	Urban	24 (22.0%)	22 (20.2%)	46 (21.1%)
Literacy Status	Literate	97 (89.0%)	98 (89.9%)	195 (89.4%)
	Illiterate	12 (11.0%)	11 (10.1%)	23 (10.6%)
Occupation	Employed	46 (42.2%)	43 (39.4%)	89 (40.8%)
	Unemployed	63 (57.8%)	66 (60.6%)	129 (59.2%)
Tobacco	Tobacco chewer	5 (4.6%)	4 (3.7%)	9 (4.1%)
	Non-Tobacco chewer	104 (95.4%)	105 (96.3%)	209 (95.9%)
Comorbidity	Yes	60 (55.0%)	71 (65.1%)	131 (60.1%)
	No	49 (45.0%)	38 (34.9%)	87 (39.9%)
Complications	Yes	35 (32.1%)	47 (43.1%)	82 (37.6%)
	No	74 (67.9%)	62 (56.9%)	136 (62.4%)

Table 2: HbA_{1C} **Distribution at Baseline and Follow-up Intervals.**

Time Point	HbA_{1C} Range	Control Group (*n*=109)	Intervention Group (*n*=109)	*p*-value
Baseline	≤8%	2 (1.8%)	3 (2.8%)	0.32
	>8%	107 (98.2%)	106 (97.2%)	
3 months	≤8%	3 (2.8%)	5 (4.5%)	0.55
	>8%	106 (97.2%)	104 (95.4%)	
6 months	≤8%	36 (33.0%)	77 (70.6%)	<0.001*
	>8%	73 (67.0%)	32 (29.4%)	
9 months	≤8%	44 (40.3%)	95 (87.1%)	<0.001*
	>8%	65 (59.6%)	14 (12.8%)	

Table 3: **Fasting Blood Glucose (FBG) Levels at Follow-up Intervals.**

Time Point	FBG Range (mg/dL)	Control Group (*n*=109)	Intervention Group (*n*=109)	*p*-value
Baseline	≤126	17 (15.6%)	21 (19.3%)	0.59
	>126	92 (84.4%)	88 (80.7%)	
3 months	≤126	40 (36.7%)	30 (27.5%)	0.01*
	>126	69 (63.3%)	79 (72.5%)	
6 months	≤126	51 (46.7%)	89 (81.7)	<0.001*
	>126	58 (53.2%)	20 (18.3%)	
9 months	≤126	80 (73.3%)	103 (94.4%)	<0.001*
	>126	29 (26.6%)	6 (5.5%)	

(94.5% vs. 73.4%; $p<0.001$; 95% CI, 12.7%-29.5%) compared to controls (Table 6).

DISCUSSION

This randomized controlled trial provides strong evidence that pharmacist-led Comprehensive Medication Management (CMM) significantly improves both medication adherence and glycemic control in women with Type 2 Diabetes Mellitus (T2DM). The baseline comparability of demographic and clinical characteristics between the control and intervention groups strengthens the attribution of these improvements to the intervention.

Key findings and interpretation

Over the 9-month follow-up, the intervention group demonstrated a consistent and substantial reduction in glycated Hemoglobin (HbA_{1C}) and Fasting Blood Glucose (FBG) levels compared to controls, with differences becoming evident by the second follow-up (6 months) and persisting thereafter. By 9 months, 87.1% of intervention participants achieved HbA_{1C}≤8% compared to 40.3% in the control group ($p<0.001$), and by 9 months, 94.4% achieved FBG ≤126 mg/dL versus 73.3% in controls ($p<0.001$). These results highlight the importance of structured follow-up, targeted counseling, and active patient engagement in sustaining glycemic control. Similar benefits have been reported in pharmacist-led care models in Saudi Arabia (Alghadeer *et al.*,

Table 4: **Medication Adherence (MA) Score-Category at Different Time Points).**

Time Point MA Score Category	Control Group (*n*=109)	Intervention Group (*n*=109)
Baseline Low adherence (<6)	43 (39.4%)	41 (37.6%)
Moderate adherence (6-8)	39 (35.8%)	33 (30.3%)
High adherence (>8)	27 (24.8%)	35 (32.1%)
3 Months Low adherence (<6)	40 (36.7%)	22 (20.2%)
Moderate adherence (6-8)	44 (40.4%)	34 (31.2%)
High adherence (>8)	25 (22.9%)	53 (48.6%)
6 Months Low adherence (<6)	38 (34.9%)	17 (15.6%)
Moderate adherence (6-8)	43 (39.4%)	31 (28.4%)
High adherence (>8)	28 (25.7%)	61 (56.0%)
9 Months Low adherence (<6)	36 (33.0%)	13 (11.9%)
Moderate adherence (6-8)	37 (33.9%)	37 (33.9%)
High adherence (>8)	36 (33.1%)	67 (61.5%)

2021) and Nigeria (David *et al.*, 2021), indicating reproducibility across different healthcare contexts.

Medication adherence and its role in outcomes

Improvement in medication adherence emerged as a pivotal mechanism underlying better glycemic outcomes. In the intervention group, mean MA scores increased from 5.73±1.88 at baseline to 7.12±1.58 at 9 months (p<0.001), with 88.1% achieving moderate to high adherence versus 67.0% in controls. Patients with higher adherence consistently showed better HbA_{1C} and FBG control. This adherence-outcome relationship aligns with findings from (Wu *et al.*, 2023; Erku *et al.*, 2017; Butt *et al.*, 2016; Abubakar and Atif, 2021), while also supporting the predictive validity of MA scores demonstrated in (Pertiwi *et al.*, 2021; Safitri and Yaswir, 2022).

Clinical relevance

Our findings reinforce the broader literature advocating pharmacist-led, patient-centered interventions to overcome clinical inertia in diabetes care (Khunti *et al.*, 2022). Through structured involvement, pharmacists can empower patients to maintain long-term glycemic control, thereby reducing the risk of complications associated with T2DM. Importantly, the intervention proved feasible and effective in a resource-limited setting, echoing (Ali *et al.*, 2023) and suggesting potential scalability in similar healthcare environments.

Strengths and limitations

A notable strength of this study is its targeted focus on women with T2DM, an underrepresented group in diabetes research. The randomized design, adequate sample size, and structured follow-up enhance the reliability of the results. Limitations include the relatively short 9-month follow-up, which may not fully capture long-term sustainability, and reliance on self-reported adherence, which could introduce reporting bias.

Table 5: Comparison of Mean MA scores Between Control and Intervention Groups (n=109 each).

Timepoint	Control Group (Mean±SD)	Intervention Group (Mean±SD)	p-value
Baseline	5.68±1.91	5.73±1.88	0.742
3rd month	5.72±1.86	6.42±1.71	0.014
6th month	5.78±1.85	6.89±1.64	0.001
9th month	5.81±1.82	7.12±1.58	<0.001

Table 6: HbA_{1C} and FBG-Based Adherence Classification Over Time.

Time Point	Group	Low Adherence	Moderate/High Adherence	p-value
		(HbA_{1C}>8%)	(HbA_{1C}≤8%)	
Baseline	Control	107 (98.2%)	2 (1.8%)	0.32
	Intervention	106 (97.2%)	3 (2.8%)	
3 months	Control	106 (97.2%)	3 (2.8%)	0.55
	Intervention	104 (95.4%)	5 (4.6%)	
6 months	Control	73 (67.0%)	36 (33.0%)	<0.001
	Intervention	32 (29.4%)	77 (70.6%)	
9 months	Control	65 (59.6%)	44 (40.4%)	<0.001
	Intervention	14 (12.8%)	95 (87.2%)	
		(FBG >126 mg/dL)	(FBG ≤126 mg/dL)	
Baseline	Control	92 (84.4%)	17 (15.6%)	0.59
	Intervention	88 (80.7%)	21 (19.3%)	
3 months	Control	69 (63.3%)	40 (36.7%)	0.01
	Intervention	79 (72.5%)	30 (27.5%)	
6 months	Control	58 (53.2%)	51 (46.8%)	<0.001
	Intervention	20 (18.3%)	89 (81.7%)	
9 months	Control	29 (26.6%)	80 (73.4%)	<0.001
	Intervention	6 (5.5%)	103 (94.5%)	

Implication and future research

Further studies should evaluate the cost-effectiveness of pharmacist-led CMM, assess long-term impacts on complication rates, and explore patient-reported outcomes such as quality of life. Incorporating objective adherence measures (e.g., pill counts, pharmacy refill records, or electronic monitoring) could improve accuracy in assessing intervention impact. Multi-center trials would also help validate generalizability across diverse patient populations and healthcare systems.

CONCLUSION

This randomized controlled trial demonstrated that pharmacist-led comprehensive medication management significantly improved medication adherence and glycemic control in women with type 2 diabetes mellitus over a 9-month period. The intervention group achieved higher rates of HbA_{1C} ≤8% and FBG ≤126 mg/dL and showed greater improvements in MA scores compared to controls. These results support integrating pharmacist-led care into routine diabetes management to enhance treatment adherence and achieve better clinical outcomes, particularly in resource-limited settings.

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ABBREVIATIONS

DM: Diabetes Mellitus; **CMM:** Comprehensive Medication Management; **MAS:** Medication Adherence Scale; **OHAs:** Oral Hypoglycemic Agents.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVAL

The present study forms part of a randomized controlled trial entitled "Impact of Clinical Pharmacist–Led Comprehensive Medication Management on Diabetic Women in a Tertiary Care Hospital: A Randomized Controlled Study." Ethical approval was obtained from the Institutional Ethics Committee of KLE Academy of Higher Education and Research (KAHER), Belagavi (Ref. No.: KAHER/EC/22-23/134). The trial was registered with the Clinical Trials Registry of India (CTRI/2022/12/048461). Written informed consent was obtained from all participants prior to enrollment.

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