

Original Research Article

Integrated model of digital health and clinic care pathway: a prospective observational study to manage glycated haemoglobin levels and time in range among Indian subjects with type 2 diabetes mellitus

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ABSTRACT

Background: Good glycaemic control is difficult to achieve, especially with high glycated haemoglobin (HbA1c). The benefits of short-term dietary treatments and structured monitoring across severity levels are unknown. Severity-based category transitions may provide more clinically meaningful insight than mean HbA1c change alone.

Methods: To evaluate glycaemic change using a severity-stratified framework and to identify clinical and behavioral predictors of category improvement, with particular focus on baseline HbA1c, disease duration, and continuous glucose monitoring derived time-in-range. The analysis was performed on a cohort of 808 adults.

Results: To evaluate glycaemic change using a severity-stratified framework and to identify clinical and behavioral predictors of category improvement, with particular focus on baseline HbA1c, disease duration, and continuous glucose monitoring derived time-in-range. The analysis was performed on a cohort of 808 adults. At baseline, 23.4% were classified as controlled, 41.5% as uncontrolled, and 35.1% as severely uncontrolled. By 3–4 months, the proportion achieving glycaemic control had increased to 43.4%, corresponding to an absolute improvement of 20.0%. Overall mean HbA1c reduction was $1.34 \pm 1.79\%$ (median 1.00%, IQR 0.20–2.15), with 68.0% achieving clinically meaningful improvement ($\geq 0.5\%$; $p < 0.001$).

Conclusions: Severity-stratified assessment provides clinically meaningful insight into real-world glycaemic outcomes. Structured monitoring combined with early metabolic feedback appears particularly effective in individuals with severe hyperglycaemia.

Keywords: Diabetes type 2, Continuous glucose monitoring, Time in range, HbA1c, Digital health program

INTRODUCTION

Diabetes is a rapidly growing global health epidemic, with type 2 diabetes mellitus (T2DM) being one of the most prevalent chronic diseases worldwide.¹ According to the International Diabetes Federation (IDF), nearly 589 million adults (9.3%) are living with diabetes in 2025, projected to rise to 700 million by 2045.² India bears a significant burden, with approximately 101 million individuals diagnosed as diabetic and 136 million as prediabetic.^{3,4} Alongside a substantial proportion of

undiagnosed cases.³⁻⁵ Despite the advancements in treatment and technology, achieving optimal diabetes control remains challenging.^{6,7} The primary challenges include limited personalization of care, inadequate self-management education, poor adherence, and fragmented healthcare systems.^{8,9}

Glycated haemoglobin (HbA1c) remains the standard diagnostic and monitoring tool, with thresholds defined by World Health Organisation (WHO) and ADA guidelines, which are also supported by Indian recommendations.^{10,11}

Behavioral counselling and diabetes self-management education have shown improvements in glycaemic outcomes and complication risk.¹² More recently, digital health interventions have emerged as scalable solutions, offering continuous and holistic support.¹³ Evidence suggests that such programs can improve HbA1c and weight outcomes, particularly in individuals with higher baseline HbA1c, while maintaining glycaemic stability in others.¹⁴ However, sustaining long-term engagement remains a key limitation.⁸

Continuous glucose monitoring (CGM) is one such innovation that enables real-time glucose tracking and improved clinical decision making.¹⁵ Its use in T2DM management has been observed in India, with studies suggesting significant HbA1c reduction following short term CGM use.¹⁶⁻¹⁸ CGM devices provide detailed insights such as time-in-range (TIR) and glucose trends, supporting personalized care and improved glycaemic outcome.^{19,20} By combining real-time analytics with personalized clinical feedback, CGM shows the potential of digital health in the management of chronic disease.^{16,21}

This study aims to evaluate the effectiveness of a structured diabetes care program on glycaemic outcomes in adults with type 2 diabetes. Key outcomes include absolute HbA1c change (Δ HbA1c), clinically meaningful improvement ($\geq 0.5\%$), and transitions across predefined severity categories (controlled $< 7.0\%$, uncontrolled 7.1–9.0%, severely uncontrolled $\geq 9.1\%$). Additionally, the study examines associations between baseline HbA1c, CGM derived metrics and glycaemic improvement using regression and spline-based systems along with the impact of clinical and demographic factors.

METHODS

Study design

This prospective, observational, multi-centre study was conducted across clinics in 50 Indian cities between 2022 and 2024. The study protocol was approved by the Biomedical and Health Research Committee of Apollo Hospitals Enterprise Limited (AHM-ACD-062/10-24), and the study adhered to the ethical principles outlined in the Declaration of Helsinki (2013) and relevant national guidelines. Informed consent was obtained from all 808 participants.

Adults with confirmed T2DM and complete pre- and post-program data were included. Participants were recruited through physician referrals, in-clinic advertisements, and outreach efforts via diabetes support organizations. Individuals with type 1 diabetes, prediabetes or incomplete data were excluded. Throughout the study period, routine follow-up assessments were conducted to monitor progress and verify data accuracy. Baseline assessment included demographic details, diabetes duration, body weight, BMI, HbA1c, comorbidities, diabetes-related complications, and treatment history.

Participants were enrolled in a structured 90 or 120-day diabetes care program delivered alongside standard care. The intervention integrated CGM via the Smit.fit, “now LilliaCare AI” platform, health coaching, nutritionist support and physician supervision. Baseline HbA1c was assessed on Day 0, followed by CGM initiation on day 1. Early CGM insights were reviewed through multidisciplinary consultations within the first week.

Participants recorded diet, activity, and medication adherence via the smit.fit app, enabling behaviour–glucose correlation. Personalized lifestyle and treatment adjustments were made based on CGM data. Follow-up CGM reviews and consultations were conducted periodically on day 30, 60, 90 and 120, with continued monitoring of adherence and glycaemic indicators including estimated HbA1c and TIR. Final evaluation was performed at day 90 or 120, including repeat HbA1c testing to assess program effectiveness.

Statistical analysis

Data from participants enrolled in structured diabetes management programs were analyzed using a retrospective observational design. Participants with baseline HbA1c and end-of-program HbA1c measurement between 90 and 120 days were included. Baseline glycaemic status was defined using the first recorded HbA1c at enrollment, while end of the program HbA1c was defined as the HbA1c test conducted between 90-120 days from the baseline test. The primary outcome was HbA1c improvement, calculated as the difference between baseline and follow-up HbA1c values, with positive values indicating improvement.

$$\Delta HbA1c = HbA1c_{\{baseline\}} - HbA1c_{\{end\ of\ the\ program\}}$$

Participants were categorized into clinical severity groups based on HbA1c values at baseline and follow-up: controlled ($< 7.0\%$), uncontrolled (7.1–9.0%), and severely uncontrolled ($\geq 9.1\%$). Transitions between severity categories were evaluated using a transition matrix. Row-normalized transition percentages were computed to quantify the proportion of participants remaining stable, improving, or worsening in glycaemic severity over time. Severity change was encoded numerically to identify improvement (movement to a lower severity category), stability, or worsening (movement to a higher severity category).

Descriptive statistics were summarized as means with standard deviations or medians with interquartile ranges (IQR), based on distribution, also as minimum and maximum values. HbA1c improvement was summarized overall and stratified by glycaemic severity transitions. Statistical significance of HbA1c change was assessed using one-sample t-tests against a null hypothesis of no change, along with Wilcoxon signed-rank tests used as non-parametric alternatives. Between-group comparisons

employed non-parametric methods due to skewed distributions.

Subgroup analyses focused on clinically meaningful improvement pathways, including transitions from severely uncontrolled to uncontrolled or controlled states and from uncontrolled to controlled status. For each transition group, HbA1c improvement magnitude was quantified using descriptive statistics and tested against both parametric and non-parametric methods. Feature-wise associations between baseline characteristics, engagement metrics, treatment factors, and HbA1c improvement were explored using univariate non-parametric tests and Spearman correlation for continuous variables.

A multivariable linear regression model was also constructed with HbA1c improvement as the independent variable, adjusting for baseline glycaemic severity, engagement metrics, clinical burden indicators, and type of diabetes medicine -related factors. All analyses were conducted using Python, leveraging standard scientific libraries including NumPy, Pandas, and SciPy.

RESULTS

A total of the 1,500 participants initially enrolled, 808 with T2DM who completed the 90–120-day intervention was included in the final analysis after applying the inclusion and exclusion criteria and excluding dropouts. At the baseline, patients were commonly using insulin-providers (IPs) in combination with insulin enhancers (IEs), specifically GLP-1 receptor agonists and DPP-4 inhibitors, as part of their oral antidiabetic agents (OADs). More detail about the patients’ demographics and OAD medicines are provided in Table 1.

Table1: Baseline demographic parameters.

Variables	Mean±SD/N (%)
Age in years	52.34±11.99
Male	544 (67.3)
Duration of diabetes (years)	7.99±7.53
Weight (kg)	72.50±13.92
BMI (kg/m ²)	26.53±4.68
Comorbidities	643 (79.6)
Diabetes related complications	159 (19.7)
Diabetes treatment	616 (76.2)
OADs	
IPs and IEs	461 (57.1)
GEs and GRs	12 (1.4)
Insulin sensitizers (IS)	72 (8.9)
No medicine	263 (32.5)

OAD: oral antidiabetic agent, GE: glucose excretors, grs: glucose restrictors, IES: insulin enhancers, IPS: insulin providers, IS: insulin sensitizers

HbA1c levels showed a statistically significant reduction from baseline to post-program 8.62%±1.95 to 7.55%±1.51

($p<0.001$). A significant decrease in BMI was also observed over the study period. Among the 447 participants with complete weight data at post-program. Mean BMI reduced from 26.53±4.68 to 26.03±4.56 ($p<0.001$). The mean reduction in HbA1c was observed as 1.07%±1.53, with a median improvement of 0.80% (IQR 0.10–1.80). HbA1c reduction was highly statistically significant (Wilcoxon signed-rank test, $p<0.001$). Clinically meaningful reduction in HbA1c ($\Delta\text{HbA1c} \geq 0.5\%$) was observed in 61.1% of participants. Overall, 620 participants demonstrated HbA1c reduction, 162 experienced worsening, and 26 showed no change in HbA1c over the study period. Participants were further classified into three baseline HbA1c groups: controlled (<7%, $n=189$), uncontrolled (7.1–9%, $n=335$), and severely uncontrolled ($\geq 9.1\%$, $n=284$). HbA1c decreased significantly in all groups, with reductions of 0.05% in the controlled group, 0.69% in the uncontrolled group, and 2.18% in the severely uncontrolled group (all $p<0.001$) as shown in Table 2.

Table 2 presents the results of paired sample t-test, which evaluate the change in HbA1c from baseline to the end of the program, stratified by baseline HbA1c category. Additionally, transition matrices were used to analyse transitions between severity categories from baseline to end of program (Table 3). Moreover, to evaluate differences in HbA1c reduction among patients in these subgroups, ANOVA was conducted. A statistically significant difference in HbA1c reduction was observed across the three subgroups ($p<0.001$). Correlation analysis revealed a positive correlation ($r=0.647$) between baseline HbA1c and HbA1c reduction, indicating that individuals with higher baseline HbA1c showed greater reductions. Category improvement was defined as any downward transition in glycaemic severity, including transitions from uncontrolled to controlled, severely uncontrolled to controlled, or severely uncontrolled to uncontrolled. In the category “enhancement subgroup” ($n=330$), glycaemic outcomes improved significantly (Wilcoxon signed-rank test, $p<0.001$) with a mean HbA1c decrease of 2.23%±1.43, and a median decrease of 1.90%.

Participants transitioning from uncontrolled to controlled glycaemic status ($N=147$) demonstrated a highly significant (Wilcoxon signed-rank test, $p<0.001$) mean reduction of HbA1c 1.41%±0.75 (median 1.30%), 95.2% of participants in this group achieved a clinically meaningful improvement ($\Delta\text{HbA1c} \geq 0.5\%$).

The severely uncontrolled to controlled subgroup ($n=45$) experienced the largest magnitude of glycaemic improvement, with a mean HbA1c reduction of 4.20%±1.29 (median 4.00%). Participants who transitioned from severely uncontrolled to uncontrolled status ($n=138$) also showed substantial glycaemic improvement, with a mean HbA1c reduction of 2.46%±1.31 (median 2.20%) and 97.8% achieved significant clinically meaningful improvement (Wilcoxon signed-rank test, $p<0.001$).

A small subset of participants (N=44) experienced worsening of the HbA1c category, with a mean HbA1c increase of 1.05%±1.06 (median 0.70%). This deterioration was statistically significant (Wilcoxon signed-rank test, p<0.001), and 70.5% met the threshold for clinically meaningful worsening (Δ HbA1c \leq -0.5%).

This group played a pivotal part of the study, showing that overall program-related outcomes were strongly skewed toward glycaemic improvement. The impact of age on HbA1c reduction across different age groups was analysed via ANOVA, as detailed in Table 4.

Table 2: Baseline HbA1c categorization impact (paired t-test).

Baseline HbA1c category	Total participants, N (%)	Pre-program HbA1c (%), mean±SD	Post-program HbA1c (%), mean±SD	P value
Controlled (\leq7%)	189 (23.4)	6.47±0.43	6.42±0.80	<0.001
Uncontrolled (7.1-9%)	335 (41.5)	7.96±0.56	7.27±0.99	<0.001
Severely uncontrolled (\geq9.1%)	284 (35.1)	10.83±1.38	8.65±1.67	<0.001

HbA1c: glycated haemoglobin, SD: standard deviation

Table 3: Baseline-to-end of program matrix of glycaemic severity categories.

Baseline HbA1c category/end of program HbA1c category	Controlled (%)	Uncontrolled (%)	Severely uncontrolled (%)
Controlled	159 (84.1)*	29 (15.3)†	1 (0.5)‡
Uncontrolled	147 (43.9)*	174 (51.9)†	14 (4.2)‡
Severely uncontrolled	45 (15.8)*	138 (48.6)†	101 (35.6)‡

*Indicated the most favorable end-of-program category for that baseline group, † indicates an intermediate category, ‡ indicates the least favorable end-of-program category

No statistically significant differences were observed in mean HbA1c reduction across age categories. However, a weak negative correlation was observed between age and HbA1c reduction ($r=-0.087$, $p<0.05$), suggesting a slight tendency for older participants to experience lower HbA1c reductions than younger individuals, though the effect size was small and not clinically significant. This suggests that age alone may not strongly predict the program's impact on HbA1c levels.

A weak negative correlation ($r=-0.098$, $p<0.01$) was observed between diabetes duration and HbA1c reduction, suggesting that longer diabetes duration was associated with slightly smaller HbA1c reductions. Patients diagnosed with diabetes within the past year showed significant improvements in HbA1c levels.

At the end of the program, 69.2% (n=559) of participants maintained their baseline medication regimen, however, 30.8% required adjustments, including stopping or reducing Insulin in 4.8% (n=39), reducing OAD in 13.2% (N=107), complete discontinuation for 7.5% (n=61) and only 5.2% (N=42) required a medication increase. End of the treatment profiles showed 50.9% (N=412) on IP/IE treatments, 8.5% (N=69) on IS, 1.8% (N=15) on GE/GR, and 38.6% (N=312) were not on any medication. Among participants who were not on any medication regime during baselining, the majority (n=180, 22.3%) continued without pharmacotherapy throughout the program.

These findings highlight that while most participants-maintained treatment stability, a substantial portion of the population had experienced de-escalation of medications,

including reduction or discontinuation of insulin, suggesting meaningful clinical improvement in a subset of individuals.

HbA1c reduction was significantly associated with changes in medication dosage ($p<0.001$). Patients who increased their medication dosage (n=42) had the largest reduction in HbA1c (2.01±1.97%), while those who stayed on their baseline dosage (n=559) had a modest reduction (1.03±1.53%). Patients who were not on allopathic med, also demonstrated a notable reduction (1.43±2.03%).

Table 4: Age and HbA1c reduction (ANOVA).

Age group (years)	Total participants, N (%)	HbA1c reduction (mean±SD)
Below 40	127 (15.7)	1.27±1.59
41-49	201 (24.9)	1.06±1.56
50-59	226 (27.9)	1.08±1.49
60-69	188 (23.3)	0.95±1.45
Above 70	66 (8.2)	0.95±1.67
Total	808	1.06±1.53

The presence of comorbidities (including obesity, hypertension, dyslipidaemia, and hypothyroidism) as well as diabetes-related complications (like neuropathy, retinopathy, and nephropathy) did not significantly affect the level of HbA1c reduction ($p>0.05$).

Notably, 72.2% participants in the severely uncontrolled baseline HbA1c group experienced a statistically significant reduction ($p<0.001$) of more than 1% in their

HbA1c levels, whereas only 6.9% of participants in the controlled group achieved similar reductions in HbA1c.

Adjusted logistic regression for category improvement

An adjusted logistic regression model was utilized to identify predictors for the glycaemic category improvements observed in 40.8% of participants. The model demonstrated strong statistical significance (likelihood ratio test, $p < 0.001$) and explained a meaningful proportion of outcome variance (pseudo $R^2 = 0.11$). Baseline HbA1c emerged as the strongest predictor of category improvement. Each 1% increase in baseline HbA1c was associated with 58% higher odds of improvement (adjusted OR 1.58, 95% CI 1.41–1.76; $p < 0.001$) as shown in table 5. This indicates that individuals with greater baseline disease severity experienced greater likelihood of clinically meaningful category transition. Second week time in range (TIR) was independently associated with improvement, with each 1% increase in TIR corresponding to a 2.6% increase in odds of category improvement (adjusted OR 1.03, 95% CI 1.01–1.04; $p < 0.001$). In contrast, higher time in range during the first week showed a modest inverse association, likely reflecting early behavioral adjustment effects. Longer diabetes duration was associated with reduced odds of improvement (adjusted OR 0.96 per year, 95% CI 0.94–0.99; $p = 0.003$), suggesting diminishing glycaemic reversibility with increasing disease chronicity. Age, gender, presence of complications, and comorbidities were not independently associated with category improvement after adjustment.

Figure 1 presents a forest plot of the adjusted odds ratios (ORs) and 95% confidence intervals from a multivariable logistic regression model; this model is analyzing characteristics linked to improvement in glycaemic severity classification. Odds ratios are displayed on a logarithmic scale. Overall, the model demonstrates that baseline disease severity and dynamic early glycaemic control, particularly improvement in time in range during follow-up, are key determinants of clinically meaningful improvement in the glycaemic category.

Figure 2 demonstrates a strong, non-linear association between baseline HbA1c and subsequent HbA1c improvement. Overall, higher baseline HbA1c levels were associated with progressively greater absolute reductions in HbA1c, explaining approximately 43% of the variance in $\Delta HbA1c$ ($R^2 = 0.43$, $p < 0.001$). At lower baseline HbA1c levels (<7%), the magnitude of improvement was minimal, consistent with a ceiling effect among already well-controlled participants.

Between baseline HbA1c values of approximately 7–9%, HbA1c improvement increased gradually, reflecting moderate but clinically meaningful reductions in this subgroup. Spline analysis showed a pronounced acceleration in HbA1c reduction beyond baseline HbA1c

values of approximately 9–10%, with the spline curve demonstrating a steep upward trajectory.

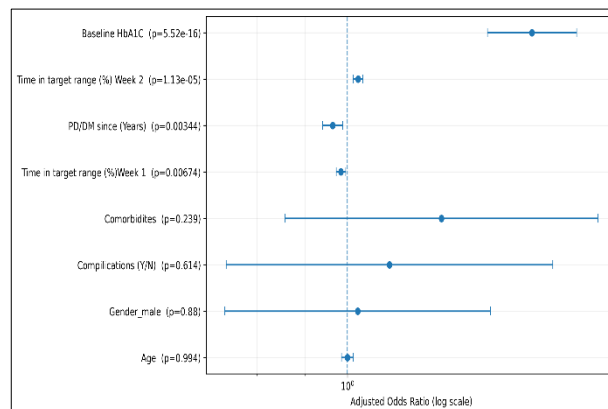


Figure 1: Adjusted odds ratios for category improvement in glycaemic severity.

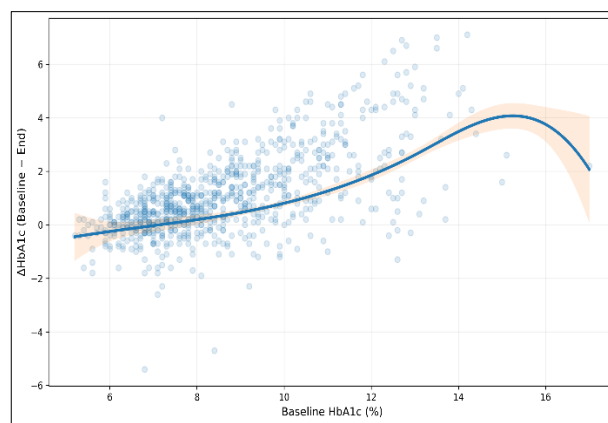


Figure 2: Non-linear association between baseline HbA1c and HbA1c improvement ($\Delta HbA1c$).

Participants with severe baseline hyperglycaemia (HbA1c >10%) experienced the largest absolute improvements, with $\Delta HbA1c$ frequently exceeding 2–4%. This pattern indicates that baseline glycaemic severity is a dominant determinant of absolute improvement. At very high baseline HbA1c levels (>15%), the benefit appeared to plateau or slight attenuation, accompanied by widening confidence intervals, likely reflecting smaller sample sizes and increased variability in extreme values. This spline analysis highlights a clear severity-dependent, non-linear response to intervention, wherein patients with more severe baseline hyperglycaemia derive disproportionately greater absolute glycaemic benefit. These findings support severity-stratified outcome assessment and underscore that mean HbA1c change alone may underestimate clinically meaningful improvement in high-risk populations.

DISCUSSION

Our study indicated a significant improvement in glycaemic control across all baseline HbA1c categories among users with T2DM CGM-powered diabetes care

program. The mean HbA1c decreased by $1.07 \pm 1.53\%$, with the largest reduction (2.18%) observed in a patient with baseline HbA1c $>9\%$. This finding suggested that individuals with poorer baseline glycaemic control (higher initial HbA1c) may experience greater improvement in glycaemic outcomes. Our findings were consistent with the study by Dixon et al, which reported significant HbA1c reductions (up to 2.3%) in patients with baseline HbA1c $>9\%$ in a telehealth CGM-based intervention, while in patients with HbA1c $<7\%$, a stable glycaemic control was maintained.²²

A short-term estimated HbA1c values derived from 7-day CGM data at baseline were compared with estimated HbA1c calculated from 7–14 days of CGM data following dietary intervention. The observed reductions in estimated HbA1c after structured dietary guidance further reinforce the clinical utility of CGM-based monitoring in capturing early glycaemic improvements. An overall $\sim 8\%$ relative reduction in estimated HbA1c was observed between the first and subsequent assessment, supporting the early metabolic impact of structured glycaemic monitoring (Table 4). Since CGM-derived estimated HbA1c cannot be equated with laboratory HbA1c measurements however, temporal changes in estimated HbA1c offer valuable evidence of the early metabolic effects of structured dietary guidance and prompt intervention. In a similar line, a systematic review and meta-analysis found that CGM use in cystic fibrosis-related diabetes for a minimum of 6 weeks resulted in a 0.4% greater reduction in HbA1c than SMBG. Our findings are consistent with this trend, suggesting that access to real-time CGM data may facilitate more effective and timely glucose management.

A significant improvement in the TIR metric from CGM (40.32% to 47.48%; $p < 0.001$) was also observed in our study. Unlike HbA1c, TIR provides a more detailed picture of daily glucose trends and is linked to lower risks of diabetes-related complications. Prior validation studies have shown strong correlations between increasing TIR and reductions in HbA1c as well as risk of retinopathy and nephropathy, where TIR improved from 18% to 74% with CGM compared to SMBG.^{23,24}

Baseline glycaemic severity stand out as a central determinant of improvement. This aligns with findings from landmark trials such as the UK Prospective Diabetes Study (UKPDS) and ADVANCE, which demonstrated that individuals with higher baseline HbA1c levels exhibit greater absolute glycaemic reductions following intervention, largely due to a larger modifiable glycaemic burden.^{25,26} In addition, our study observed that integrating structured coaching with CGM within a diabetes care program was associated with improved outcomes in patients with T2DM. Healthcare providers and certified health coaches educated patients, strengthening patient engagement and adherence.²⁷ Collectively, these findings support a precision-oriented diabetes management approach in which baseline severity, disease duration, and early CGM metrics inform intensity of follow-up and

therapeutic escalation. Such risk-stratified frameworks are increasingly advocated in contemporary diabetes guidelines and digital health models aiming to optimize outcomes while allocating healthcare resources efficiently.²⁸

However, reliance on the patient self-reported data introduces information bias and missing data, potentially compromising analytical methods and data handling. Moreover, the heterogeneity in the data entering and potential recall bias from self-reported measures can introduce measurement error that could affect the population level analysis.

CONCLUSION

In conclusion, the present study demonstrated that the CGM-powered digital technology-based diabetes care program has the potential to improve glycaemic control among patients with T2DM. The study also highlighted the importance of integrating digital health solutions (CGM with digital coaching) with conventional diabetes care to optimize diabetes management. This investigation demonstrated how severity-based glycaemic evaluation offers more clinically significant information than just mean HbA1c change. Higher baseline HbA1c was the strongest determinant of improvement, while longer disease duration modestly reduced response probability. Early improvements in time-in-range were independently associated with category transition, suggesting that short-term CGM metrics may predict downstream glycaemic benefit. These findings support risk-stratified, adherence-focused diabetes management models and reinforce the value of structured monitoring in individuals with poor baseline control. Future research with a larger sample is warranted to evaluate the long-term efficacy, scalability, and cost-effectiveness of this program, facilitating wider adoption of such interventions in routine clinical practice.

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