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A Digital Platform Combined with Behavior-Focused Care-Management Coaching for Gestational Diabetes: A Retrospective Cohort Study

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Abstract

Background: Gestational diabetes mellitus (GDM) increases maternal and neonatal morbidity, and glycemic control becomes progressively difficult as insulin resistance rises in late gestation. We evaluated glycemic trajectories and perinatal outcomes among GDM participants managed within the digitally enabled, behavior-focused, human-supported One Th1ng™ care model. **Methods:** This IRB-exempt retrospective study included GDM participants enrolled August 2024–July 2025 at Pediatrix/Obstetrix sites in Denver, Colorado. A descriptive analysis evaluated glucose trajectories across gestational weeks 30–37, and a phase-based analysis compared a 2-week baseline with a 2-week early intervention using linear mixed models. **Results:** Of 139 participants, 77 contributed glucometer data between weeks 30–37, and 38 (28 diet-controlled, 10 insulin-treated) met phase-based criteria. Fasting glucose decreased by 2.86 mg/dL (95% CI: 1.52–4.21, p=0.0001) and postprandial glucose by 2.26 mg/dL (95% CI: 0.34–4.19, p=0.0227). Fasting reduction was greater among insulin-treated patients (6.97 vs. 1.37 mg/dL; interaction p=0.0006). Mean glucose remained within ADA targets across weeks 30–37. Among 53 participants with delivery data, primary cesarean rate was 5.7%, NICU admission 5.9%, and preterm birth 4.1%. **Conclusion:** Participation in the One Th1ng™ care model was associated with early glycemic improvements, particularly among insulin-treated patients, alongside favorable perinatal outcomes including low preterm birth and primary cesarean rates.

Keywords: gestational diabetes mellitus; digital health; telehealth; remote patient monitoring; blood glucose self-monitoring; health coaching; behavioral change; multidisciplinary care; glycemic control; pregnancy outcomes; maternal outcomes; neonatal outcomes

1. Introduction

Gestational diabetes mellitus (GDM) is one of the most common pregnancy complications globally and is independently associated with increased risks for women and their offspring. It affects 6–8.3% of U.S. pregnancies(Martin & Gregory, 2023) and ~14% globally.(Wang et al., 2022) Typically, insulin sensitivity decreases throughout the pregnancy and by approximately 50% by the third trimester. This is driven by placental hormones, adipocyte-derived cytokines, and metabolic changes that redirect glucose across the placenta to support fetal growth.(Brown, Alwan, et al., 2017; Brown, Grzeskowiak, et al., 2017; Brown, Martis, et al., 2017; Tieu, McPhee, et al., 2017; Tieu, Shepherd, et al., 2017) Maternal euglycemia is normally maintained by a compensatory 200–250% increase in insulin secretion.(Brown, Alwan, et al., 2017; Brown, Grzeskowiak, et al., 2017) One of the conditions under which GDM develops is when β-cells fail to mount this compensatory response, resulting in glucose intolerance from reduced peripheral glucose disposal and inadequate suppression of hepatic glucose production.(Brown, Alwan, et al., 2017)

However, GDM is not a single disease, but represents multiple causes of inadequate β-cell function.(Buchanan et al., 2025) Recent evidence identifies three pathophysiological subtypes: insulin-resistant GDM (~50–60% of cases), associated with higher complication rates; insulin-deficient GDM (~15–30%); and mixed GDM.(Hivert et al., 2024) Underlying causes include pre-existing insulin resistance, autoimmunity, and monogenic disorders.(Buchanan et al., 2025),(Baz et al., 2016)

Maternal hyperglycemia increases the maternal–fetal glucose gradient, enhancing transplacental glucose transfer and triggering fetal hyperinsulinemia, a key anabolic signal that drives excess fetal growth (macrosomia) and related complications.(Brown, Grzeskowiak, et al., 2017; Brown, Martis, et al., 2017; Hofer et al., 2023) The implications are significant for both mother and child.(Venkatesh et al., 2022) Short-term maternal risks include preeclampsia (OR 1.69, 95% CI 1.31-2.18), gestational hypertension, cesarean delivery (OR 1.16, 95% CI 1.03–1.32 in non-insulin–treated; higher with insulin OR 1.12, 95% CI 0.80-1.56), preterm delivery (OR 1.51, 95% CI 1.26–1.80), induction of labor for macrosomia, increased perineal trauma, and polyhydramnios.(Hofer et al., 2023; Martis et al., 2018; Raman et al., 2017; Sweeting et al., 2024; Ye et al., 2022) Fetal and neonatal complications include macrosomia (OR 1.57, 95% CI 1.25-1.97), shoulder dystocia (OR 1.50, 95% CI 1.07-2.10) and birth trauma (including brachial plexus palsy), neonatal hypoglycemia (OR 1.57, 95% CI 0.36-6.44), respiratory distress syndrome (OR ~1.57, 95% CI 1.19-2.08), hyperbilirubinemia (OR ~1.28, 95% CI 1.02-1.62), polycythemia, hypocalcemia, lower Apgar scores, and increased NICU admissions (OR ~2.29, 95% CI 1.59-3.31).(Farrar et al., 2017; Hofer et al., 2023; Martis et al., 2018; Raman et al., 2017; Tieu, McPhee, et al., 2017; Yamamoto et al., 2020)

Many women exhibit chronic, progressive β-cell dysfunction identified during pregnancy, explaining the strong link between GDM and future type 2 diabetes (T2DM).(Buchanan et al., 2025),(Baz et al., 2016) Long-term maternal risk of T2DM is substantial, reaching ~20% at 10 years, 30% at 20 years, and 50% at 40 years, with a lifetime risk of 50–60%, representing a 7–10-fold increase compared to women without GDM, and is also associated with increased cardiovascular disease risk.("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026; Damm et al., 2016; Fu & Retnakaran, 2022; Hofer et al., 2023; Song et al., 2018) Offspring are also at increased long-term risk, including overweight and obesity (OR ~1.57), T2DM (OR ~4.50), neurodevelopmental disorders such as autism (OR 1.38) and intellectual disability (OR 1.70), and adverse cardiometabolic profiles.(Guan et al., 2025; Hivert et al., 2024)

These effects can persist well beyond pregnancy for both mother and offspring, underscoring the need for accessible, effective care during this critical period and highlighting an important opportunity for prevention through well-designed care models.

Current guidelines recommend universal screening at 24–28 weeks' gestation, followed by structured glycemic management that includes nutrition therapy, physical activity, glucose monitoring, and pharmacologic treatment when indicated.("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026; "ACOG Practice Bulletin No. 190: Gestational Diabetes Mellitus," 2018) Targets for glucose management include fasting glucose of 70–95 mg/dL, 1-hour postprandial glucose <140 mg/dL, or 2-hour postprandial glucose <120 mg/dL when achievable without hypoglycemia.("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026) Several randomized trials have confirmed that treatment reduces maternal and perinatal morbidity, including macrosomia, shoulder dystocia, preeclampsia, and birth trauma.(Alwan et al., 2009; Crowther et al., 2005; Landon et al., 2009) However, insulin resistance increases steeply across late gestation, with total daily insulin requirements rising by approximately 5% per week through 36 weeks, often doubling over the course of pregnancy.("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026; "ACOG Practice Bulletin No. 190: Gestational Diabetes Mellitus," 2018; Valent et al., 2025) This rapid physiologic change creates a structural mismatch with traditional episodic care models, which typically rely on weekly glucose log review and clinic visits every 2–3 weeks.("ACOG Practice Bulletin No. 190: Gestational Diabetes Mellitus," 2018) As a result, dose adjustments and behavioral modifications may lag behind evolving metabolic demands, contributing to suboptimal glycemic control during the very period when fetal growth is most sensitive to maternal hyperglycemia.("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026; "ACOG Practice Bulletin No. 190: Gestational Diabetes Mellitus," 2018; Brown, Alwan, et al., 2017; Brown, Grzeskowiak, et al., 2017; Kantorowska et al., 2023; McGovern et al., 2022)

Digital health strategies incorporating remote monitoring and mobile health (mHealth) applications have emerged as promising tools to address these limitations. A meta-analysis of 28 randomized controlled trials involving 3,228 women with GDM found that digital health interventions improved glycemic control with moderate-to-high certainty, yielding lower fasting plasma glucose, 2-hour postprandial glucose, and HbA1c, along with reduced rates of cesarean delivery and macrosomia.(Leblalta et al., 2022) Systematic reviews of smartphone-based applications for GDM management have similarly reported improved treatment adherence, enhanced patient self-management, and personalized health care delivery.(Garg et al., 2022; Giaxi et al., 2025) Pilot studies of app-assisted care pathways have demonstrated superior glycemic indices compared to standard care, with app-using patients achieving lower fasting and postprandial values while maintaining non-inferiority for adverse maternal and neonatal outcomes.(Smyth et al., 2025) Feasibility studies of integrated mHealth platforms incorporating smartphone applications, clinician portals, and remote data review have confirmed high user satisfaction and increased frequency of blood glucose review between clinic visits.(Varnfield et al., 2021) However, fewer studies have evaluated care models that combine digital remote data capture with structured human coaching and predefined clinical escalation pathways within existing obstetric workflows.

The physiologic adaptation of increasing insulin resistance across late gestation, combined with heterogeneity in insulin secretion, psychosocial factors, and cultural influences on dietary behavior, makes maintaining maternal glycemic control progressively more challenging as pregnancy advances.(Hivert et al., 2024; Valent et al., 2025) Current intervention models have yet to fully integrate digital data capture with structured behavioral reinforcement and timely clinical adjustment within a unified care framework. Integration of these components has the potential to improve glycemic trajectories and, in turn, maternal and neonatal outcomes. We evaluated longitudinal glycemic trajectories and perinatal outcomes among individuals with GDM managed within the One Th1ngTM care

model. We hypothesized that participants would demonstrate stabilized or declining glucose trajectories following adoption of One Th1ngTM. This care model was designed to augment established perinatal diabetes education through structured between-visit management and coordinated communication, rather than replace existing clinical workflows.

2. Materials and Methods

2.1. Study Design and Population

Through this retrospective cohort study, pregnant participants diagnosed with gestational diabetes mellitus (GDM) who participated in the One Th1ng™ digitally enabled, behavior-focused, human-supported, multidisciplinary care model between August 2024 and July 2025 at Pediatrix/Obstetrix-affiliated sites in Denver, Colorado were evaluated. This retrospective analysis of de-identified data was reviewed and approved by the HCA-HealthONE Institutional Review Board. Inclusion criteria were age ≥18 years, singleton gestation, diagnosis of GDM based on the Carpenter-Coustan criteria,("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026) smartphone access, and submission of glucose data via patient-performed glucometer measurements. Exclusion criteria included preexisting type 1 or type 2 diabetes mellitus, multifetal gestation, incomplete medical records, or insufficient longitudinal glucose data. Consistent with ADA Standards of Care recommendations("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026), participants self-monitored their glucose daily, including a fasting measurement and 1-hour postprandial measurements following each meal.

Participants were included in the first analysis if they had at least 3 weeks of program participation and at least one fasting and one postprandial glucometer-derived glucose measurements daily between gestational weeks 30 and 37. To minimize the influence of the initial onboarding period on glycemic trends, glucose data from the first 2 weeks of each participant's enrollment were excluded from this analysis.

Participants were included in the second, phase-based, analysis if they had sufficient glucometer-derived glucose data during the first 4 weeks of the program. A qualifying day was defined as one with both a fasting glucose value and at least one postprandial measurement. To be included, participants needed ≥4 qualifying days in each of the first 4 program weeks and had to enroll by 33 weeks' gestation. Weeks 1–2 were defined as the baseline phase, and weeks 3–4 as the early intervention phase.

2.2. Digital Care Model

The One Th1ng™ care model was designed to extend glycemic monitoring and behavioral support beyond traditional prenatal visits through an integrated digital platform and structured, human-delivered coaching. Following referral from the obstetric practice, participants completed an onboarding call with a Client Success Navigator, typically within 12–24 hours. During this call, the navigator confirmed the glucose monitoring method (glucometer or continuous glucose monitor [CGM], based on insurance coverage and access), collected baseline clinical and lifestyle information (including dietary patterns, schedule constraints, cultural preferences, and social factors such as food access and transportation), established communication expectations, and assigned each participant to a dedicated Care Management Coach. Coaches were board-certified or functional nutritionists and registered nurses trained in the RenewRx proprietary behavior change methodology.

Participants then entered a 3–5 day data collection period, during which they began monitoring glucose and logging meals while the care team reviewed data for early trends and risk signals. This was followed by the first formal coaching session. Coaching was

structured and protocol-driven, focusing on behavioral pattern recognition, individualized meal planning (including practical carbohydrate strategies, protein and fiber pairing, and culturally appropriate food choices), and small, but impactful, sustainable habit changes to reduce overwhelm and improve adherence. Ongoing support included one-to-one coaching sessions one to two times per month, in-app messaging two to three times per week, and continuous data review by the care team.

Clinical escalation pathways were developed with each referring practice. When glucose values exceeded predefined thresholds, concerning symptoms were reported, or medication adjustment appeared necessary, the Care Management Coach sent a structured summary to the clinical team through a dashboard integrated with the practice's EMR. These summaries included observed trends, prior interventions, relevant participant context, and suggested next steps. This allowed for early identification of worsening glycemic patterns and more timely clinical follow-up. Providers also received periodic summaries of glucose trends, escalation events, and adherence to support more focused and efficient visits. Participants were able to record glucose measurements through standard point-of-care glucometers, which is the current standard of care for GDM, while a subset used CGM based on clinical need and insurance coverage.

As this study reflects an early-stage deployment, the digital platform and clinical workflows were iteratively refined throughout the study period to optimize the care model, a process typical of early-phase health technology implementations.

2.3. Glucose Data Processing and Outcomes

For analysis, only glucometer data of the participants were included, as self-monitored glucometer measurements remain the current standard of care. Glucose values <50 mg/dL were excluded as physiologically unlikely (1 reading excluded).

A primary analysis was conducted to observe mean glucose over gestational weeks 30-37. Glucose observations were included for all participants that met base inclusion criteria. Weekly averages were calculated in a stepwise fashion, with postprandial observations averaged into days before they were averaged into weeks.

The secondary, phase-based, analysis assessed the initial impact of the One Th1ng™ care model by comparing within-patient changes in mean weekly fasting and postprandial glucose between a 2-week baseline phase and a subsequent 2-week early intervention phase, with the first 2 weeks of enrollment retained as the baseline comparator so that each participant served as her own control.

Secondary outcomes included mode of delivery, neonatal intensive care unit (NICU) admission, birth weight, and gestational age at delivery.

2.4. Statistical Analysis

For the descriptive analysis of glucose trends, linear mixed models were used to evaluate weekly trajectories across gestational weeks 30–37. The first two weeks in the program were excluded as a stabilization period (referred to as baseline phase in the analysis described below), and analyses were limited to ≤37 weeks' gestation to reduce bias from delivery-related attrition. Results are presented as estimated weekly means with 95% confidence intervals.

The phase-based analysis compared daily mean glucose between a 2-week baseline phase and a subsequent 2-week early intervention phase. Fasting and 1-hour postprandial glucose were analyzed separately using linear mixed models to assess within-subject changes. An interaction term (phase × insulin) was included to evaluate differences between diet-controlled and insulin-treated subgroups.

Across both analyses all models accounted for repeated measures using random intercepts and were adjusted for advanced maternal age (≥35 years), gestational age at

enrollment, and insulin status (diet-controlled vs insulin-controlled). Statistical significance was defined as $p < 0.05$. Analyses were conducted in SAS 9.4M9 (TS1M9) and R (version 4.5.2).

3. Results

3.1. Cohort Characteristics and Monitoring Modalities

Of 139 enrolled participants, 116 had GDM and submitted glucose data. After exclusions, those with preexisting diabetes, multifetal gestation, ≤2 weeks of participation, enrollment after 33 weeks' gestation, or insufficient glucometer data, 77 participants were included in the primary analysis of weekly glucose measurements during gestational weeks 30-37. Inclusion required at least one fasting and one postprandial glucometer value on a given day per week, between 30–37 weeks' gestation. Demographic and clinical characteristics are summarized in Table 1.

Table 1. Demographics and clinical characteristics in full cohort (n=77) meeting inclusion criteria.

	Freq|Mean	**%|Stdev**
Insulin-Treated, freq (%)	23	29.9%
Race/Ethnicity		
American Indian or Alaska Native	1	1.3%
Asian/Pacific Islander	14	18.2%
Caucasian/White	47	61.0%
Caucasian/WhiteAsian/Pacific Islander	1	1.3%
Caucasian/WhiteHispanic/Latino	1	1.3%
Hispanic/Latino	9	11.7%
Hispanic/Latino/Asian/Pacific Islander	1	1.3%
Unknown/Other	3	3.9%
Advanced Maternal Age, freq (%)	25	32.5%
Maternal Age [yrs], mean (stdev)	32.3	4.3
Gestational Age at Enrollment [wks], mean (stdev)	30.6	1.7

3.2. Primary Analysis: Descriptive Weekly Glucose Trends

For the longitudinal descriptive analysis, 77 participants met inclusion criteria after excluding the first two weeks of enrollment. Changes in glucometer readings are shown in Figures 1 (fasting glucose) and Figure 2 (postprandial glucose).

The model-estimated mean fasting glucose showed a gradual decline from approximately 96 mg/dL at gestational week 30 to approximately 91 mg/dL by week 37 (Figure 1). After adjustment for gestational age at enrollment and advanced maternal age, insulin-treated participants had fasting glucose values 10.72 mg/dL higher than diet-controlled participants (95% CI: 6.80–14.64, p<.0001; Table 2). Postprandial glucose remained essentially stable across the observation period, averaging approximately 120 mg/dL, well below the ADA-recommended 1-hour postprandial target of 140 mg/dL (Figure 2). The difference between insulin-treated and diet-controlled participants was smaller for postprandial glucose (4.85 mg/dL, 95% CI: −0.26–9.96, p=0.0625). Confidence intervals were wider at earlier gestational weeks, reflecting smaller sample sizes as participants enrolled at varying timepoints. Given the absence of a control group, these findings should be interpreted as descriptive rather than evidence of a causal intervention effect.

The diet-controlled group achieved a mean fasting glucose of 87.8 mg/dL, well below the ADA-recommended target of <95 mg/dL, while the insulin-treated group averaged 96.5 mg/dL, approximating the threshold.("15. Management of Diabetes in Pregnancy: Standards of Care in Diabetes-2026," 2026) Mean one-hour postprandial glucose was 117.8

mg/dL (diet-controlled) and 125.4 mg/dL (insulin-treated), both below the 140 mg/dL target. On a per-day basis, diet-controlled participants met the fasting target on 80.4% of monitored days compared to 44.0% for insulin-treated participants, while postprandial target compliance was similar between groups (93.3% vs. 90.5%; Table 3).

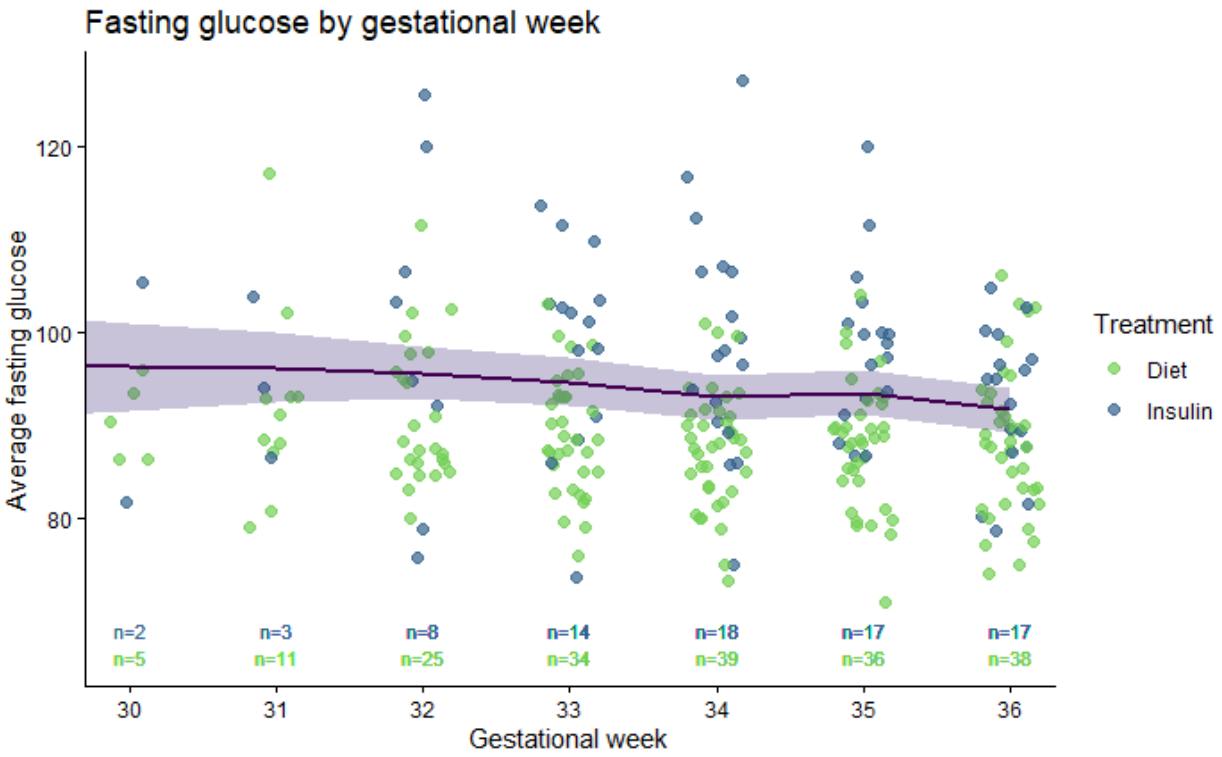

Figure 1. Fasting Glucose by Gestational Week. The solid line represents model-estimated mean glucose values by week from the linear mixed model, adjusted for maternal age at baseline, gestational week at baseline, and insulin use. Shaded bands indicate 95% confidence intervals. Individual participants are color-coded by treatment group, with blue representing insulin-treated and green representing diet-controlled.

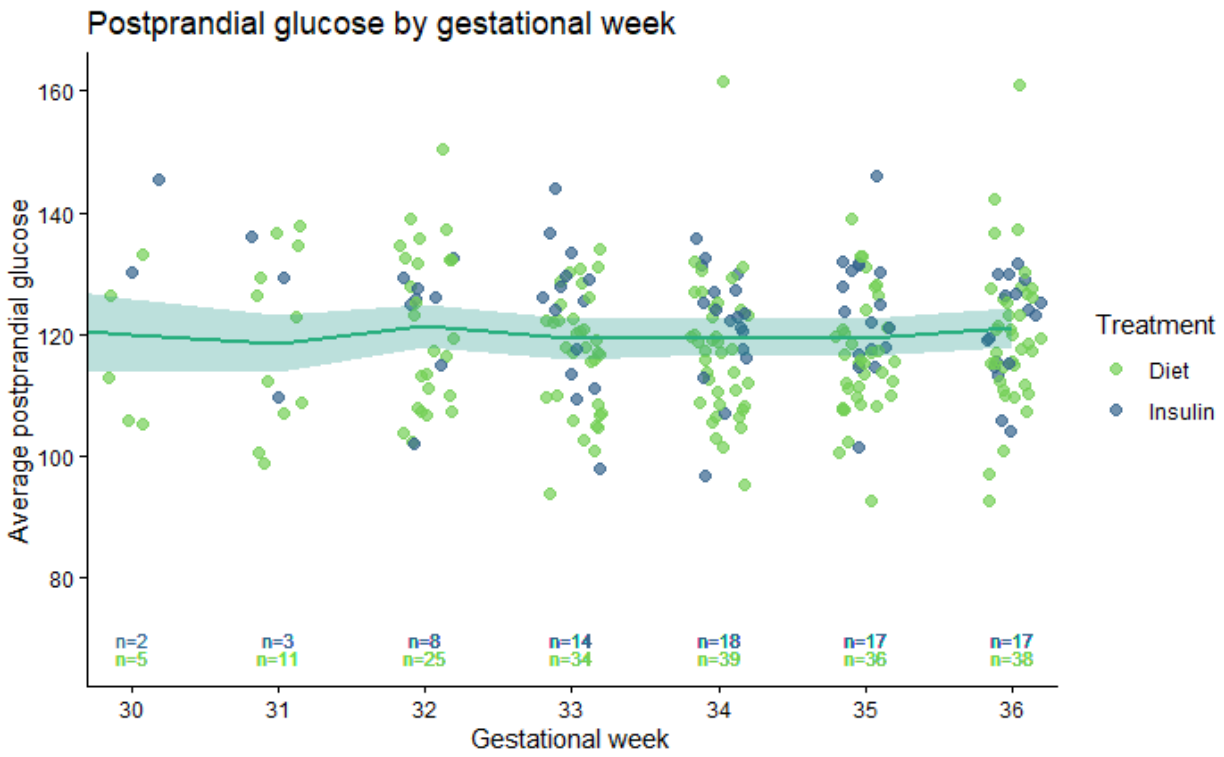

Figure 2. One-Hour Postprandial Glucose by Gestational Week. The solid line represents model-estimated mean glucose values by week from the linear mixed model, adjusted for maternal age at baseline, gestational week at baseline, and insulin use. Shaded bands indicate the 95% confidence intervals. Individual participants are color-coded by treatment group, with blue representing insulin-treated and green representing diet-controlled. Postprandial glucose was calculated by averaging daily values, then aggregating to weekly means.

Table 2. Slopes for all covariates included in the linear mixed models representing changes in glucometer derived glucose measurements across the study.

	Estimate	LCL	UCL	p-value
Fasting Glucose				
Insulin-Treated vs. Diet-Controlled	10.72	6.80	14.64	<.0001
Gestational age at enrollment per 1 week increase	1.10	-0.02	2.23	0.0549
Advanced Maternal Age: Yes vs No	-1.29	-5.23	2.66	0.5177
Postprandial Glucose				
Insulin-Treated vs. Diet-Controlled	4.85	-0.26	9.96	0.0625
Gestational age at enrollment per 1 week increase	-0.71	-2.18	0.75	0.3362
Advanced Maternal Age: Yes vs No	-2.59	-7.74	2.56	0.3191
LCL = lower 95% confidence interval, UCL = upper 95% confidence interval				

Table 3. ADA Target Compliance by Insulin Status.

By Day	Diet-Controlled	Insulin-Treated
Fasting (≤95 mg/dL)	785/976 (80.4%)	180/409 (44.0%)
1-hr Postprandial (<140 mg/dL)	911/ 976 (93.3%)	370/409 (90.5%)

3.3. Phase-Based Analysis: Early Glycemic Response

For the phase-based analysis, 38 participants (28 diet-controlled, 10 insulin-treated) met criteria for adequate early program data. Demographic characteristics are summarized in Table 4. All 38 participants contributed to both fasting and postprandial models.

Table 4. Comparison of demographics and clinical characteristics in the diet-controlled vs. insulin-treated subgroups in the phase-based analysis. (n=38).

	Diet-Controlled (n=28)		Insulin-Treated (n=10)		
Race/Ethnicity, freq	**Freq | Mean**	**% | Stdev**	**Freq | Mean**	**% | Stdev**	**p-value**
Asian/Pacific Islander	6	21.4%	3	30.0%	>0.999
Caucasian/White	16	57.1%	6	60.0%	
Unknown	1	3.6%	0	0.0%	
Hispanic/Latino	4	14.3%	1	10.0%	
Hispanic/Latino/Asian/Pacific Islander	1	3.6%	0	0.0%	
Advanced Maternal Age, freq (%)	7	25.0%	2	20.0%	>0.999
Maternal Age [yrs], mean (Stdev)	31.6	3.9	31.4	5.9	0.9329
Gestational Age at Enrollment [wks], mean (stdev)	30.4	1.8	30.4	2.2	0.9437

In this analysis, 38 participants contributed data across program weeks 1–4 (152 participant-weeks). After adjusting for gestational age at enrollment, insulin use, and maternal age, both fasting (p=0.0001) and postprandial glucose (p=0.0227) improved significantly from baseline to the early intervention phase. Mean fasting glucose decreased by 2.86 mg/dL (95% CI: 1.52–4.21), and postprandial glucose decreased by 2.26 mg/dL (95% CI: 0.34–4.19). The intervention effect differed by treatment group for fasting glucose (interaction p=0.0006), with a greater reduction in the insulin-treated subgroup (mean difference: 6.97 mg/dL, 95% CI: 4.38–9.55, p<0.0001) compared to the diet-controlled subgroup (mean difference: 1.37 mg/dL, 95% CI: −0.19–2.93, p=0.0833). In contrast, the intervention effect for postprandial glucose did not differ significantly between subgroups (interaction p=0.1680). (Table 5)

Table 5. Unadjusted average glucose values by phase and insulin subgroup.

	Baseline Phase		Early Intervention Phase	
	Mean	**Stdev.**	**Mean**	**Stdev.**
Fasting Glucose (mg/dL)				
Total cohort	94.8	14.3	92.0	10.7
Insulin-treated	108.2	11.8	101.2	10.9
Diet-Controlled	89.9	11.8	88.6	8.4
1-hr Postprandial Glucose (mg/dL)				
Total cohort	121.9	17.0	119.7	14.6
Insulin-treated	130.2	14.4	125.7	11.4
Diet-Controlled	118.9	16.9	117.4	15.1

3.4. Maternal, Delivery, and Neonatal Outcomes

Delivery and neonatal outcome data were available for 53 of 77 participants in the first analysis (Table 6).

Table 6. Maternal and Neonatal Outcomes.

Outcome	Value
Total with Delivery Data (of 77 in the first analysis)	53
Mode of Delivery	
Vaginal delivery	43 (81.1%)
Primary cesarean delivery	3 (5.7%)
Repeat/scheduled cesarean	7 (13.2%)
Labor induction	34 (68.0%)
Gestational Age at Delivery	
Mean gestational age, weeks ± SD	38.7 ± 1.2
Preterm birth (<37 weeks)	2 (4.1%)
Neonatal Outcomes	
Mean birth weight, g ± SD	3255 ± 465
Low birth weight (<2.5 kg)	3 (6.2%)
Macrosomia (>4.0 kg)	1 (2.1%)
Severe macrosomia (≥4.5 kg)	0 (0%)
NICU admission	3 (5.9%)
NICU >24 hours	1 (2.0%)
NICU ≤24 hours	2 (3.9%)
Maternal and Neonatal Morbidity	
Maternal complications	8 (15.1%)
True neonatal morbidity	3 (5.9%)

Values are n (%) or mean ± SD. Transient intrapartum events (e.g., nuchal cord, brief decelerations) that resolved without neonatal treatment were not counted.

4. Discussion

In this retrospective cohort of individuals with gestational diabetes, participation in a digitally enabled, human-supported care model (One Th1ng™) was associated with significant reductions in average daily fasting and postprandial glucose during the 2-week early intervention phase compared to baseline. Because each participant served as their own comparator, these within-subject estimates are less influenced by stable between-patient differences such as baseline metabolic severity. The reduction in fasting glucose was greater among insulin-treated participants, whereas postprandial improvements were similar across treatment groups. This pattern is consistent with higher baseline fasting glucose among insulin-treated patients and greater potential for improvement with treatment adjustment. Findings were consistent in analyses of gestational age–based trajectories in the larger cohort (n=77), where insulin-treated participants maintained higher glucose values across weeks 30–37. This is consistent with prior evidence that insulin-treated GDM reflects greater underlying metabolic impairment.(Benhalima et al., 2015)

Beyond glycemic measures, downstream perinatal outcomes in our cohort also compared favorably to published benchmarks. In this study, primary cesarean delivery occurred in 5.7% of participants, NICU admission in 5.9%, and preterm birth in 4.1%, compared to contemporary US-based GDM rates: primary cesarean section rates of 27–42%, NICU admission rates of 11.2–13%, and preterm labor rates of 11.2%.(Akinyemi et al., 2023; Venkatesh et al., 2022) The early fasting glucose reduction in the insulin-treated subgroup (−7.0 mg/dL) is comparable to the pooled effect from a meta-analysis of 28 randomized trials of digital health interventions for GDM, which reported a fasting glucose reduction of −0.33 mmol/L (~5.9 mg/dL) alongside reductions in cesarean delivery (RR 0.81, 95% CI: 0.69–0.96) and macrosomia (RR 0.67, 95% CI: 0.48–0.93).(Leblalta et al., 2022) That

a similar effect size emerged in a real-world cohort suggests structured behavioral coaching may produce comparable benefits outside controlled trial settings.

The mechanism of effect likely lies in the human coaching layer rather than the technology itself. Passive digital infrastructure such as glucose logging, automated alerts, and generic educational content appears to be insufficient on its own. A systematic review of mobile health applications for GDM found that only 12% of studied interventions addressed cultural factors influencing adherence, highlighting a critical gap in existing digital platforms.(Garg et al., 2022) Miremberg et al. demonstrated that adding daily clinician-to-patient feedback to standard monitoring improved both compliance and glycemic control,(Miremberg et al., 2018) and Leblalta et al. found that telemonitoring interventions involving bidirectional patient–provider exchange showed greater glycemic benefit than tele-education approaches alone.(Leblalta et al., 2022) In our model, the digital platform provides patient-friendly data capture and trend visualization, while the behavioral coaching layer delivers individualized, longitudinal support through trained care managers. This combination extends the reach and frequency of patient contact beyond what traditional perinatal diabetes teams can provide within standard visit-based care.

4.1. Implementation Considerations

This care model was designed to integrate into existing obstetric workflows rather than replace them, with the digital platform functioning as a complementary layer to standard prenatal care and Care Management Coaches serving as the primary point of contact between clinic visits. Patients were typically enrolled between 28–33 weeks' gestation and onboarded during a single visit, where they received a glucometer, access to the platform, and an initial coaching session focused on individualized behavioral goals. Coaches, trained in motivational interviewing and GDM-specific nutrition guidance, conducted asynchronous check-ins and escalated clinical concerns such as persistent hyperglycemia or medication non-adherence to the supervising provider. This approach did not require additional clinic visits and involved minimal physician time. Since interactions occur remotely and data are reviewed digitally, the model may be adaptable across different care settings, though implementation does require appropriate infrastructure for remote monitoring, clear escalation pathways, and trained personnel.

4.2. Limitations

This study has several strengths, including the within-patient design in which each participant served as her own comparator, reducing confounding from stable between-patient differences such as baseline metabolic severity, body composition, and genetic predisposition. The use of glucometer-derived data exclusively also reflects real-world clinical practice, enhancing the translational relevance of the findings.

However, there are limitations inherent to the study design. Without a concurrent control group, observed glucose improvements cannot be attributed solely to the care model, and the single-center, Denver-based setting limits generalizability. This concern is reinforced by a systematic review demonstrating that mHealth efficacy in GDM varies substantially by cultural and regional context.(Giaxi et al., 2025) Furthermore, restricting the analytic cohort to participants who met predefined monitoring thresholds may introduce selection bias toward more engaged individuals who could have achieved favorable glycemic control regardless of the intervention.

The role of glucose monitoring technology also warrants consideration. Although CGM has been associated with improved glycemic metrics and fewer large-for-gestational-age infants in pregnancies complicated by diabetes,(Lane et al., 2019; Murphy et al., 2008; Márquez-Pardo et al., 2020) improvements in composite neonatal outcomes have

been inconsistent, suggesting that data visibility alone is insufficient without an accompanying care structure to act on it.

Several analytic constraints should also be noted. Glycemic trajectories were restricted to gestational ages 37 weeks or less, as later observations likely reflect delivery-related attrition rather than active monitoring, potentially limiting characterization of glycemic patterns immediately before delivery. NICU admissions were classified by duration but exact length of stay was not captured. Finally, this study reflects an early deployment of the care model during which operational workflows were still maturing. Evaluation of the stabilized platform may yield different effect sizes, and the integration of automated decision-support tools represents a promising direction for future development.

5. Conclusion

In this retrospective cohort of participants with gestational diabetes, participation in a digitally enabled, behavior-focused, human-supported One Th1ng™ care model was associated with early reductions in glucose levels in both insulin-treated and diet-controlled patients. Rates of primary cesarean section, preterm delivery, and NICU admission were lower than reported national benchmarks. These findings suggest that combining digital infrastructure with longitudinal coaching may support glycemic stabilization by extending the capacity of existing perinatal diabetes teams and functioning as an adjunct to standard multidisciplinary care. Prospective, multicenter studies are needed to confirm these findings and to better define the relative contributions of digital tools and human support.

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Institutional Review Board Statement: This study was approved for exemption by the HCA-HealthONE Institutional Review Board under 45 CFR 46.104(d)(4) for retrospective review of de-identified data.

Informed Consent Statement: Participant consent was waived due to de-identified data use.

Data Availability Statement: Data supporting the findings are available from the corresponding author upon reasonable request.

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Conflicts of Interest: K.C. is a co-founder of RenewRx. J.C. is married to K.C. and holds an ownership interest in a professional corporation that provides services to RenewRx; however, no patients included in this study were part of that professional corporation. J.C. also serves in a research leadership role with RenewRx. These relationships were disclosed and managed in accordance with journal and institutional policies. The authors declare that these interests did not influence the study design, data collection, analysis, interpretation of results, or the decision to publish the findings.:

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