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Clinical Research Article

Sustained HbA1c Improvements Over 36 Months in Youth in the Teamwork, Targets, Technology, and Tight Control (4T) Study

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Abstract

Context: Youth with type 1 diabetes (T1D) struggle to meet and sustain hemoglobin A1c (HbA1c) targets. Youth enrolled in the Pilot 4T Study improved HbA1c by 0.5% at 1 year, compared to historical controls.

Objective: To assess 3 years of glycemic outcomes in the Pilot 4T Study.

Methods: The Pilot 4T Extension cohort was prospectively followed to determine changes in HbA1c and continuous glucose monitoring (CGM) metrics over 3 years at the Stanford Medicine Children's Health Diabetes Clinic. Youth with T1D in the Pilot 4T Study enrolled in the extension phase started CGM in the first month of diabetes diagnosis, received intensified education and remote patient monitoring (RPM) weekly for the first year of diabetes diagnosis, and monthly RPM in the extension phase. HbA1c and CGM metrics were evaluated over the first 3 years of diagnosis.

Results: In the Pilot 4T cohort, 78.5% (n = 102) of participants enrolled in the study extension phase and were followed through 3 years. The adjusted difference in HbA1c at 3 years was 1.2% (95% CI 0.7%-1.7%) lower in the Pilot 4T cohort than in the Historical cohort. In the Pilot 4T cohort, 68% and 37% met the <7.5% and <7% HbA1c targets at 3 years, respectively, compared to 37% and 20% in the Historical cohort.

Conclusion: Youth with T1D in the Pilot 4T extension phase sustained improvements in HbA1c over 3 years. Focusing resources on intensive management during the first year after T1D diagnosis may impact long-term glycemia.

Key Words: type 1 diabetes, pediatric diabetes, diabetes technology, health care delivery

Abbreviations: 4T, Teamwork, Targets, Technology and Tight Control; ADA, American Diabetes Association; AID, automated insulin delivery; CGM, continuous glucose monitoring; GMI, glucose management indicator; HbA1c, glycated hemoglobin; IQR, interquartile range; ISPAD, International Society for Pediatric and Adolescent Diabetes; LOESS, locally estimated scatter plot smoothing; RPM, remote patient monitoring; SMD, standardized mean difference; T1D, type 1 diabetes; TBR, time below range; TIR, time in range; TITR, time in tighter range.

Diabetes technology, including continuous glucose monitoring (CGM) and automated insulin delivery (AID) systems, is associated with improved clinical outcomes and quality of life in youth with type 1 diabetes (T1D) (1-6). The American Diabetes Association (ADA) (7) and the International Society for Pediatric and Adolescent Diabetes (ISPAD) (8) recommend the use of CGM and AID as standard of care for all children with T1D.

In the Pilot Teamwork, Targets, Technology and Tight Control (4T) Study, new-onset education was intensified with the hypothesis that modern diabetes technology could lead to lower glycated hemoglobin (HbA1c) outcomes at 1-year after diabetes diagnosis (9, 10). In this study, youth with new-onset T1D were started on CGM in the first month of diabetes diagnosis. Two-thirds of youth received remote patient monitoring (RPM) in which a Certified Diabetes Care and Education Specialist reviewed CGM data weekly and sent asynchronous messages with diabetes education and insulin dose changes using the electronic health record patient portal. The team aligned on a HbA1c target of <7.5%, which was the ADA target at the time of study enrollment (11). Consensus CGM metrics (12) were reviewed with families and reinforced during RPM messaging. When compared to historical controls, youth in the 4T Pilot Study had a 0.5% improvement in HbA1c at 1 year after diabetes diagnosis. In 4T Study 1 when the HbA1c target was lowered to <7% in line with ADA (13) and ISPAD (14) guidelines, and all youth received RPM, participants had an additional 0.6% improvement in HbA1c at 1 year after diabetes diagnosis compared to the Pilot 4T study (15). In the Pilot 4T study, outcomes

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improved in all youth similarly including those from minoritized communities and lower socioeconomic status where poorer clinical outcomes and less use of technology have been observed (16-20).

Evidence of the sustained impact of early use of diabetes technology and intensive team management is limited. In this follow-up study, we examined the 3-year glycemic outcomes in youth enrolled in the Pilot 4T study extension phase compared to the Historical cohort. We hypothesized that the improved glycemia (HbA1c and CGM metrics) in the 4T Pilot cohort compared to historical controls would persist over the 3 years of follow-up, including among subpopulations with historically worse clinical outcomes.

Methods

Study Design

This is a 2-arm longitudinal interventional study evaluating an interventional program (4T Pilot Extension Study) relative to a historical standard of care arm (Historical Study). Following the 12-month initial phase of the Pilot 4T Study, all participants were offered the opportunity to continue participation in the extension phase of the study. Participants in the 4T Pilot Extension Study were followed from their T1D diagnosis date (baseline) to their discontinuation date or July 15, 2023. As the primary study objectives focused on 1-year outcomes, this extension study was designed to become incorporated into our clinic's standard of care. With sustainability of practice in mind, the cadence of RPM was changed from once a week to once a month after the initial 12-month study, and those who did not receive RPM as part of the initial study were offered the opportunity to receive RPM in the extension study.

Participants

The protocol for the Pilot 4T Study has been reported (9, 10). Briefly, all youth with new-onset T1D diagnosed between July 25, 2018, and June 15, 2020, received routine new-onset education, which consists of education on blood glucose monitoring, carbohydrate counting, calculating insulin doses, administering insulin, monitoring for ketones, and hypoglycemia. All were offered the opportunity to start on a CGM in the first month of diabetes diagnosis (Dexcom G6, San Diego, CA). Youth who were enrolled starting in March 2019 were offered RPM with a Certified Diabetes Care and Education Specialist reviewing CGM data weekly and communicating dose suggestions and education to participants and their caregivers. CGM data review was facilitated by the Timely Interventions for Diabetes Excellence (TIDE) dashboard (21, 22). For youth who did not have their own connected devices, we provided them with an iPod Touch (Apple Inc., Cupertino, CA). Youth would need to connect to Wi-Fi either at home or at school to share the CGM data with the clinic. The Stanford Institutional Review Board approved this protocol, and consent (and assent for participants aged 7-18 years) was obtained for review of all participants. Participants consented for ongoing follow-up in the extension phase.

Cohort Descriptions

Our study population of youth newly diagnosed with T1D consists of the Historical and Pilot 4T cohorts. Youth in the Historical cohort (n = 272), diagnosed between June 2014 and December 2016, received standard new-onset education and quarterly clinic visits (23). The Pilot 4T cohort consisted of all youth diagnosed between July 2018 and June 2020 who were offered CGM within the first month.

Study Outcomes

Our primary outcome was HbA1c measured through 36 months. Our secondary outcome was achievement of the ADA's recommended HbA1c targets of <7.5% (at Pilot 4T study initiation in 2018) and <7% (as of 2020). Exploratory outcomes assessed on the Pilot 4T cohort included glucose management indicator (GMI), measured every 2 weeks, as well as sensor glucose time in range (TIR, 70-180 mg/dL), time in tighter range (TITR, 70-140 mg/dL), time below range (TBR, <70 mg/dL), and time in clinically significant hypoglycemia (<54 mg/dL). GMI was computed at 2-week intervals by applying the formula developed by Bergenstal et al (24) to CGM glucose readings, averaged across a lookback window of up to 90 days. Although other equations to estimate HbA1c are available, we chose GMI because it is the most widely used and the basis for the GMI calculation in the Dexcom Clarity report. CGM wear time was calculated as the percentage of time the CGM was worn out of eligible hours of wear over 36 months.

We measured HbA1c in multiple ways: (i) what we call point-of-care HbA1c (performed using a DCA Vantage® Analyzer; Siemens, Germany); (ii) the GMI, which has been used as a substitute for point-of-care HbA1c in the clinic (24); and (iii) starting in November 2020, we incorporated home HbA1c measurements (University of Minnesota Advanced Research and Diagnostic Laboratory) due to the COVID-19 pandemic (25).

Statistical Analysis

Key analysis sets

Analyses of the primary, secondary, and exploratory outcomes were performed on the intention-to-treat analysis set, whereby historical controls and all youth enrolled in the Pilot 4T Study were analyzed according to their cohort designation. The primary outcome was also analyzed on a sensitivity analysis set including the same participants but with follow-up censored at AID initiation.

Descriptive statistics of study population

Participants who were assessed for eligibility and completed 3-year follow-up were detailed in a CONSORT diagram (Fig. 1) (9). Baseline and follow-up characteristics of the Historical and Pilot 4T cohorts were summarized as counts with percentages, quartiles, or means with SD.

CGM-based metrics (GMI, TIR [70-180 mg/dL], TITR [70-140 mg/dL], TBR [< 70 mg/dL], and time in clinically significant hypoglycemia [<54 mg/dL]) were visualized using locally estimated scatter plot smoothing (LOESS) over the first 36 months since diabetes onset. The level of smoothing in LOESS was determined by the span parameter, and we selected the value that minimized the mean squared error via 10-fold cross-validation. TIR was also visualized as stacked bar plots over time, with time points spanning 3-month intervals.

Analysis addressing primary objective

HbA1c trajectories of the 2 cohorts were visualized using LOESS through 36 months post-diagnosis. A linear mixed-effects regression model that allows for piecewise

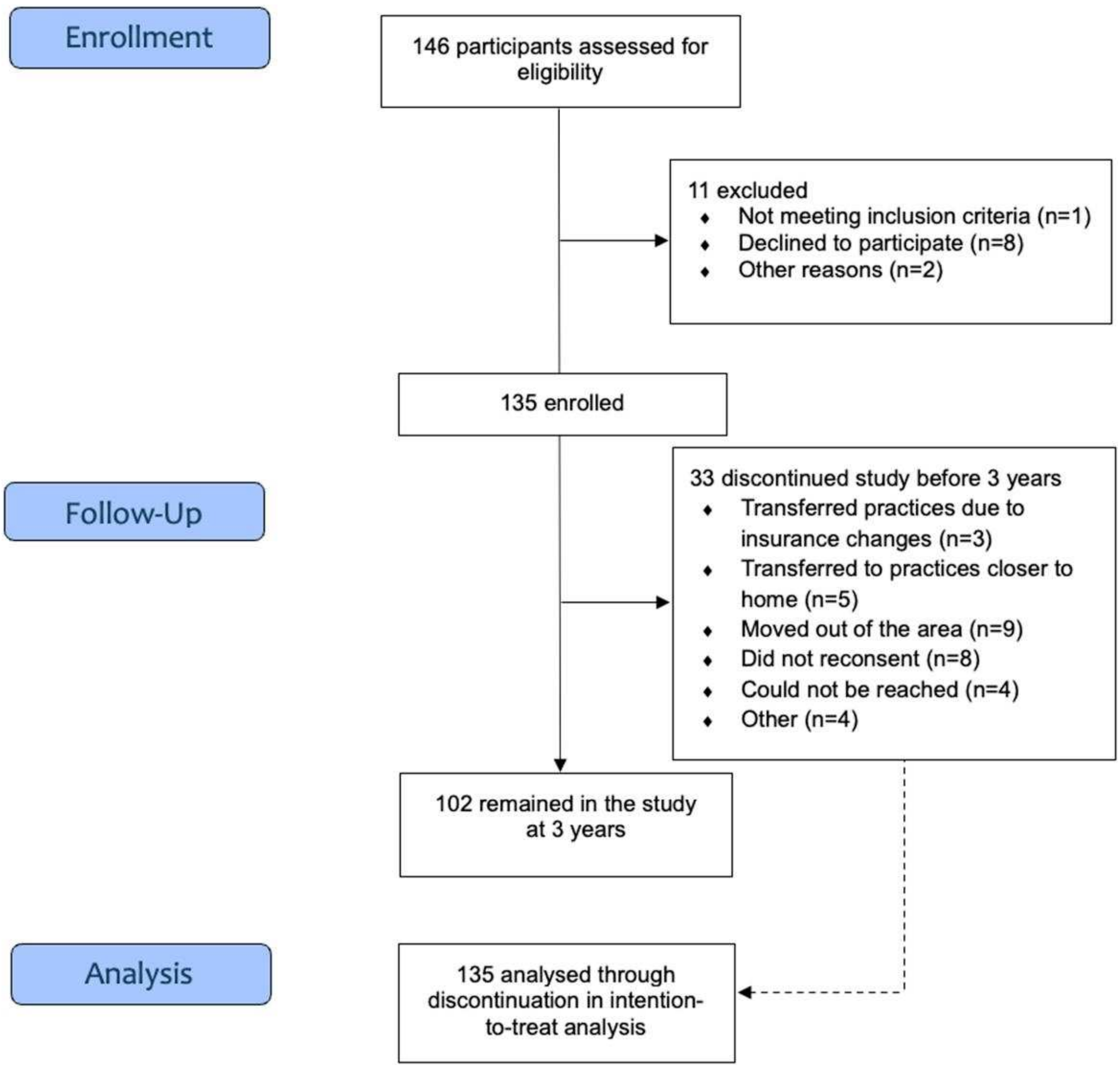


Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram of all participants.

linear slopes of (i) HbA1c levels from diagnosis to 4 months post-diagnosis (nadir in HbA1c); and (ii) from 4 months to 36 months post-diagnosis, was used to model HbA1c over time. This model adjusted for characteristics at diagnosis (age, sex, Hispanic ethnicity, and public insurance). Within-subject correlation of HbA1c was modeled through inclusion of a participant-specific random effect. Cohort differences in HbA1c (Pilot 4T minus Historical) between the 4- to 36-month slopes were estimated at 18, 24, 30, and 36 months and visualized with 95% CI using a forest plot.

To understand whether youth who did not have HbA1c measurements for the full 36 months differed from those with HbA1c measured through the study period, we tabulated baseline characteristics and GMI at 36 months according to whether HbA1c was available through 36 months in each cohort. Differences across these cross-classifications were assessed using the standardized mean difference (SMD) and interpreted using Cohen's guidelines (0.2 = small effect; 0.5 = medium effect; 0.8 = large effect).

Sensitivity analysis for primary objective

To understand whether increased use of AID in the Pilot 4T cohort contributed to improved glycemic management compared to the Historical cohort, we planned a sensitivity analysis that challenged this assumption. To that end, the same linear mixed-effects model proposed for addressing the primary objective was fitted to the intention-to-treat cohort with follow-up censored at AID initiation to evaluate the sensitivity of the findings to AID use.

Analysis addressing secondary objectives

To compare sustained trajectories on secondary measures including achieving the ADA's HbA1c targets, we presented description using bar plots over time, with HbA1c additionally supplemented with GMI calculated at 26, 52, 78, 104, 130, and 156 weeks in the Pilot 4T cohort.

All analyses were conducted in the R statistical computing framework, version 4.3.

Results

Participant Demographics

The Pilot 4T study originally enrolled 135 participants (Fig. 1). Of those, 102 (75.6%) were followed through 3 years. Among those who did not continue (n = 33), 8 transferred practices (3 due to insurance changes and 5 who found practices closer to home), 8 did not reconsent, 9 moved out of the area, 4 could not be reached, and 4 for other reasons (eg, joined another study, experienced skin reaction to study device, or switched to a different sensor).

The median age at diagnosis for the Pilot 4T cohort was 10 (interquartile range [IQR] 7, 13) years with 52.6% male, 39.3% non-Hispanic white, 77% with private insurance, and 86.7% English speaking. The median time to CGM start was 7 (IQR 5, 11) days with 91.9% (IQR 65.2%, 96.4%) CGM wear time over 3 years. Among those enrolled in the 4T Study, 66.7% (n = 90) started on an insulin pump and half of those were on automated insulin delivery (AID) systems by 36 months, compared to 53.7% on pump and 14.0% on AID systems in the Historical cohort. The median time to pump initiation was 276 (IQR 155, 493) days in the Historical cohort compared to 342 (IQR 137, 645) days in the Pilot 4T cohort. These and other characteristics are detailed in Table 1.

Table 1. Characteristics of the Historical and Pilot 4T cohorts

	Historical (2014-2016)	Pilot 4T (2018-2020)
N	272	135
Baseline characteristics		
Age (years) at T1D diagnosis, median (Q1, Q3)	10 (7, 13)	10 (7, 13)
Sex, n (%)		
Male	137 (50.4)	71 (52.6)
Female	135 (49.6)	64 (47.4)
Race/ethnicity, n (%)		
Non-Hispanic White	120 (44.1)	53 (39.3)
Non-Hispanic Black	5 (1.8)	0 (0)
Hispanic	69 (25.4)	29 (21.5)
Asian or Pacific Islander	25 (9.2)	19 (14.1)
American Indian or Alaska Native	1 (0.4)	0 (0)
Other	21 (7.7)	19 (14.1)
Unknown/Declined to state	31 (11.4)	15 (11.1)
DKA at diagnosis, n (%)	94 (34.7)	67 (49.6)
HbA1c (%) at diagnosis, mean (SD)	10.9 (2.5)	12.3 (2.1)
Insurance type, n (%)		
Private	197 (73.0)	104 (77.0)
Public	73 (27.0)	31 (23.0)
Both	0 (0)	0 (0)
No insurance	0 (0)	0 (0)
Primary language, n (%)		
English	245 (90.1)	117 (86.7)
Non-English	27 (9.9)	18 (13.3)
Follow-up characteristics		
CGM initiation within 3 years, n (%)	156 (57.4)	132 (97.8)
Initiated CGM ≤30 days, n (%)	6 (2.2)	124 (91.9)
Days to CGM initiation, median (Q1, Q3)	184 (72, 567)	7 (5, 11)
CGM wear time[a] (%), median (Q1, Q3)	N/A	91.9 (65.2, 96.4)
Insulin pump use[b] **within 3 years**, n (%)	146 (53.7)	90 (66.7)
Predictive low-glucose suspend	6 (2.2)	4 (3.0)
Open loop	106 (39.0)	47 (34.8)
Hybrid closed loop	38 (14.0)	45 (33.3)
None	126 (46.3)	45 (33.3)
Days to pump initiation, median (Q1, Q3)	276 (155, 493)	342 (137, 645)

[a]Percentage of time CGM is worn out of eligible hours of device wear.
[b]Patients may use multiple systems over the course of follow-up.

The 4T Program Improved HbA1c at 3 Years After Diabetes Diagnosis

Among the 102 participants who were followed in the Pilot 4T study for 3 years, 82 (80.0%) had HbA1c results at 3 years post-diagnosis, similar to the Historical cohort (n = 217, 79.8%). For both the Historical and Pilot 4T cohorts, HbA1c was highest at diagnosis (Fig. 2), but starting at 6 months post diagnosis, the HbA1c in the Pilot 4T cohort was lower. At 1 year, 1.5 years, 2 years, 2.5 years, and 3 years after diabetes diagnosis, participants in the Pilot 4T cohort had LOESS-based progressive and sustained improvements in their HbA1c of 0.50%, 0.72%, 0.78%, 0.95%, and 1.08%, respectively, compared to the Historical cohort.

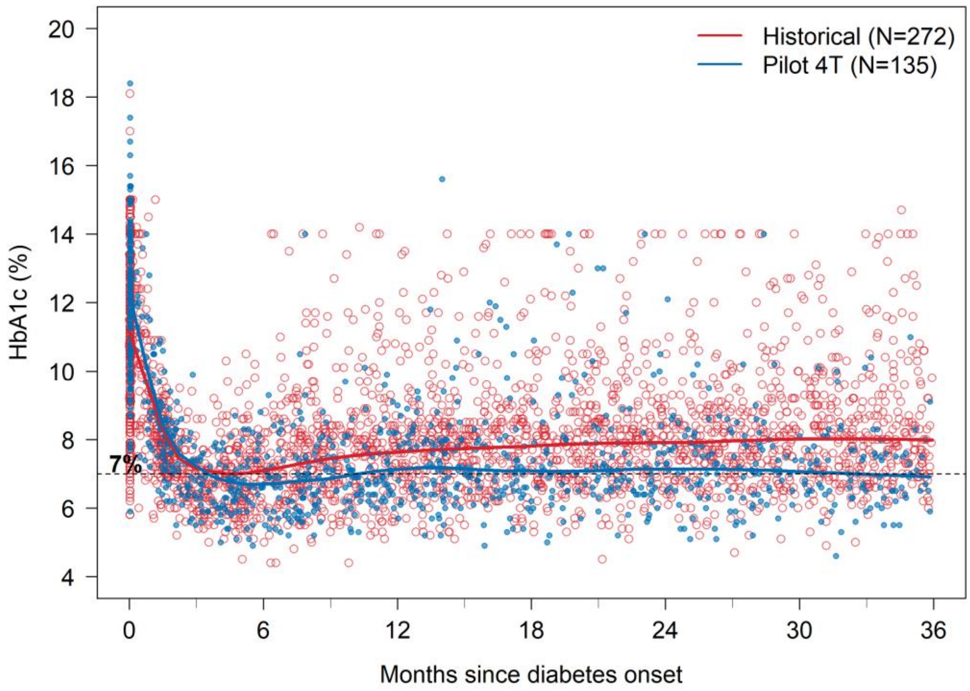
In multivariable regression analysis, the adjusted change in HbA1c from month 4 to month 36 in the Pilot 4T cohort was 1.22 (95% CI 0.70, 1.74) percentage points lower compared to that of the Historical cohort (Fig. S1) (26). When follow-up was censored at AID initiation in a sensitivity analysis, this difference was comparable at 1.24 (95% CI 0.64, 1.84) percentage points, indicating that our primary analysis of the HbA1c difference between cohorts was robust to AID usage (Fig. S2) (26).

In addition, our investigation of missing data patterns showed that differences in observed variables at baseline including GMI between youth with and without HbA1c measured through 36 months were small across cohorts (ie, SMD < 0.50) with one exception. Those without missing data had a higher HbA1c at diagnosis (SMD = 0.56) than those with missing data in the Pilot 4T cohort, although the within-cohort difference was minor (Table S1) (26). HbA1c at diagnosis was, on average, higher in the Pilot 4T cohort, possibly biasing our results to the null.

TIR Remains High With a Low Incidence of Hypoglycemia Over the First 3 Years of Diabetes Diagnosis

To complement the HbA1c data, we calculated GMI at 2-week intervals throughout the study period. CGM data was available for a median of 91.9% (IQR 65.2%, 96.4%) of the 36 months of the study period. GMI (Fig. 3A) and average glucose steadily (Fig. 3B) increased until ∼60 weeks post-diagnosis and remained fairly stable during the remainder of the study period. TIR (70-180 mg/dL, Fig. 3C) and TITR (70-140 mg/dL. Figure 3D) steadily declined until ∼60 weeks post-diagnosis before stabilizing. TBR (<70 mg/dL) and clinically significant hypoglycemia (<54 mg/dL) remained low and below clinical target recommendations (12).

The peak TIR was 68% at 6 months post-diagnosis and declined to 63% at 1 year and 1.5 years post-diagnosis. At 2 years post-diagnosis, the TIR was 62% and at 3 years, the TIR was 61% (Fig. 4).



Historical	7.08%	7.63%	7.81%	7.92%	8.02%	7.99%
Pilot 4T	6.69%	7.13%	7.09%	7.14%	7.07%	6.91%

Figure 2. Scatter plot of glycated hemoglobin A_{1c} (HbA1c) levels over time, with locally estimated scatter plot smoothing (LOESS). Mean HbA1c is highest at diabetes diagnosis and reaches a nadir at approximately 4 months after diabetes diagnosis. Individuals in the Pilot 4T cohort had lower mean HbA1c throughout the 36-month period after diabetes diagnosis compared to those in the historical cohort.

Participants in the Pilot 4T Study Achieved HbA1c Targets at Higher Rates Compared to Historical Controls

When using HbA1c plus GMI, at 3 years after diabetes diagnosis, 68% of youth in the Pilot 4T cohort had an HbA1c < 7.5% and 37% reached an HbA1c < 7% (Fig. 5). In the Historical cohort, 37% and 20% reached HbA1c goals of <7.5% and <7%, respectively.

Discussion

The Pilot 4T study showed that a team-based approach with early introduction of diabetes technology (CGM) and consistent tight targets improved HbA1c and CGM metrics at 1 year after diabetes diagnosis compared to Historical controls (9). In the Pilot 4T Extension Phase, all youth who consented and followed up in our clinic received monthly RPM. Youth in the extension phase had over a 1 percentage point lower HbA1c at 36 months post-diagnosis compared to those in the Historical cohort, even when adjusting for AID use. Youth in the Pilot 4T cohort had a 3-year TIR of 61% with a low incidence of hypoglycemia. A greater proportion of youth in the Pilot 4T study achieved an HbA1c < 7.5% and <7% compared to the Historical cohort. The sustainability of the intervention was seen even when changing the cadence of RPM from once a week to once a month, suggesting that focusing resources on the first year of diabetes can have long-term impact on glycemia.

There are some limitations to our study. The study took place during the COVID-19 pandemic when many visits were converted to telehealth, and many individuals have continued with telehealth in the post-pandemic period. As a result, we do not have a complete set of HbA1c values on all participants despite implementing home HbA1c kits. However, we do have CGM data for ongoing participants and have shown similar data when using CGM data or HbA1c data. In addition, the available HbA1c data was preferentially available in youth who typically have higher HbA1c (youth from minoritized communities and those on public insurance) (16). The study was not a randomized controlled trial, and the results were compared to a historical cohort; however, the historical cohort had similar results to a contemporaneous group from the T1D Exchange Quality Improvement registry (27). This study and follow-up were performed at a single center; however, the interventions can be implemented at multidisciplinary pediatric diabetes clinics and warrant further study.

Time to insulin pump initiation in the first 3 years of diabetes diagnosis increased in the Pilot 4T cohort compared to the Historical cohort. One hypothesis is that despite advances in AID technology, youth did not see the need for additional technology since HbA1c outcomes were improved. Also, it is possible that care team members may have emphasized CGM as standard of care early after diagnosis with less emphasis on AID. In the ongoing 4T Study 2, we introduced a pre-AID class within the first 3 months of diabetes diagnosis, and we hypothesize that early use of AID may lead to further sustained improvements in glycemic outcomes (28, 29) and improve upon these results, especially with longer duration of T1D.

Previous data show that early HbA1c outcomes can influence HbA1c trajectories up to 10 years post-diagnosis (30-32). This suggests that focusing education early in the course of diabetes diagnosis can improve longer term outcomes. The

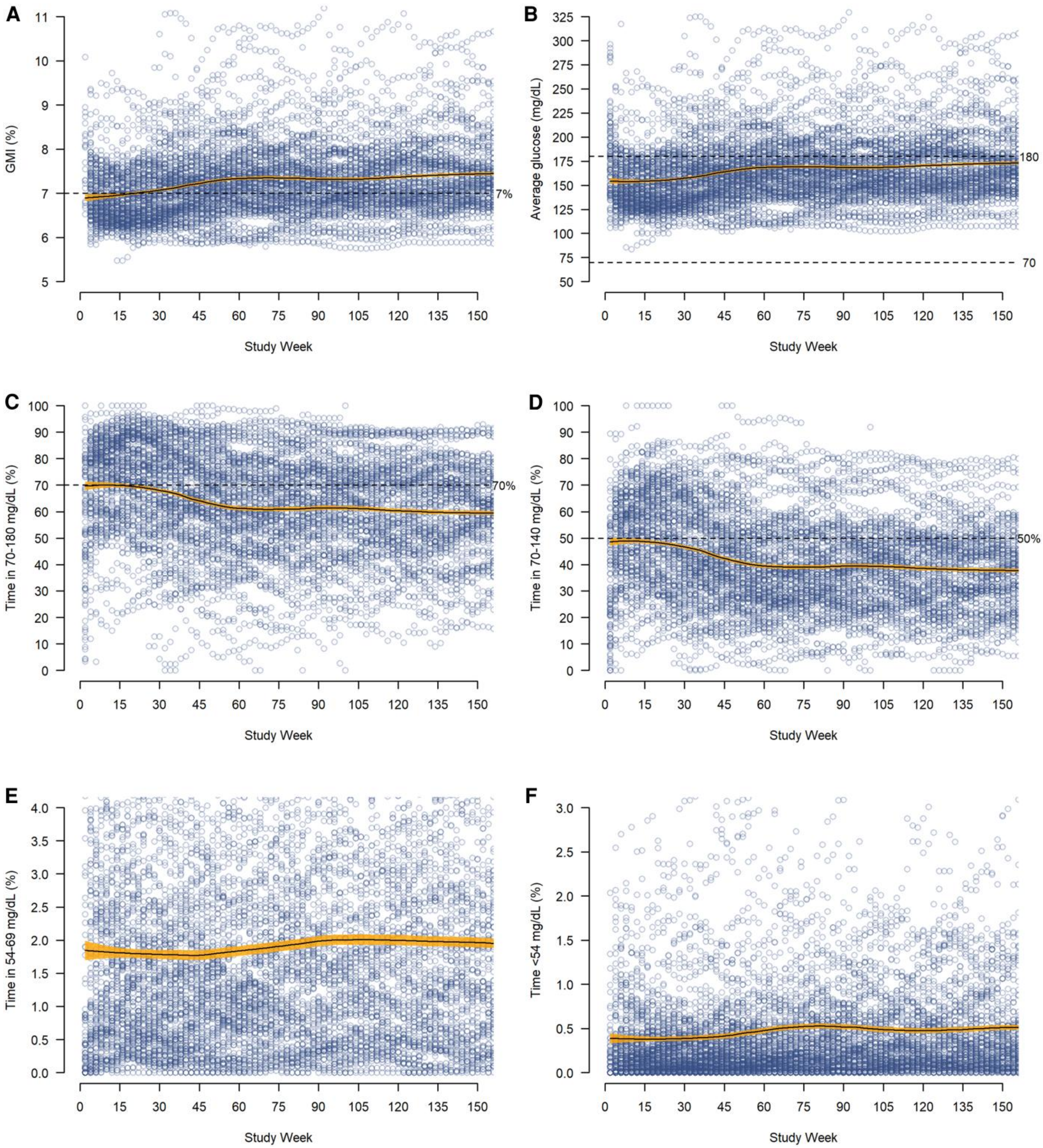


Figure 3. Scatter plot of glucose management indicator (GMI), average CGM glucose, time in range (TIR), time in tighter range (TITR), time in hypoglycemia, and time in clinically significant hypoglycemia at 2-week intervals in the Pilot 4T cohort, with locally estimated scatter plot smoothing (LOESS). Panel A, GMI is highest in the first month of diagnosis, lowest at approximately 4 months after diabetes diagnosis, and slowly increases until 60 weeks after diabetes diagnosis before stabilizing. Panel B, Average glucose is highest at diagnosis, lowest at approximately 4 months after diabetes diagnosis, and slowly increased 60 weeks after diabetes diagnosis before stabilizing. Panels C and D, TIR and TITR are lowest in the first month of diagnosis, highest at approximately 4 months after diabetes diagnosis, and slowly decreases until 60 weeks after diabetes diagnosis before stabilizing. Panels E and F, Time in hypoglycemia and time in clinically significant hypoglycemia remain low throughout the follow-up period.

data from the 4T Pilot Extension Cohort also shows that intensified early education can improve outcomes even 3 years post-diagnosis. There is data to suggest that lower HbA1c targets during the partial remission phase and first year of T1D (33) can improve longer term outcomes. In 4T Study 1, we showed that further lowering the HbA1c target in the first year of diagnosis can improve outcomes in the first year (15). It is important to see if this can lead to even more

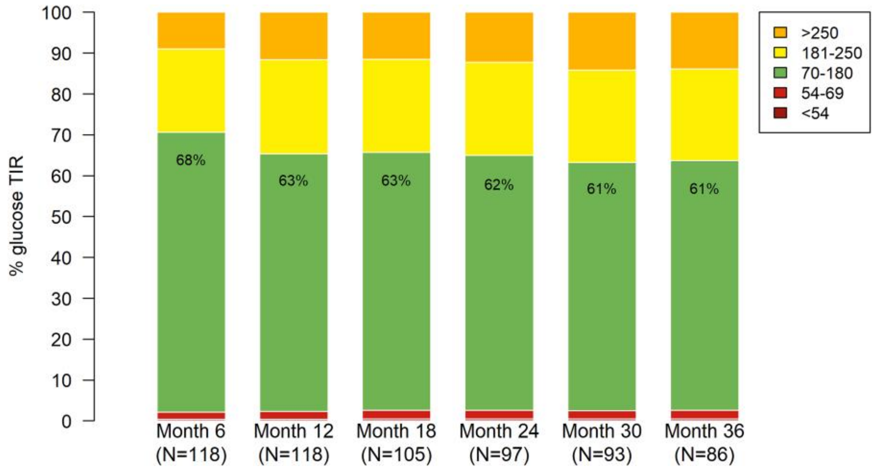


Figure 4. Glucose distribution in the Pilot 4T cohort. Over the first 36 months of diabetes diagnosis, time in range (TIR) was 61% in the 4T cohort with a low incidence of hypoglycemia.

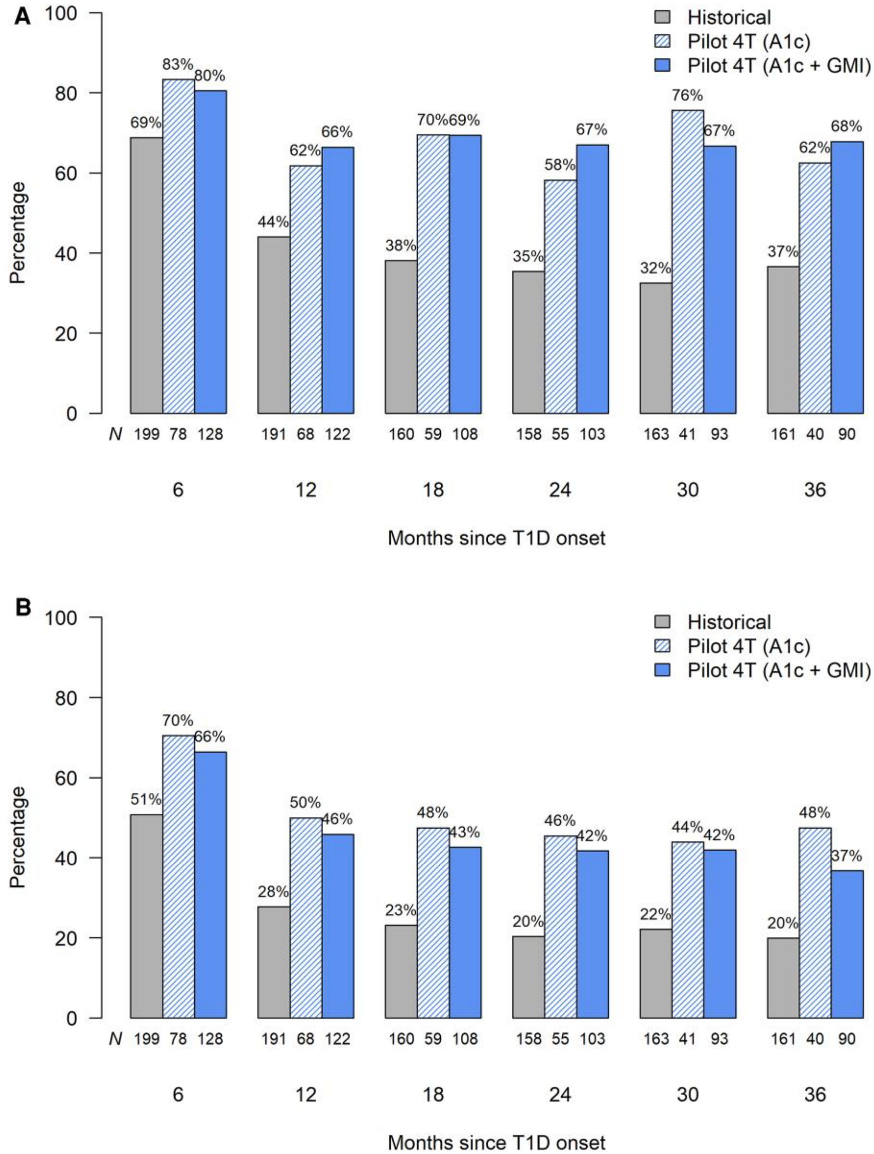


Figure 5. Proportion achieving HbA1c targets over time. Proportion of participants achieving an HbA1c target of (A) less than 7.5%, and (B) less than 7% are shown in the Pilot 4T (solid bar with GMI supplementation and patterned bar without GMI supplementation) and Historical (gray) cohorts.

sustained improvements in HbA1c outcomes. While improved glycemic outcomes are important, it is important to also focus on quality of life for youth with T1D. The 4T Program, including early introduction of technology, improved youth distress with longer duration of CGM use and increased technology acceptance (34-36).

The 3-year follow-up data of participants in the Pilot 4T Study extension demonstrates that intensive education in the new-onset period combined with early technology use and frequent insulin dose adjustments and followed by moderate RPM have the potential to sustain improved outcomes in youth with T1D. Incorporating additional diabetes technologies, such as AID systems, early in the course of T1D, incorporating lower targets (<6.5%) in the first year of diagnosis, and delivering structured exercise education (37) may have the potential to further improve and sustain outcomes in youth.

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Data Availability

Restrictions apply to the availability of some or all data generated or analyzed during this study to preserve patient confidentiality. The corresponding author will on request detail the restrictions and any conditions under which access to some data may be provided.

Clinical Trial Information

ClinicalTrials.gov registration no. NCT03968055.

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