Group Visits to Improve Technology Use, Glycemic Control, and Quality of Life in High Risk Children with Type 1 Diabetes

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List of Abbreviations

ADA	American Diabetes Association
AE	Adverse Event
CDCES	Certified Diabetes Care and Education Specialist
CGM	Continuous Glucose Monitor
CITI	Collaborative Institutional Training Initiative
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CV	Coefficient of Variation
DCC	Data Coordinating Center
DCCT	Diabetes Control and Complications Trial
DKA	Diabetic Ketoacidosis
DSMB	Data and Safety Monitoring Board
DSMP	Diabetes Self-Management Profile
ED	Emergency Department
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
GMI	Glucose Management Indicator
GMP	Good Manufacturing Practices
HIPAA	Health Insurance Portability and Accountability Act
HRQoL	Health Related Quality of Life
ICH	International Conference on Harmonization
IRB	Institutional Review Board

LAR	Legally Authorized Representative
PAID	Problem Areas In Diabetes
PHI	Protected Health Information
PI	Principal Investigator
QC	Quality Control
REDCap	Research Electronic Data Capture
SAE	Serious and Reportable Adverse Events
SEDS	Self-Efficacy for Diabetes
SES	Socioeconomic Status
SMA	Shared Medical Appointment
SOC	System Organ Class
SOP	Standard Operating Procedures
T1D	Type 1 Diabetes
T1DAL	Type 1 Diabetes and Life
TAR	Time Above Range
TBR	Time Below Range
TIR	Time In Range

Protocol Summary

Title:	Group Visits to Improve Technology Use, Glycemic Control, and Quality of Life in High Risk Children with Type 1 Diabetes
Brief Summary:	We propose to conduct a prospective cohort pilot study to assess the impact of SMA visits in underserved youth with poorly controlled T1D. The trial will employ an enrollment visit, SMA visits every 3 months over a 12 month study period, followed by a 6-month observational period to assess feasibility and acceptability of SMA and the impact on glycemic control, self-management skills, and health related quality of life.
Study Population:	Inclusion criteria are: ages 8-12, T1D duration of at least 1 year, at least one A1C value > 8% in the past year, Black race and/or Latinx ethnicity, public health insurance, and English fluency in the youth and parent.
Study Site(s):	This study will be conducted entirely at Children's National Hospital and Specialty Care Locations
Number of Participants:	20 parent-child dyads (40 participants)
Accrual Ceiling:	20 parent-child dyads (40 participants)
Study Duration:	18-24 months
Subject Duration:	18 months
Objective(s):	**Primary Objective:** To evaluate the feasibility and acceptability of SMA among underserved youth with T1D as measured by recruitment, CGM initiation, retention, satisfaction surveys, and semi-structured interviews. **Secondary Objectives:** To evaluate the preliminary impact of SMA on glycemic control, self-management skills, self-efficacy, diabetes related quality of life, and treatment satisfaction among underserved T1D youth
Methodology:	Prospective cohort pilot study

Outcome Measures:	**Primary Outcome:** Feasibility as assessed by recruitment, (>60% of reached/ eligible participants), CGM initiation (>80%), SMA sessions attended (>80%), and study retention (>80%). Acceptability as assessed by user satisfaction surveys (>80%), perceived utility of the intervention content, and perceived benefits from participation (>80% reporting satisfaction and perceived utility). **Secondary Outcomes:** Differences in the following within subject measures across the SMA intervention and during the follow-up period: 1) CGM time in range from 70-180 mg/dL (TIR), 2) time below range (< 70 mg/dL) (TBR), 3) time above range (≥ 180 mg/dL) (TAR), 4) mean sensor glucose, 5) coefficient of variation (CV) of glucose, 6) CGM wear time, 7) episodes of DKA, 8) episodes of severe hypoglycemia, 9) ED visits, hospital admissions, 10) A1c, 11) qualitative measures exploring self-management, satisfaction, health related quality of life [Type 1 Diabetes and Life (T1DAL), Diabetes Self-Management Profile (DSMP), Self-Efficacy for Diabetes (SEDS), Problem Areas in Diabetes (C-PAID), CGM Benefits and Burdens].
Study Intervention/ Procedures:	Secure REDCap surveys will be completed either ahead of or at each visit by patients and caretakers. During intervention SMA visits, the facilitator role will be shared by a pediatric endocrinologist, certified diabetes care and education specialist (CDCES), nutritionist, and psychologist. SMA sessions will consist of facilitator led-discussions, and youth and caregivers will individually meet with the endocrinologist at different time points during the session. Patient CGM data will be analyzed 2 weeks ahead of visits, and we will summarize self-management skills, health-related quality of life measures, and treatment satisfaction at each intervention visit.
Statistical Analysis:	CGM data will be analyzed using library GLU in R.73 using mixed effect models. The independent variables will be baseline time in range, child age, and a random subject effect to account for correlation of measurements on the same subject. Interaction terms of age and baseline time in range with the intervention will explore possible effect modification ($p<0.10$) of these characteristics. Differences in participant self-management skills and patient satisfaction will be reported as mean Likert scale score and standard deviation. Similar analysis using linear longitudinal

regression analysis will be conducted. Results will be reported as least-squares means (LSMEANS) with standard errors. Casewise deletion will be used to handle missing data.

Study Design Schematic

Table 1. Schedule of study procedures.

Construct	Measure	Initial SMA	3mo SMA	6mo SMA	9mo SMA	12mo SMA	15mo	18mo
14-Day CGM Markers of Glycemic Control	Mean CGM Glucose	X	X	X	X	X	X	X
	Coefficient of Variation	X	X	X	X	X	X	X
	Glycemic Mgmt Indicator (GMI)	X	X	X	X	X	X	X
	CGM Wear Time	X	X	X	X	X	X	X
	CGM TIR	X	X	X	X	X	X	X
	CGM TBR	X	X	X	X	X	X	X
	CGM TAR	X	X	X	X	X	X	X
A1c		X	X	X	X	X	X	X
Youth Surveys	T1DAL	X	X	X	X	X	X	X
	DSMP	X	X	X	X	X	X	X
	SEDS	X	X	X	X	X	X	X
	PAID	X	X	X	X	X	X	X
	CGM Ben & Bur	X	X	X	X	X	X	X
	SMA Evaluation	X	X	X	X	X	X	X
Parent Surveys	P-T1DAL	X	X	X	X	X	X	X
	P-DSMP	X	X	X	X	X	X	X
	P-SEDS	X	X	X	X	X	X	X
	P-PAID	X	X	X	X	X	X	X
	CGM Ben & Bur	X	X	X	X	X	X	X
	SMA Evaluation	X	X	X	X	X	X	X
Semi-Structured Dyad Interview						X		

Section 1: Key Roles

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Section 2: Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

There are significant disparities in type 1 diabetes (T1D) care and outcomes. Hemoglobin A1c (A1c) levels and rates of acute and chronic T1D complications are highest among publicly insured youth and those from racial-ethnic minority groups and low socioeconomic status (SES).[1-3] CGM use has been associated with improved glycemic control and health related quality of life in youth with T1D[4], however rates of uptake and sustained use are lowest among racial and ethnic minority youth and those from lower income households.[1,5,6] SMA have shown great promise for improving glycemic control, self-management skills, and self-efficacy in adolescents with T1D[7], but have not been specifically developed to meet the needs of underserved youth. We aim to develop SMA specifically designed to meet the needs of racial, ethnic, and socioeconomically underserved youth in order to address disparities in T1D care and outcomes.

We are including relevant preliminary data that supports the individual components proposed in the current intervention, including the need to include diverse populations in CGM research, key intervention components of promoting positive quality of life factors around diabetes management, and the positive impact that SMA can have on underserved diabetes patients and their caretakers.

Health disparities among type 1 diabetic patients: Health disparities exist among individuals with T1D of different races and ethnicities, with minorities having worse long-term outcomes compared to non-Hispanic whites in the U.S.[3] Minority youth with diabetes are significantly more likely to have higher A1C levels, elevated cardiovascular risk factors, early signs of kidney disease, retinopathy, and neuropathy as compared to non-Hispanic white youth.[3] Black/African American and Hispanic youth remain woefully underrepresented in diabetes technology trials. Unfortunately, this mirrors the reality of real-world clinical care: non-Hispanic Black and Hispanic youth are much less likely to use CGMs as part of T1D management, and worse, those who are not using these technologies report that they have not been offered the option to use these treatment modalities.[8] Using data from the T1D Exchange, Agarwal and colleagues reported that 72% of non-Hispanic White young adults (ages 18-25) used CGM as compared to 18% of non-Hispanic Black youth and 40% of Hispanic Youth.[9] The source of health disparities in T1D technology access and use are complex and multifaceted. Targeted, evidence-based support for technology use and psychosocial functioning must address multiple systems and be responsive to the needs of diverse youth with T1D. However, diabetes distress and lower rates of diabetes technology use are modifiable barriers that are critical to address according to the tenets of social cognitive theory, which recognizes that knowledge, self-efficacy, and psychosocial factors all impact health behaviors and outcomes. Interventions rooted in this theory hold the potential to address barriers in attaining health equity among youth with T1D.[10]

Health related quality of life in people living with T1D : Health related quality of life (HRQoL) has become a fundamental focus of comprehensive healthcare.[11] Impaired

HRQoL has been found in children and adolescents with several chronic conditions, including diabetes.[11] Chronic disease during childhood can result in more frequent depressive moods and other negative emotions, lower life satisfaction, poorer school performance, and negative self-esteem and self-concept.[12-14] Having diabetes requires many behavior changes, which can lead to stress in both the patients and their families,[15] and studies have shown that adolescents with diabetes have a lower life satisfaction and health perception than healthy adolescents.[16,17] Diabetes-specific emotional distress and quality of life are psychosocial variables that are strongly associated with key diabetes outcomes, such as adherence and metabolic control.[18,19] Social support from classmates and caretakers,[20,21] as well as adaptation and coping skills are key to improving medical outcomes.[22]

Benefits of CGM therapy: CGMs are minimally invasive devices that use a subcutaneous sensor to report and record changes in interstitial glucose values every 5 minutes to 15 minutes.[23] This technology can alert patients to hypoglycemia and hyperglycemia and also allows them to make diabetes treatment decisions without the need for a confirmatory fingerstick blood glucose level. Improvements in the accuracy and usability of CGM, better insurance coverage, and greater acceptance by both clinicians and patients have led to dramatic increases in the use of this technology over the past decade. [1,24-32] In 2011, just 6% of all patients in the United States Type 1 Diabetes Exchange (T1DX) registry were using CGM as compared to 27% in the period from 2016-2018.[1] Continuous glucose monitor (CGM) use among youth with T1D is recommended whenever possible,[33] and has been associated with decreased hypoglycemia and severe hypoglycemia,[34,35] improvement in A1c, and improved quality of life and treatment satisfaction.[1]

Positive effects of SMA in diabetes: The American Diabetes Association (ADA) recommends that education and social support is continually offered to youth and their caregivers at routine clinic visits,[33] however this is challenging within the constraints of the current clinical care model. Shared medical appointments (SMA), wherein small groups of patients participate in group education sessions in place of traditional clinic visits, have been successfully employed in pediatric chronic disease management, and are well suited for diabetes care.[7,36-39] SMA visits allow additional time for interprofessional self-management education, skill building, self-efficacy, and peer support.[40] Specifically in pediatric T1D, SMA has been shown to allow for discussion of a greater breadth of topics while also placing greater focus on behavioral and psychosocial needs.[41,42] Adolescents participating in SMA exhibit improved glycemic control and reduced diabetes distress through the development of a supportive community.[7] Increased satisfaction with follow up care can also translate into improved attendance and engagement in regularly scheduled clinical care. However, to date, the use of SMA has not been well-studied in underserved youth and has not been used specifically to promote uptake and sustained use of diabetes technologies.

2.2 Scientific Rationale

The primary aim of this pilot study is to assess the impact of a 12-month SMA model employing interprofessional facilitator-mediated discussion to promote the uptake and

sustained use of CGM, while also providing peer support, and fostering community in order to improve glycemic control and promote health equity among youth with T1D. Although SMAs have been used in T1D, few have been designed specifically to improve health equity by addressing the needs of diverse youth and their families. This proposed intervention will be developed to meet the needs of non-Hispanic Black and Latinx youth with public insurance. Furthermore, this SMA will be the first specifically developed to support uptake and sustained use of diabetes technology among youth who have been historically least likely to access these technologies.[1,5,6]

We expect that the SMA model will lead to high rates of SMA retention and satisfaction, greater CGM wear time and sustained use, improved glycemic control, and improved diabetes specific quality of life, self-management behaviors, and self-efficacy scores compared to patients in the traditional individual appointment model. The interprofessional model incorporating CDCES, psychology, and nutrition will allow for youth and caregivers to interact with the entire diabetes care team and will also allow for sufficient time to focus on both education and strategies to cope with the psychosocial burdens and challenges needed to optimize adherence and outcomes. Lessons learned from this comprehensive interprofessional SMA will also provide insights that will allow for development of additional strategies needed to promote equal opportunity for all youth to achieve health and quality of life targets without being hindered by race, ethnicity, or socioeconomic status.

We propose to recruit up to 20 underserved children with poorly controlled T1D and their primary diabetes caregiver. Inclusion criteria are: ages 8-12, T1D duration of at least 1 year, at least one A1c value $\geq$ 9% in the past year, Black race and/or Latinx ethnicity, public health insurance, and English fluency in the youth and parent. For the purposes of this study, because non-Hispanic black and Latinx youth with public healthcare insurance are the least likely to have access to CGM technology, we will use the term underserved to specifically refer to this population.[1]

Primary and secondary outcomes will be evaluated at baseline, 4 follow-up points during the SMA intervention, and 3 and 6 months after the final group visit. A 3-month interval for SMA and assessment was chosen to correspond to standard clinical follow up visit schedule. Participant data will be matched by age, race, insurance status, duration of diabetes, in the routine follow up model, in order to evaluate the impact of SMA on the outcomes of interest.

2.3 Potential Risks

Questionnaires and SMA Visit

As part of the study, participants will participate in SMA and complete validated questionnaires which include questions about their private attitudes, feelings and behavior regarding the management of diabetes. It is possible that some people may find these discussions and/ or questionnaires to be mildly upsetting, however these questionnaires have been used in previous research and these types of reactions have been uncommon. Participants who are upset or worried after completing questionnaires

or participating in the study will be referred to our diabetes psychology team for additional support.

Privacy Concerns
Data downloaded from the CGM will be collected for the study as measures of diabetes self-management behaviors. Some people may be uncomfortable with the researchers' having such detailed information about their daily diabetes habits, however this too is part of routine diabetes care. The group setting of the SMA removes much of the privacy that is provided to patients and their families during a routine individual visit. Some families might feel uncomfortable talking about personal experiences or attitudes related to their own diabetes care in front of other people. Description of the SMA will be clear during the consent process so that only families who are comfortable sharing in a group setting will choose to participate in the study. Participants and their caretakers will also have the option to withdraw from the intervention at any time if they become uncomfortable with the lack of privacy in the SMA.

Other Risks
Some participants may develop skin irritation or allergic reactions to the adhesives used to secure the CGM. If these reactions occur, different adhesives or under dressings will be tried (such as with IV 3000, Tegaderm, etc.), sites will be rotated more frequently, and a mild topical steroid cream may be required.

Many of the risks associated with participation in this study are the same risks facing all patients receiving routine clinical care for T1D. Patient's diabetes data is routinely downloaded as a part of clinical care and is done in compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations. While there is concern that the questionnaires may be upsetting to some participants, these types of reactions are rare and there are psychology staff available in our clinic should these types of reactions occur. The potential benefits for improvements in glycemic control and health-related quality of life far outweigh the minimal risks.

2.4 Potential Benefits

The purpose of this study is to reduce healthcare disparities, promote technology uptake, and improve the glycemic control in underserved youth with T1D. Improvements in glycemic control may reduce both short-term risks of T1D, including hypoglycemia, hyperglycemia, and DKA, and the long-term risks of T1D, including nephropathy, neuropathy, retinopathy, cardiovascular disease, and neurocognitive dysfunction. The SMA visit structure may also have benefits on health related quality of life for youth and their caregivers. It is expected that the results of this study will inform the design of future randomized controlled studies that have the potential to alter future provider practices and reduce healthcare disparities.

Section 3: Objectives and Endpoints

3.1 Primary Objective(s)

To evaluate the feasibility and acceptability of SMA among underserved youth with T1D as measured by recruitment, CGM initiation, retention, satisfaction surveys, and semi-structured interviews.

3.2 Secondary Objective(s)

To evaluate the preliminary impact of SMA on glycemic control, self-management skills, self-efficacy, diabetes related quality of life, and treatment satisfaction among underserved T1D youth, as measured by CGM data, and a battery of validated survey measures completed by the youth and their caretaker.

3.3 Primary Outcome Measure(s)

Given the novelty of the SMA approach for underserved youth and promotion of CGM technology uptake and sustained use, feasibility and acceptability of the intervention will serve as the primary outcome measure. We will track recruitment, enrollment, participation, and retention through a CONSORT table (Table 2) for the intervention group. Feasibility benchmarks include: recruitment (>60% of reached/eligible participants), CGM initiation, (>80%), SMA sessions attended (>80%), and retention (>80%). In addition, feasibility encompasses demographic characteristics of the enrolled sample, with enrollment and overall increased uptake of CGM among youth from historically underrepresented racial and ethnic backgrounds (Black race and/or Latinx ethnicity) and income levels. Attrition data and team feedback will help determine how recruitment rates may be improved. Acceptability will be assessed using satisfaction surveys and determined by a high level of satisfaction with participation, perceived utility of the intervention content, and perceived benefit from participation (>80% reporting that they were satisfied and perceived utility and benefit). We will report summary statistics on each feasibility and acceptability item in the questionnaires (mean and standard deviation as well as percent answering a specific Likert level). Acceptability also will be examined by key demographic characteristics, including participant age and race/ethnicity. Parent-child dyads will participate in semi-structured interviews to assess satisfaction with the SMA. Thematic analysis of qualitative data will be conducted by two team members who will independently review interview transcripts to generate initial codes. Initial codes will be discussed by the group to generate a list of second-cycle codes and each team member will then apply the coding framework to all transcripts before

Table 2. Analytical plan for Aim 1, feasibility and acceptability.

Construct	Measure	Interval
Recruitment Feasibility/ Acceptability	# referred # screened # enrolled % eligible who enroll	Study initiation through completion of recruitment
Intervention Feasibility	#/% sessions attended	SMA visits every 3mo
Intervention Acceptability	Child/parent satisfaction ratings Child/parent qualitative interview	After completion of intervention
Retention Feasibility/ Acceptability	% who initiate CGM % who continue on CGM % completing follow-up assessments	All assessment time points
Assessment Feasibility	% participants with missing A1c data % participants with missing CGM data % participants with missing survey data	All assessment time points

identifying dominant themes. ATLAS.ti software will be used to organize and analyze the qualitative data.

3.4 Secondary Outcome Measure(s)

Secondary outcomes will include CGM metrics and chart review that can be used to assess effects on glycemic control, and survey measures designed to explore potential psychosocial benefits, including changes in self-management skills, self-efficacy, treatment satisfaction, and diabetes related quality of life. We will look at differences in the following measures from baseline to completion of the SMA intervention, as well as 3 and 6-months after completion of the SMA intervention: 1) CGM time in range from 70-180 mg/dL (TIR), 2) time below range (< 70 mg/dL) (TBR), 3) time above range (≥ 180 mg/dL) (TAR), 4) mean sensor glucose, 5) coefficient of variation (CV) of glucose, 6) CGM wear time, 7) episodes of DKA, 8) episodes of severe hypoglycemia, 9) ED visits, hospital admissions, 10) A1c, 11) qualitative measures exploring self-management, satisfaction, health related quality of life as measured with the following validated questionnaires (T1DAL, DSMP, SEDS, C-PAID, CGM Benefits and Burdens scale).

CGM time in range from 70-180 mg/dL (TIR) has been correlated with A1c values, which have classically been used as primary outcomes in T1D studies because of their association with microvascular complications.[43] This connection to long-term complications also makes TIR a better primary outcome measure than survey measures because this data has greater potential to alter real-world prescribing practices than patient perceptions captured by questionnaire. We have chosen to focus on TIR rather than A1c because of the propensity for A1c variation in Non-Hispanic Black youth who also have a higher propensity for hemoglobin variants.[44]

Additional CGM derived measures of glycemic control are commonly used outcomes in studies of T1D technology.[45] A1c has been included because it has classically been considered the gold standard. The acute complications of T1D being examined are also frequently used in T1D studies. The survey measures exploring quality of life are among the most widely accepted outcome measures in their specific topic areas.[11,46-49]

Section 4: Study Design

Dyads of youth with T1D aged 8-12 years and their primary diabetes caretakers identifying as non-Hispanic Black or Latinx will be recruited to participate in a prospective cohort pilot study exploring feasibility and acceptability of SMA and the impact on glycemic control, self-management skills, and health related quality of life. This trial will employ an enrollment visit, SMA visits every 3 months over a 12-month study period, and a follow-up 6-month observational period to continue to evaluate outcomes once patients return to routine individual follow up care. The study will include a single intervention group participating in the SMA visits (n=20).

All staff participating in the SMA visit will receive comprehensive training on how to facilitate the SMA discussion sessions effectively. All topics that will be covered at each SMA visit will be reviewed by the study staff ahead of the visit. Potential participants will

be screened for participation using our electronic medical records system and will be approached during routine clinical visits. After explaining all study procedures, informed consent using an IRB-approved consent form will be obtained for all participants. After obtaining consent, a blinded Dexcom G6 CGM will be placed on the participant. Participants will be instructed to wear the blinded CGM for 10 days in order to obtain baseline glycemic control data prior to starting the SMA visit intervention. At the completion of the 10 day wear period, participants will mail back the blinded CGM in a pre-addressed envelope so that the data can be assessed within 30 days of the wear time. Because SMA visits will be used in place of routine clinic visits and because participants will not require any additional in person study visits, we anticipate significant interest in participation with minimal barriers. Secure REDCap surveys will be sent to participants via email 1 week before each follow-up visit. If the surveys have not been completed at the time of the visit the participant will be asked to complete the measures using an iPad or paper in clinic at the time of their visit. Youth who elected not to use a CGM for routine clinical care, will be asked to wear a blinded professional CGM for 10 days prior to each visit whenever possible.

SMA Structure: SMAs will consist of 4-6 underserved youth with T1D and their primary diabetes caregiver. All youth and caretakers will complete standard check-in procedures with the clinic medical staff, including routine clinical intake questionnaires, vital sign assessments and point-of-care fingerstick A1c measurements. Before each session, dyads will be invited to submit questions to the research team that will then be anonymously reviewed and discussed among the group during the SMA. In the event that no questions are submitted by families, the facilitator will begin the discussion with stories and questions related to technology use and potential barriers in order to focus the discussion on the aspect of diabetes management being highlighted in that specific SMA. After discussing the questions, the facilitator will lead a group discussion focusing on the topic of the day. During each visit, the facilitator role will be shared by a pediatric endocrinologist, CDCES, nutritionist, and psychologist. Youth and caregivers will individually meet with the endocrinologist at different time points during the session to update personal management plans and goals of care. The group visit will conclude with a review of the core concepts discussed. Youth will be encouraged to set and share individual goals to be addressed before the next SMA.

Enrollment visit: This visit will occur at a routine clinic visit once a patient expresses interest in participating in the study. Alternatively, patients expressing interest in enrolling who are unable to do so at a routine clinic visit will have the option to come back for enrollment at a different time. A study team member will meet with the patient and family to review the study details and obtain consent. Randomization will be completed after consent has been obtained. A blinded Dexcom G6 pro CGM will be placed on the patient and be worn for 10 days in order to collect baseline data prior to starting the intervention. Phone applications that will allow for sharing of CGM data between patients and the diabetes clinical care team will be downloaded and established before the end of the visit.

Initial SMA: The structure of the group visits will be reviewed with patients and families, and all members of the diabetes team will introduce themselves and explain their role in diabetes care. As some patients will be CGM naïve before this visit, education will focus on insertion and removal of the CGM along with appropriate use of the CGM receiver, alerts and alarms, data sharing, and troubleshooting common CGM problems. Established sharing of CGM data between patients and the diabetes clinical care team will be confirmed before the end of the visit. The group visit will conclude with a review of the core concepts discussed, and patients will set goals for the next SMA.

Follow Up SMA: Follow up SMA will be scheduled 3, 6, 9, and 12 months from the initial group visit. CGM data from 14 days prior to each SMA will be reviewed by the endocrinologist ahead of the group visit. Discussions and education guided by the facilitators will focus on issues that have been described in the literature as potential barriers to CGM use and adherence. Recurrent alerts and alarms can result in alarm fatigue,[50] and falsely low glucose readings and sensor or transmitter failures have been cited as reasons for discontinuing CGM use.[51] The continuous nature of CGM data has been shown to place significant demands on patients and their families,[50] and to create stress related to the constant need for diabetes-related attention.[52] Follow up visits will focus on optimized use of CGM alarms and prevention of alarm fatigue. Psychologists and CDCES will discuss strategies to cope with the on-body presence and potential embarrassment resulting from CGM wear and to optimize parent-child communication surrounding CGM. Nutritionists will highlight the impact of different foods on glycemic trends and discuss strategies to optimize control. SMA will also allow ample opportunity to jointly review de-identified CGM reports and how to effectively interpret data and make management changes in response to CGM data, empowering patients and families to improve self-management and reduce stress related to CGM use. Active participation in discussions and group exercises will continue to strengthen the community feeling and social support network within the SMA group. Any participant that chooses to discontinue CGM during the 12 month study period will wear a blinded CGM 10 days prior to the follow up visits to allow for complete data collection. Upon completion of the final SMA visit at month 12, dyads will be contacted to schedule a semi-structured interview and will then return to standard clinical care.

3-Month and 6-Month Post-Intervention Follow-Ups: Survey measures and assessments of glycemic control will be repeated after 3 months and 6 months of routine clinical care to assess for long-lasting effects of the intervention.

Section 5: Study Enrollment and Withdrawal

5.1 Study Population, Recruitment and Retention

We propose to recruit up to 20 dyads of underserved children with poorly controlled T1D and their primary diabetes caregiver who express an interest in starting CGM therapy. We aim to recruit children with T1D ages 8-12 with T1D duration for at least 1 year, at least one A1c value > 8% in the past year, Black race and/or Latinx ethnicity, public health insurance, and English fluency in the youth and parent. The lower limit of the age inclusion criteria was selected so that patients will be able to fully participate in the SMA visits. The inclusion criteria were selected in order to demonstrate the effects that that

CGM technology can have in patients who are the least likely to have access to diabetes technologies.

Potential participants will be screened for participation using our electronic medical records system of the diabetes outpatient clinic, in accordance with the HIPAA rules. This study will include the vulnerable study population of children aged 8-12 years old, however no special considerations will need to be taken given that there is no greater than minimal risk with study participation. Parents/guardians will have access to the results of the children's participation once the study has been completed, as to not bias results while the intervention is still ongoing.

Eligible participants will be approached to participate during routine clinic visits after discussion with their primary endocrine clinician. For patients who cannot be approached in person at the time of the visit, we will attempt to contact individuals by email or phone. The email will include an option to opt-out of further contact. If a cellphone number is listed, the study team will also send a text (using a study designated number) after attempting to call. If an email address is not on file, a letter will be sent via mail. The text will not contain PHI and provides general information about the project and encourages those interested to respond and talk via phone**.** Patients and families who are still considering whether to enroll after the clinic appointment will be contacted by phone or text message after the visit. Participants will be offered parking or transportation reimbursement for each of the group clinic visits, and $20 at each of the visits as well as at the 3-month and 6-month post intervention visit for completion of survey measures, regardless of if a patient withdraws early. Non-English speaking individuals will be excluded as the Dexcom CGM technology is currently available only in English.

5.2 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Patients clinically diagnosed with T1D managed with insulin injections for at least 1 year
2. Non-Hispanic Black or Latinx ethnicity
3. Public healthcare insurance
4. Male or female ages ≥ 8 and ≤ 12 years
5. No prior use of CGM within 60 days of enrolment
6. Poorly controlled T1D: one A1c value > 8% in the preceding year
7. Fluent in English as the Dexcom technology is currently available only in English
8. Participation of the primary diabetes caregiver

5.3 Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Use of insulin pump therapy for diabetes management at time of enrolment
2. Major illnesses other than T1D
3. Significant cognitive limitations and major psychiatric disorders in the child or parent

4. Concurrent use of any non-insulin diabetes medication to control blood glucose levels.
5. Concurrent participation in any other clinical studies during study period

5.4 Vulnerable Subjects

This research will involve the federally recognized vulnerable subject population of children. As this research will not involve greater than minimal risk, no special considerations will need to be taken. Adequate provisions will be made for soliciting the assent of the children and the permission of their parents or guardians.

5.5 Recruitment

All patients scheduled for routine clinical diabetes appointments at Children's National Specialty Care Locations will be screened through chart review by study team members to assess for eligibility after a HIPAA authorization waiver for recruitment is granted. We anticipate enrolling 5-7 patients per month over 3-4 months to meet our target enrollment of up to 20 participants. Patients will be approached to participate during routine clinical visits. For patients who cannot be approached in person at the time of the visit, we will attempt to contact individuals by email or phone. The introductory email will be co-signed by the PI and Dr. Grundman, CNH Child and Adolescent Diabetes Program. The email will include an option to opt-out of further contact. If a cellphone number is listed, the study team will also send a text (using a study designated number) after attempting to call. If an email address is not on file, a letter will be sent via mail. The text will not contain PHI and provides general information about the project and encourages those interested to respond and talk via phone**.** Patients and families who are still considering whether to enroll after the clinic appointment will be contacted by phone or text message after the visit. Once a potential participant has been identified, a study team member will give an IRB approved study information letter to the participant's legally authorized representative (LAR). If the LAR expresses interest in the study, a copy of the IRB approved consent will be provided to the LAR. The informed consent will be signed by the LAR and assent will be obtained from the patient at an in-person visit before any research interventions are done. For patients who cannot be approached in person at the time of the visit, we will attempt to contact individuals by phone and obtain e-consent and/or e-assent with REDCap. The REDCap link of the IRB approved consent will be provided to the LAR via text or email. The informed consent will be electronically signed by the LAR and assent will be obtained electronically from the patient. All study team pre-screening materials that contain patient information will be maintained on password protected computers. Only authorized team members will have access to the pre-screening materials, Any pre-screening PHI that was collected will be destroyed once study enrollment has been completed.

5.6 Retention

To enhance participant retention, we will obtain multiple methods for contact for participants and their parents. Patients and parents will receive reminders- via email, text, and/ or phone call as per participants' preference to alert them to upcoming SMA visits. Participants will also receive reimbursement for transportation or parking.

Participants who complete the survey measures will be compensated with $20 at the baseline and for each follow-up visit. If a participant unexpectedly misses an in-person SMA visit, the participant's legally authorized representative will be contacted by a member of the study team to check on the participant's welfare and to see if there are any barriers to the participant attending future group sessions. Efforts will be made to have participants join an alternative session to make up for any missed scheduled SMA sessions.

5.7 End of Participation Criteria and Procedures

Participants are free to withdraw from participation in the study at any time upon request. The reason for participant discontinuation or withdrawal from the study will be recorded on the Premature Termination Case Report Form (CRF). Subjects who sign the informed consent but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, begin the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, will try and be replaced.

Participants who experience significant psychological distress as a result of the intervention or whose presence at SMA visits will be terminated from study participation. Anyone experiencing psychological distress will be referred to the diabetes psychology team for support (Drs. Monaghan and Streisand, Co-I's).

Section 6: Study Procedures

6.1 Informed Consent/Assent and HIPAA Authorization

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study. It continues throughout the individual's study participation. Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant. Written documentation of informed consent will be required prior to starting intervention/administering study intervention. Child assent form and informed consent form will be submitted with this protocol. Consent forms will be Institutional Review Board (IRB)-approved and the participant/legally authorized representative (LAR) will be asked to read and review the document. The principal investigator and co-investigator will explain the research study to the participant and answer any questions that may arise. This conversation will take place in a private room. Assent will be conducted for patients 12 years of age. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants/families/LAR will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants/family/LAR should have the opportunity to discuss the study with their family or surrogates, or think about it prior to agreeing to participate. The participant's caregiver or LAR will sign the informed consent document and the participant will sign the Assent form prior to any procedures being done specifically for the study. Assent for subjects aged 8-12 years old will be obtained and documented on the parental/LAR consent form.

Participants/families/LAR must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent and assent documents will be given to the participants/families/LAR for their records. The rights and welfare of the participants will be protected by emphasizing that the quality of their medical care will not be adversely affected if they decline to participate in this study.

6.2 Screening Process

Patients scheduled for routine clinical diabetes appointments will all be screened for participation up to 90 days prior to the scheduled visit using chart review. This will be conducted in accordance with the HIPAA rules. Those meeting inclusion criteria based on chart review will be discussed with their provider to assess confidence that the potential participant can successfully operate the CGM and is capable of adhering to the protocol. Suitable participants identified through screening will be approached in person to participate at the time of a clinic appointment. Patients and families who are still considering whether to enroll after the clinic appointment will be contacted by phone after the visit.

Before completing any procedures or collecting any data that are not part of usual care, written informed consent will be obtained. Informed consent will be obtained in a manner that will minimize undue influence or coercion and will allow participants sufficient time to review the document and answer questions before signing. Ideally all discussion of the study will be conducted in person, however in the event that this is not possible the research team will contact participants via phone within 28 days of initially discussing the study.

A caregiver/legal guardian (referred to subsequently as “caregiver”) will be provided with the Informed Consent Form to read and will be given the opportunity to ask questions. Potential participants will be given a Child Assent Form to read and discuss with his/her caregiver and study personnel. If the parent and child agree to participate, the Informed Consent Form and Child Assent Form will be signed, either in person or electronically via REDCap. A copy of the consent form will be provided to the participant and his/her parent and another copy will be added to the participant’s study record.

As part of the informed consent process, each participant will be asked to sign an authorization for release of personal information. The investigator, or his or her designee, will review the study-specific information that will be collected and to whom that information will be disclosed. After speaking with the participant, questions will be answered about the details regarding authorization. A participant is considered enrolled when the informed consent form has been signed.

6.3 Study Interventions and Follow-Up

Enrollment visit

Those who have met eligibility criteria and express interest in study participation will meet with study staff to review the study specifics in more detail and obtain consent. Randomization will occur after consent has been obtained. A blinded Dexcom G6 pro

CGM will be placed on the patient and be worn for 10 days in order to collect baseline data prior to starting the SMA intervention. Phone applications that will allow for sharing of CGM data between patients and the diabetes clinical care team will be downloaded and established before the end of the visit.

Initial SMA visit

After enrollment is complete, data will be collected from routine clinical care, including height, weight, BMI, and a point of care fingerstick A1c. A battery of validated survey measures exploring diabetes-specific quality of life will be completed by the parent and youth, including: T1DAL, DSMP, SEDS, PAID, CGM benefits and burdens, and an SMA evaluation. The caregiver will be asked to complete parental versions of the P-T1DAL, P-DSMP, P-PAID, P-SEDS, CGM benefits and burdens, and SMA evaluation. Surveys will be completed by caregiver, preferably the one most involved in medical care, but not both. If the caregiver elects not to complete these measures the patient is still eligible to participate in the study. Participants will have the option to complete these measures online or in clinic. Secure REDCap surveys will be sent to participants via email 1 week before their visit. If the survey has not been completed at the time of the visit, the participant will be given the option to complete the measures using an iPad or paper in clinic at the time of their visit.

The structure of the group visits will be reviewed with patients and families, and all members of the diabetes team will introduce themselves and explain their role in diabetes care. As some patients will be CGM naïve at this visit, education will focus on insertion and removal of the CGM along with appropriate use of the CGM receiver, alerts and alarms, data sharing, and troubleshooting common CGM problems. Established sharing of CGM data between patients and the diabetes clinical care team will be confirmed before the end of the visit. The group visit will conclude with a review of the core concepts discussed, and patients will set goals for the next SMA. After completing the visit, patients will continue using the CGM for diabetes management.

Follow up SMA at 3, 6, 9, and 12-months

Follow up SMA will be scheduled 3, 6, 9 and, 12 months from the initial group visit. Data will be collected from routine clinical care, including height, weight, BMI, and a point of care fingerstick A1c. Survey measures will be completed again as described previously. CGM data will be analyzed for the 14 days preceding each visit. Chart review from the time of the initial baseline visit will be conducted to assess the incidence of DKA, severe hypoglycemia, ED visits, and hospital admissions. Details obtained from the chart review will be confirmed with participants. Data from the CGM will be obtained through online software used to securely query these devices for routine clinical care (Dexcom Clarity).

Discussions and education guided by the facilitators will focus on issues that have been described in the literature as potential barriers to CGM use and adherence. Recurrent alerts and alarms can result in alarm fatigue,[50] and falsely low glucose readings and sensor or transmitter failures have been cited as reasons for discontinuing CGM use.[51] The continuous nature of CGM data has been shown to place significant demands on patients and their families[50], and to create stress related to the constant need for

diabetes-related attention.[52] Follow up visits will focus on optimized use of CGM alarms and prevention of alarm fatigue. Psychologists and CDCES will discuss strategies to cope with the on-body presence and potential embarrassment resulting from CGM wear and to optimize parent-child communication surrounding CGM. Nutritionists will highlight the impact of different foods on glycemic trends and discuss strategies to optimize control. SMA will also allow ample opportunity to jointly review deidentified CGM reports and how to effectively interpret data and make management changes in response to CGM data, empowering patients and families to improve self-management and reduce stress related to CGM use. Active participation in discussions and group exercises will continue to strengthen the community feeling and social support network within the SMA group. Any participant that chooses to discontinue CGM during the 12 month study period will wear a blinded CGM 10 days prior to the follow up visits to allow for complete data collection.

If a visit is missed by the participant, he/she will have the option to attend a different group's SMA that corresponds to the same timing as the SMA that was missed. In the event of withdrawal or early termination, participants will be asked to come for an end of study visit. If any participant chooses to discontinue CGM use, they will be asked to wear a blinded CGM for each of the 10 day periods ahead of their planned clinic visits.

Upon completion of the final SMA visit at month 12, dyads will be contacted to schedule a semi-structured interview and will then return to standard clinical care. A structured focus group guide consisting of broad, open-ended questions to elicit details from patients and parents will be provided to facilitators. These sessions will last 45 minutes (± 15 minutes). The sessions will be recorded on two separate devices and subsequently transcribed to allow for data analysis.

3-Month and 6-Month Post-Intervention Follow-Up
Survey measures and assessments of glycemic control will be repeated 3 months and 6 months after the final SMA.

6.4 Description of Study Procedures/Evaluations

Study Visits

All SMA appointments will be scheduled at the time that consent is obtained. Biometric data (height, weight, BMI, A1c) will be obtained as part of routine care. Data from 14 days prior to the visit for the CGM will be obtained through online software used to securely query these devices for routine clinical care (Dexcom Clarity). Secure REDCap surveys will be sent to participants via email 1 week before their visit (including the T1DAL, DSMP, SEDS, PAID, CGM Benefits and Burdens, and an SMA evaluation for patients; and for parents: P-T1DAL, P-DSMP, P-SEDS, and P-PAID, CGM Benefits and Burdens, and SMA evaluation). If the surveys have not been completed at the time of the visit participants will be given the option to complete the measures using an iPad or paper surveys in clinic at the time of their visit.

Prior to the study visit, chart review will be conducted to assess the interval incidence of DKA, severe hypoglycemia, ED visits, and hospital admissions. This will be conducted in accordance with the HIPAA rules. Information obtained through chart review will be

corroborated with patients during study visits to ensure accuracy. Biometric data, CGM data obtained from Clarity, and A1c values will be provided to participants as part of routine clinical care. The results from the battery of questionnaires will not be provided to patients.

Primary Outcome

Given the novelty of the SMA approach for underserved youth and promotion of CGM technology uptake and sustained use, feasibility and acceptability of the intervention will serve as the primary outcome measure. We will track recruitment, enrollment, participation, and retention through a CONSORT table (Table 2) for the intervention group. Feasibility benchmarks include: recruitment (>60% of reached/eligible participants), CGM initiation, (>80%), SMA sessions attended (>80%), and retention (>80%). In addition, feasibility encompasses demographic characteristics of the enrolled sample, with enrollment and overall increased uptake of CGM among youth from historically underrepresented racial and ethnic backgrounds (Black race and/or Latinx ethnicity) and income levels. Attrition data and team feedback will help determine how recruitment rates may be improved. Acceptability will be assessed using satisfaction surveys and determined by a high level of satisfaction with participation, perceived utility of the intervention content, and perceived benefit from participation (>80% reporting that they were satisfied and perceived utility and benefit as indicated by a Likert scale score of 4 or 5). We will report summary statistics on each feasibility and acceptability item in the questionnaires (mean and standard deviation well as percent answering a specific Likert level). Acceptability also will be examined by key demographic characteristics, including participant age and race/ethnicity.

Parent-child dyads will participate in semi-structured interviews to assess satisfaction with the SMA. Thematic analysis of qualitative data will be conducted by two team members who will independently review interview transcripts to generate initial codes. Initial codes will be discussed by the group to generate a list of second-cycle codes and each team member will then apply the coding framework to all transcripts before identifying dominant themes. ATLAS.ti software will be used to organize and analyze the qualitative data.

Secondary Outcomes

Secondary outcomes will include CGM metrics that can be used to assess effects on glycemic control and survey measures designed to explore potential psychosocial benefits, including changes in self-management skills, self-efficacy, treatment satisfaction, and diabetes related quality of life. CGM time in range from 70-180 mg/dL (TIR) has been correlated with A1c values, which have classically been used as primary outcomes in T1D studies because of their association with microvascular complications.[43] We have chosen to focus on use TIR rather than A1c because of the propensity for A1c variation in Non-Hispanic Black youth who also have a higher propensity for hemoglobin variants.[44] CGM data will be obtained at each follow up visit through online software used to securely query the device for routine clinical care. Glycemic variability indicators will be obtained from CGM downloads for the 14 days prior to a follow-up data collection time point. As guided by published standardized

CGM metrics,[53] data will be transformed to identify number of measurements and percent TIR, time below range (<70 mg/dL) (TBR), and time above range (≥180 mg/dL) (TAR), mean sensor glucose, and coefficient of variation (CV) of glucose values during each 14-day period. We also will track the percent CGM wear time.

CGM data will be analyzed using library GLU in R.73 using mixed effect models. These models will quantify the impact of our intervention on glucose control over time. The independent variables will be baseline time in range, child age, and a random subject effect to account for correlation of measurements on the same subject. Interaction terms of age and baseline time in range with the intervention will explore possible effect modification ($p<0.10$) of these characteristics. We will also explore differences between intervention time points and average outcome by parent education level and income.

A battery of validated survey measures exploring diabetes-specific self-management skills and quality of life will be completed by the child and caretaker, including: Type 1 Diabetes and Life (T1DAL), Diabetes Self-Management Profile (DSMP), Self-Efficacy for Diabetes (SEDS), and Problem Areas in Diabetes (C-PAID). Perceived benefits and barriers to CGM use will be assessed using the CGM Benefits and Burdens scale. Surveys will be completed by a single, consistent parent/caregiver throughout the study, preferably the one most involved in medical care.

We will summarize self-management skills and treatment satisfaction from baseline to completion of the SMA visits, as well as 3-months and 6-months after completion of the SMA intervention. Differences in participant self-management skills and patient satisfaction will be reported as mean Likert scale score and standard deviation. Similar analysis using linear longitudinal regression analysis will be conducted. Results will be reported as least-squares means (LSMEANS) with standard errors. Casewise deletion will be used to handle missing data.

6.5 Study Team Training and Intervention Reliability

All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP training. Study team members will be trained in how to properly score the various questionnaire results, so that scoring practices are objective and standardized. Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Separate semi-structured qualitative interviews will be conducted with patients and parents upon completion of the study to gain insight into satisfaction with the SMA visits. The sessions will be recorded on two separate devices and subsequently transcribed to allow for data analysis.

6.6 Concomitant Interventions and Procedures

Not applicable

Section 7: Safety Assessments and Reporting

7.1 Adverse Events (AEs)

Risk to participants is minimal. While it is unlikely that participants will experience any risk, there may be minimal distress associated with completing questionnaires that ask about diabetes management, mood, or diabetes technology burden. Participants may also feel some distress related to discussing diabetes management, mood, or technology burden in the group SMA setting. Another potential source of risk in this study is the risk of gathering sensitive social, behavioral, and medical information. Data collection via the internet will be conducted through secure applications (REDCap) and no more than minimal risk.

7.2 Study Halting Rules

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, the sponsor and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the sponsor, IRB and/or Food and Drug Administration (FDA).

Section 8: Statistical Considerations and Analysis

8.1 Statistical and Analytical Plans *(SAP)*

There will not be a formal SAP

8.2 Statistical Hypotheses

Primary Outcome: feasibility and acceptability of SMA among underserved youth with T1D.

Hypothesis 1a. Rates of SMA retention (>80%) at 12-months and satisfaction with visits (>80%) will be high.

Null Hypothesis 1a: n/a

Hypothesis 1b: Thematic analysis of semi-structured interviews will identify high satisfaction with SMA.
Null Hypothesis 1b: n/a

Secondary Outcome: preliminary impact of SMA on glycemic control, self-management skills, self-efficacy, diabetes related quality of life, and treatment satisfaction among underserved children with T1D and their caregivers
Hypothesis 2a. CGM percentage wear time and sustained use, as defined by use within the 2 weeks prior to the visit, will be greater upon completion of the SMA intervention at 12 months compared to baseline
Null Hypothesis 2a: CGM percentage wear time and sustained use, as defined by use within the 2 weeks prior to the visit, will not be significantly different upon completion of the SMA intervention at 12 months

Hypothesis 2b. CGM time in range (70-180 mg/dL) will be greater and the glucose management indicator (GMI) lower for youth upon completion of the SMA intervention group at 12 months compared to baseline.
Null Hypothesis 2b: CGM time in range (70-180 mg/dL) will not be significantly different upon completion of the SMA intervention at 12 months

Hypothesis 2c. Diabetes-specific quality of life, self-management behaviors, and self-efficacy scores will be greater upon completion of the SMA intervention at 12 months compared to baseline.
Null Hypothesis 2c: Diabetes-specific quality of life, self-management behaviors, and self-efficacy scores will not be significantly different upon completion of the SMA intervention at 12 month

8.3 Analysis Datasets
Data analysis will be conducted according to a per-protocol analysis as we will be unable to obtain appropriate data from those who withdraw from the study. Participants with incomplete data will be included in analyses when possible.

8.4 Description of Statistical Methods
General Approach
Descriptive measures will be used to summarize participant demographic information. P-values and confidence intervals will be two-tailed. Covariates will be pre-specified. Tests to assess normality will be performed and data transformation or non-parametric analyses will be used when necessary.

Analysis of the Primary Efficacy Endpoint(s)
We will track recruitment, enrollment, participation, and retention through a CONSORT table (Table 2) for the intervention group. Feasibility benchmarks include: recruitment (>60% of reached/eligible participants), CGM initiation, (>80%), SMA sessions attended (>80%), and retention (>80%). In addition, feasibility encompasses demographic characteristics of the enrolled sample, with enrollment and overall increased uptake of CGM among youth from historically underrepresented racial and ethnic backgrounds

(Black race and/or Latinx ethnicity) and income levels. Attrition data and team feedback will help determine how recruitment rates may be improved. Acceptability will be assessed using satisfaction surveys and determined by a high level of satisfaction with participation, perceived utility of the intervention content, and perceived benefit from participation (>80% reporting that they were satisfied and perceived utility and benefit). We will report summary statistics on each feasibility and acceptability item in the questionnaires (mean and standard deviation well as percent answering a specific Likert level). Acceptability also will be examined by key demographic characteristics, including participant age and race/ethnicity.

Parent-child dyads will participate in semi-structured interviews to assess satisfaction with the SMA. Thematic analysis of qualitative data will be conducted by two team members who will independently review interview transcripts to generate initial codes. Initial codes will be discussed by the group to generate a list of second-cycle codes and each team member will then apply the coding framework to all transcripts before identifying dominant themes. ATLAS.ti software will be used to organize and analyze the qualitative data.

Analysis of the Secondary Efficacy Endpoint(s)
Glycemic variability indicators will be obtained from CGM downloads for the 14 days prior to a follow-up data collection time point. As guided by published standardized CGM metrics,[53] data will be transformed to identify number of measurements and percent TIR, time below range (<70 mg/dL) (TBR), and time above range (≥180 mg/dL) (TAR), mean sensor glucose, and coefficient of variation (CV) of glucose values during each 14-day period. We also will track the percent CGM wear time.

CGM data will be analyzed using library GLU in R. using mixed effect models. These models will quantify the impact of our intervention on glucose control over time. The independent variables will be baseline time in range, child age, and a random subject effect to account for correlation of measurements on the same subject. Interaction terms of age and baseline time in range with the intervention will explore possible effect modification ($p<0.10$) of these characteristics. We will also explore differences between time points and average outcome by parent education level and income. Results will be reported as least-squares means (LSMEANS) with standard errors. Casewise deletion will be used to handle missing data.

A battery of validated survey measures exploring diabetes-specific self-management skills and quality of life will be completed by the child and caretaker, including: Type 1 Diabetes and Life (T1DAL), Diabetes Self- Management Profile (DSMP), Self-Efficacy for Diabetes (SEDS), and Problem Areas in Diabetes (C-PAID). Perceived benefits and barriers to CGM use will be assessed using the CGM Benefits and Burdens scale. Surveys will be completed by a single, consistent parent/caregiver throughout the study, preferably the one most involved in medical care. We will summarize self-management skills and treatment satisfaction by different time points. Differences in participant self-management skills and patient satisfaction will be reported as mean Likert scale score and standard deviation. Similar analysis using linear longitudinal regression analysis will be conducted. Results will be reported as least-squares means (LSMEANS) with

standard errors. Casewise deletion will be used to handle missing data.

The incidence of DKA and DKA event rate per 100 person-years, incidence of severe hypoglycemia and severe hypoglycemia event rate per 100 person-years, incidence of ED visits and ED visit event rate per 100 person-years, incidence of hospital admissions and hospital admission event rate per 100 person-years, will also be compared using linear longitudinal regression analysis. Results will be reported as least-squares means (LSMEANS) with standard errors. Casewise deletion will be used to handle missing data.

Baseline Descriptive Statistics
Age, gender, race, duration of diabetes, height, weight, BMI, and A1c

Sub-Group Analyses
The primary and secondary endpoints will be analyzed without regard to age and sex given the narrow inclusion criteria for age and the lack of evidence to suggest sex-based differences in glycemic control among youth with T1D. Race/ ethnicity will not be factored in as the study will not have a large enough sample size and sufficient power to stratify findings based on race/ethnicity.

Tabulation of Individual participant Data
Individual participant data will be listed by measure and time point.

Exploratory Analyses
Thematic analysis of qualitative data from interview transcripts will be performed by two research team members. Initial codes will be developed independently by these team members who will then generate a second-cycle list of codes. All team members will then apply the revised coding framework to the transcription. The team will meet to reach consensus on the final codes and identify dominant themes.

8.5 Sample Size
As this is a pilot study, we plan to enroll up to 20 parent-child dyads. We anticipate low dropout rates, but do plan to enroll new subjects to keep the total number of subjects at up to 20 in case of attrition. If there is a sufficient number of new subjects enrolled to replace those that drop out, a new SMA group will be created so that newly enrolled subjects will be able to start the intervention from the baseline visit.

8.6 Measures to Minimize Bias
Not applicable

Section 9: Data Quality and Oversight
9.1 Study Team Quality Assurance and Quality Control
Study staff will perform internal quality management of study conduct, data and biological specimen collection, documentation and completion. An individualized quality management plan will be developed to describe the study's quality management.

Quality control (QC) procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to the site(s) for clarification/resolution.

Following written Standard Operating Procedures (SOPs), the study staff will verify that the clinical trial is conducted and data are generated and biological specimens are collected, documented (recorded), and reported in compliance with the protocol, International Conference on Harmonization Good Clinical Practice (ICH GCP), and applicable regulatory requirements (e.g., Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP)).

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

9.2 Data Safety and Monitoring Plan

Safety oversight will be under the direction of the PI without a Data Safety Monitoring Board.

Clinical site monitoring is conducted to ensure that the rights and well-being of trial participants are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with International Conference on Harmonization Good Clinical Practice (ICH GCP), and with applicable regulatory requirement(s).

- The PI will direct the conduct of site monitoring on-site prior to the start of the study and will direct review 100% of the data.
- Independent audits will not be conducted.

Section 10: Ethical Considerations

10.1 Ethical Standard

The study team will ensure that this study is conducted in full conformity with the Regulations for the Protection of Human Subjects of Research codified in 45 Part 46 of the Code of Federal Regulations, Children's National Policies and Procedures and Good Clinical Practices.

10.2 Institutional Review Board (IRB)

The protocol, informed consent form(s) and all participant materials will be submitted to the Children's National IRB for review and approval. Approval of both the protocol and the consent form will be obtained before any participant is consented. Any change to the protocol, consent, and participant information sheets or letters will require IRB approval before implementation and use. The IRB will determine whether previously consented participants need to be re-consented and whether consent of more than one parent is required for minors.

The IRB will be notified of study team updates via an amendment. DSMB Reports will be submitted at the time of the continuing review or with another applicable IRB transaction. Other study events (e.g., protocol deviations, data monitoring reports) will be submitted per the Children's National IRB Reportable Events Module.

10.3 Maintaining Subject Privacy

To protect privacy, identification numbers will be used to identify all study information, and only authorized study personnel will have access to study records, with the permission of the PI. When participants fill out questionnaires, their responses will be paired with this unique number instead of their names. Each participant's identifying data will be separated from the study data and all clinically- relevant and study data will be stored in a password-protected database, on a password-protected computer, or in a locked filing cabinet in a locked office. Information about subjects will not be accessible to any non-authorized study personnel without the written consent of the subject. SMA sessions will occur as a group with other participants and caregivers, but each youth and their caregiver will meet with the pediatric endocrinologist individually and have the opportunity to discuss sensitive information in private.

10.4 Maintaining Study Data Confidentiality

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor. All research activities will be conducted in as private a setting as possible.

Dr. Majidi assures that informed consent is obtained prior to performing any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan. Study data are accessible at all times for the PI to review. The PI review(s) study conduct on a weekly basis. The PI review(s) AEs individually in real-time and in aggregate on a twice weekly basis. The PI review(s) serious and reportable adverse events (SAEs) in real-time. The PI ensures all protocol deviations, AEs, and SAEs are reported to the IRB according to the applicable regulatory requirements.

The sponsor representatives and regulatory authorities (e.g., IRB, OHRP) may inspect all documents and records required to be maintained by the investigator. The clinical study site will permit access to such records.

The study participant's contact information and data will be securely stored at Children's National Hospital for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or FDA requirements. The research data will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The

study data entry and study management systems used by research staff will be secured and password protected. At the end of the study, all study databases will be archived at Children's National.

10.5 Study Support and Conflicts of Interest

Salary support for this study is provided by the American Diabetes Association. REDCap® support is provided by The Clinical and Translational Science Institute (CTSI) at Children's National. All key study personnel will follow the Human Research Protections Program Investigator, Study Staff, and Family Member Conflicts of Interest (COI) Policy. The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership will follow established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

Section 11: Data Handling and Record Keeping

11.1 Data Management Responsibilities

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant enrolled in the study. Data recorded in the electronic case report form (eCRF) derived from source documents should be consistent with the data recorded on the source documents.

Clinical data (including adverse events (AEs), concomitant medications, and expected adverse reactions data) and clinical laboratory data will be entered into REDCap. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents

11.2 Data Capture Methods

The PI is responsible for ensuring the accuracy, completely, legibility, timeliness, and completeness of the data reported. Source data includes all information and original records of clinical findings, observations, or other activity necessary for the reconstruction and evaluation of the trial. Examples of original source documentation include electronic medical records, laboratory reports, participant questionnaires, and online software. Source data will be recorded for each participant enrolled in the study into final data capture. Data reported from source documents will be consistent with the

source documents. Research data will be entered into a password protected, secure, HIPAA compliant, spreadsheet with a built-in audit trail. IRB approved research team members who have current HIPAA and CITI GCP and human subjects protection training will be authorized to extract data from source documents and enter it into the data spreadsheet. Data should be entered directly from the source documents into the spreadsheet within 14 days of collection.

11.3 Study Record Retention Policy

Clinical trial documents will be retained for a minimum of 3 years after the termination of the study.

Section 12: Publication Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers for 3 years after the completion of the primary endpoint by contacting the PI.

Section 13: References

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