

Research on Optimizing the Use of Technology With Education (ROUTE-T1D)

NCT05564481

DOCUMENTS INCLUDED:

1. IRB-approved Study Protocol with Statistical Analysis Plan (last approved by CNH IRB on April 9th, 2024)
2. Informed Consent Form (last approved by CNH IRB on April 12th, 2024)

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RESEARCH STRATEGY

SIGNIFICANCE

Effective CGM use may prevent the decline in glycemic control across adolescence. Type 1 diabetes (T1D) is one of the most common chronic conditions in childhood, affecting nearly 1 out of every 400 youth.^{32,33} T1D management requires near-constant vigilance and engagement in complex daily tasks to maintain health, including frequent glucose monitoring with responsive dosing and administration of insulin, careful attention to diet and physical activity, and avoidance of hypo- and hyperglycemia.¹ Adolescence is a particularly challenging time for T1D management. Engagement in daily self-care behaviors typically declines and up to 80% of adolescents with T1D do not meet recommendations for glycemic control (A1c).² The steepest rate of deterioration in glycemic control occurs from ages 10 to 16.^{4,34} Further, significant disparities in health outcomes are evident in youth with T1D: elevated A1c levels (i.e. poorer glycemic control) are associated with race/ethnicity (Black/African American, Hispanic), lower socioeconomic status (SES), and public insurance.⁵ *Early adolescence is a critical window for intervention to positively impact T1D self-management and glycemic control and there must be attention to youth with T1D from diverse racial and ethnic backgrounds and income levels.*

Prior research points to two key areas for intervention in adolescents with T1D: glucose monitoring and parent-child relationships around diabetes care. Inconsistent glucose monitoring coupled with high diabetes-related family conflict are two of the strongest predictors of a high-risk trajectory of poor glycemic control across adolescence.³⁵ Advanced diabetes technologies can assist with consistency of glucose monitoring but have traditionally been underutilized by adolescents. A continuous glucose monitor (CGM) is a sensor-inserted device paired with a receiver that provides real-time glucose readings every 5 minutes, offering critical feedback about actual or impending hypoglycemia and hyperglycemia and access to data reports that provide visual feedback on glucose trends and the glycemic impact of T1D self-care behaviors. CGM may be used with any insulin regimen, including multiple daily injections, stand-alone insulin pump therapy, and as part of an automated insulin delivery system.³⁶ Data indicate that consistent CGM use, regardless of the insulin regimen, improves glycemic control,^{8-10,37,38} with every 1-day/week increase in sensor usage increasing the positive impact on glycemic control.³⁹ A 10% increase in CGM-derived time in range translates to a 0.5% decrease in A1c, which is a clinically meaningful change.⁴⁰ Yet improvements in glycemic control have long been elusive for adolescents.² While CGM use is increasing in younger children with T1D, adolescents are the least likely age group to use CGM and the mean A1c for adolescent CGM users remains elevated above recommended glycemic targets.⁸ In fact, the mean A1c for adolescents has continued to rise in recent years *despite* advances in diabetes technology.² Additionally, 10-20% of youth discontinue using CGM systems and 30% of adolescent CGM users do not wear the device ≥ 5 days per week as recommended.^{9,10} Rates of CGM initiation also are lower for adolescents with elevated A1c levels, youth who identify as Black/African American or Hispanic, and youth with public insurance.^{10,12,37,41} *CGM has demonstrated benefits on glycemic control for persons with diabetes but adolescents have not demonstrated similar clinically meaningful improvements in glycemic control, likely due to unique barriers accessing and using CGM.*^{10,18} *Enhancing developmentally- and culturally-tailored behavioral support for effective CGM initiation and sustained use may improve T1D health outcomes.*

Promoting parent-adolescent problem-solving and supportive communication around CGM data can improve T1D outcomes. Across studies with diverse populations, developmentally-appropriate diabetes-specific parental involvement is associated with better adherence and glycemic control.⁴²⁻⁴⁵ Further, declines in adherence across adolescence are predicted by declines in parental involvement and increases in diabetes-specific conflict, suggesting that supportive parent engagement in diabetes activities – including glucose monitoring – is a key intervention target.^{44,46-48,52} Optimal CGM use during adolescence requires teens and parents to work together to problem-solve challenges related to CGM use, including managing alarms, coping with daily hassles of device use, managing expectations around glucose data, and addressing barriers such as device cost, sensitivity to peers, and data sharing.^{18,49,50} Further, CGM poses unique challenges for parents and adolescents given the constant presentation of data and ability to share data in real-time. It is essential to support positive parent-adolescent communication around CGM data for optimal use.³⁶ Parents and adolescents express high hopes that diabetes technology will improve family relationships and psychosocial functioning.⁵¹ Yet family conflict and diabetes distress remain stable with CGM use and conflict around diabetes care is associated with greater perceived CGM burden.^{17,18,53} Prior research suggests higher perceived CGM burden and parent-adolescent conflict around glucose data contribute to resistance to or discontinuation of CGM.^{17,19,54,55} *There is an unmet need to tailor technology to individual needs of adolescents, understanding unique developmental factors and offering solutions to experienced challenges, particularly within the early months of CGM initiation.*¹¹

Thus, parents and adolescents may benefit from targeted behavioral strategies to promote positive parent-adolescent engagement and reduce conflict around T1D self-care with CGM. Preliminary results from a study supporting CGM use in young children with T1D diagnosed ≥ 3 months found participation in a family behavioral intervention resulted in lower diabetes burden, reduced hypoglycemia fear, and higher satisfaction with

technology.⁵⁶ However, behavioral interventions for adolescents using CGM have received less attention. Our preliminary data and the current research literature suggests that there are two key processes to target for adolescents initiating CGM: problem-solving and supportive parent-adolescent communication around glucose data.⁵⁷ Problem solving is a cornerstone of diabetes self-management education, and problem-solving interventions have been found to decrease diabetes distress and improve self-management.⁵⁷ Integrating problem-solving strategies during periods of transition, such as entering adolescence or starting a new technology, have high potential to improve skills related to diabetes management and reduce perceived diabetes distress. Family conflict also must be addressed, as increased conflict around diabetes care can trigger premature transition of diabetes responsibility to youth and related deterioration in glycemic control.⁵² Targeted interventions promoting positive parent-adolescent communication can reduce family conflict and reduce adherence barriers.^{25,58} *Developmentally appropriate parent involvement in T1D care is essential but requires exploration among youth using CGM. Interventions for adolescents should target both problem solving and conflict to optimize the use of diabetes technology and improve health outcomes.*

Behavioral interventions can be delivered by novel interventionists. Multicomponent interventions targeting family and diabetes-specific behavioral processes evidence the most success in improving glycemic control.⁵⁹ Health care provider-delivered interventions hold particular promise to improve diabetes self-management.²⁹ However, few studies have explored how health care providers (HCPs) – including certified diabetes care and education specialists (CDCES) - can systematically deliver education paired with behavioral intervention content.²³ A behavioral intervention targeting CGM problem-solving skills and T1D distress in parents of young children resulted in a 9% increase in time in range glucose levels and improved CGM satisfaction.³⁰ Tailored CDCES-delivered diabetes coaching after a youth's diagnosis resulted in improved A1c levels 12 months post-diagnosis.³¹ Strategies such as CDCES-led interactive vignettes and modeling of problem-solving also are effective.^{60,61} Further, intervention delivery via telehealth can positively impact problem-solving and T1D outcomes, with high participant satisfaction.^{62,63}

Additional behavioral support may be required to engage parents and youth from traditionally underrepresented and harder to reach backgrounds. In the T1D community, peers serve as role models and key sources of social support. Connecting parents and teens with other parents and families of youth who are successfully using CGM may be a critical behavioral mechanism to support CGM adoption and provide perspectives on “lessons learned” from starting this technology.²⁶ Connection with a peer parent consultant not only provides social support through affirmational (e.g. active listening) and instrumental (e.g. answering questions based on personal experience) ways but also can guide decisions about T1D care and build essential T1D skills.⁶⁴ In pediatrics, peer-based interventions are highly feasible and acceptable,^{26,65,66} including for parents of youth with T1D during targeted periods of development.⁶⁷⁻⁶⁹ Access to parent consultants when initiating a new T1D technology offers a brief, feasible, and potentially translatable intervention with high potential for sustainment in clinical care. Parent consultants may be especially important in the context of CGM health disparities, as parents can discuss concerns and benefits related to CGM use with a trusted peer with similar cultural backgrounds or family resources. *CDCES and peer parent consultants are well positioned to deliver behavioral intervention content.*

Health disparities in CGM access, sustained use, and glycemic outcomes must be addressed. It is important to highlight that the majority of research exploring CGM use has been conducted with non-Hispanic White youth with private insurance.^{8,70,71} Black/African American and Hispanic youth and youth from low-income households remain woefully underrepresented in diabetes technology trials.^{8,72,73} Unfortunately, this mirrors the reality of real-world clinical care when it comes to use of technology: non-Hispanic Black youth, Hispanic youth, and youth with public insurance are much less likely to use CGM as part of T1D management.^{12,37,73} Using data from the T1D Exchange, Agarwal (Consultant) and colleagues reported that 71% of non-Hispanic White young adults (ages 18-25) used CGM as compared to 28% of non-Hispanic Black youth and 37% of Hispanic Youth.⁷³ A single-site study at mid-Atlantic pediatric tertiary care center similarly found that fewer non-Hispanic black youth (31%) and Hispanic youth (33%) initiated CGM within the first year after a diagnosis of T1D as compared to non-Hispanic white youth (54%) and, of those who did initiate CGM, nearly 40% of non-Hispanic black youth discontinued CGM within the first year.¹² HCPs with higher percentages of Black/African American patients report more caution regarding referring patients for diabetes technology.⁷⁴ Further, HCPs may not address concerns about challenges and side effects of technology use and a tailored, culturally sensitive approach is needed when introducing and discussing diabetes technology.⁷³ The source of health disparities in T1D technology access and use are complex and multifaceted, and social determinants of health may not be easily modifiable.⁷⁵ However, it is increasingly clear that interventions to address disparities in CGM access and use must target both modifiable patient/family and health care provider (HCP) factors, including tailored peer support to address family hesitation or misconceptions about CGM and targeted HCP education, resources, and feedback to reduce bias and eliminate disparities in CGM access.⁷³ *Evidence-based support for technology use and psychosocial functioning must address multiple systems and be responsive to the needs of all youth with T1D.*

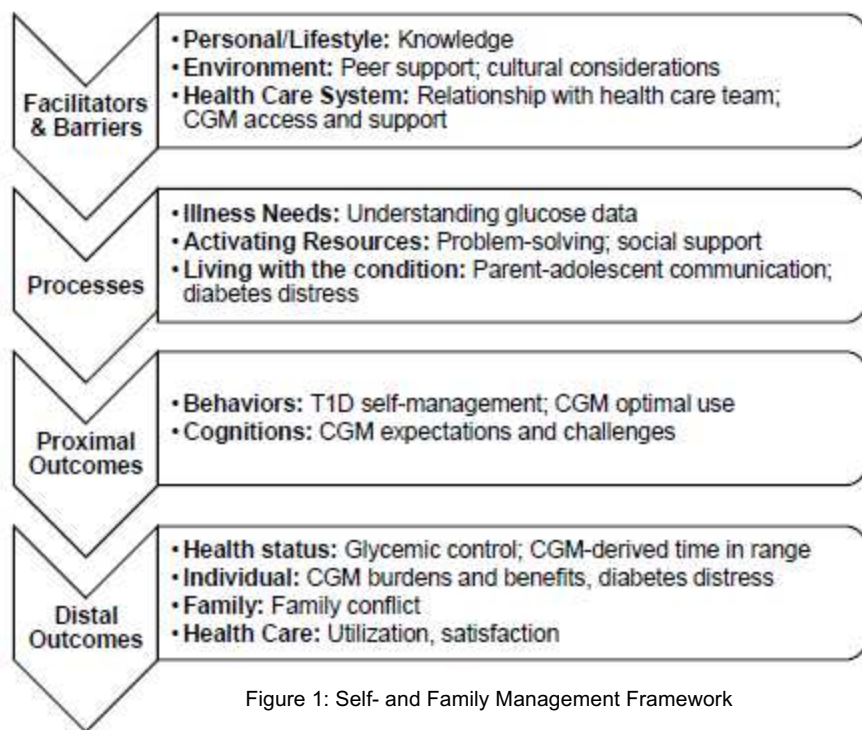


Figure 1: Self- and Family Management Framework

Theoretical Framework. The proposed multi-system pilot intervention targeting youth and family interactions around CGM decisions and HCP biases and referrals for CGM technology is grounded in the Self- and Family-Management Conceptual Framework (see Figure 1).⁷⁶ This framework uses a developmental focus for disease management, highlighting the interplay between self and parental efforts for T1D care while also accounting for emotional and activating resources. Further, this model highlights key contributors of the health care system that may influence T1D outcomes, and incorporates multiple ecological systems involved in T1D self-management for adolescents.

Specific intervention content for youth with T1D and parents is directly informed by the Information-Motivation-Behavioral Skills (IMB) framework.^{77,78} The IMB model of health behavior change attends

to: 1) an individual's knowledge or information about the target behavior; 2) motivation to perform the target behavior; and 3) skills needed to execute the behavior at a high level across a variety of situations. Motivation to perform the behavior can be internal or external (e.g. via social support through positive parent-adolescent interactions, support from a parent consultant and CDCES). Behavioral skills encompass both the necessary skills for parents and youth to execute a behavior such as managing CGM alarms and utilizing Ambulatory Glucose Profiles and their perceived competence in his or her skills to perform these tasks. The IMB Model has been applied to diabetes self-management behaviors and is particularly relevant for the information, motivation, and behavioral skills needed when initiating use of a new diabetes technology.^{79,80} The IMB model directly supports the need for personalized education based on CGM features that fit the family's expectations and goals (i.e., Information), tracking of CGM skills and challenges over time (i.e., internal Motivation), integration of targeted social support via peer parent consultants to share experiences (i.e., external Motivation), and promoting positive parent-adolescent communication and problem-solving with glucose data to gain additional insight into glycemic variability across situations (i.e., Skills).⁸⁰

INNOVATION

Innovation is highlighted through: 1) attention to multiple targets for intervention to reduce CGM disparities; 2) a focus on prevention through intervention delivery near the time of CGM initiation or when CGM wear time is suboptimal; and 3) leveraging existing technology enhancements (e.g. telehealth, ambulatory glucose profiles). CGM use is high in younger children but comparably lower in adolescents.⁸ This study is one of the first to examine behavioral support for CGM use in an early adolescent population, potentially preventing CGM discontinuation or resistance later in adolescence as youth take on more independent responsibility for T1D care. Innovation is balanced with the need for sustainable intervention components with eventual application in clinical care and education.

1. Health disparities in diabetes technology access are complex. However, it is essential to move forward with addressing modifiable barriers. The proposed intervention targets multiple stakeholders involved in CGM uptake, including referring HCPs, CDCES, T1D community members (through peer parent consultants), and the adolescent patient and family. Mobilizing support at each of these levels is essential to both identify sources of health disparities in T1D technology uptake and enact feasible strategies to reduce identified disparities. For example, clinician behaviors related to the introduction of and support for CGM use are critical modifiable targets with potential to enhance CGM access.⁸¹ Interactive, ongoing HCP focused education on disparities paired with accessible patient resources and distributed electronic dashboards detailing CGM uptake among patient populations (e.g. race/ethnicity; age; insurance type) are low burden, integrated intervention tools with a high likelihood for increasing awareness of entrenched disparities in T1D technology access and changing HCP practices.^{81,82} Further, increasing access to the T1D community through connection with peer parent consultants with CGM experience from racial, ethnic, and family income backgrounds representing the diverse patient

population receiving care at CNH can increase informational and instrumental support, address CGM questions in a sensitive and supportive way, and ultimately improve CGM uptake and use.⁸³⁻⁸⁵

2. Delivery of behavioral intervention content near the time of CGM initiation or when CGM wear time is suboptimal has the potential to address some recognized challenges in the standard approach to CGM education and teach parents and adolescents critical skills that can prevent later discontinuation and increase utilization of CGM.^{18,30} The proposed intervention will equip adolescents and parents with tools to solve the problems of managing T1D with technology, and the fundamental skills associated with problem solving and positive parent-adolescent communication are applicable to other T1D self-management challenges commonly experienced during adolescence.⁸⁶

3. The proposed intervention utilizes technology enhancements available in clinical care, including telemedicine and CGM reports. Intervention content is delivered by a CDCES via telemedicine, which eases participant burden of travel while maintaining a face-to-face interaction. Prior research has demonstrated that behavioral intervention content can be delivered via telemedicine with parents and adolescents together on the same call and positively impact on health outcomes.^{62,87} Further, CDCES will help adolescents and parents utilize reports commonly available with CGM profiles to engage in structured problem-solving and facilitate interpretation of data trends, skills that are highly relevant for lifelong T1D management.

As a package, this intervention promotes key T1D management skills needed by all adolescents and their caregivers. Any intervention leveraging T1D technology with the potential to improve glycemic control in youth must be responsive to all youth with T1D, including youth from historically underrepresented racial and ethnic and family income backgrounds. Thus, it is essential to simultaneously impact patient and family skills related to CGM use and related family processes while also working to reduce barriers to CGM access and use at the health care system level. The findings of this intervention will meaningfully inform T1D clinical care related to the introduction of T1D technologies, and potentially disrupt the observed cycle of adolescent technology uptake and then discontinuation. The strategies evaluated in this intervention can be used as a model for youth with other chronic illnesses that require parent-child collaboration for daily regimen adherence and symptom monitoring, such as Crohn's disease, cystic fibrosis, and asthma.

APPROACH

Preliminary Data. As noted in PAS-20-160, Preliminary Data on the proposed intervention are not required for this small R01 mechanism. 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 and key intervention components of promoting positive parent-adolescent communication around glucose data, CDCES-led problem-solving with glucose data, and use of peer parent consultants.

Disparities in CGM use at Children's National Hospital (CNH). In preparation for this submission, we extracted data from the electronic health record on all young adolescent patients (n=93; M age=12.02±1.64 years; 37.2% non-Hispanic White; 92.5% reported primary English language; 51.2% public insurance) diagnosed at CNH over an 18 month period and receiving ongoing T1D care. In this sample, 61.2% (57 out of 93) of young adolescents initiated CGM within 18 months of diagnosis. There were significant differences in initiation by race and ethnicity, with 80% of non-Hispanic White youth initiating CGM but only 47.3% of youth from other racial and ethnic backgrounds initiating CGM ($X^2 = 9.60, p < .01$). The same pattern emerged for insurance, with only 42.6% of youth on public insurance initiating CGM as compared to 77.8% of youth on private insurance ($X^2 = 11.86, p < .01$). 22 of the 93 youth had a documented referral for CGM but did not initiate it, reflecting a need to improve CGM education and resources to improve uptake (e.g. CGM resources to reflect varying levels of health literacy; peer parent support). Further, 12 out of 57 youth discontinued CGM at some point within 12 months of CGM start.

For a different cross-sectional study, we recruited 100 adolescent participants with T1D aged 11-17 yrs diagnosed with T1D >1 year and a parent to complete self-report measures on psychosocial functioning and eating behavior (M age=14.0±1.8; 55% male; 48% non-Hispanic white).⁸⁸ In this sample, 43 out of 100 adolescent participants reported using CGM (64.7% non-Hispanic White; 25.5% Black/African American; 9.8% Hispanic), which reflects disproportionately higher use among non-Hispanic white participants. Further, 17% of all adolescents discontinued CGM use within 12 months post-study. Mean A1c was lower among CGM users (M A1c=8.99%) versus those not using CGM (M A1c=9.95%; $p < .05$) but remained elevated above the current recommendations for glycemic control.⁸⁹ There was a trend for CGM users to be younger (M age=13.70 yrs vs. 14.34 yrs, $p = .07$). There were no significant differences in measures of psychosocial function, including anxiety and depression, between adolescents using CGM and those not using CGM. *The study team is well-positioned to enroll harder to reach adolescents, including youth from diverse racial and ethnic backgrounds and youth with public insurance, and support the initiation of CGM while addressing both glycemic and psychosocial outcomes.*

Parent-adolescent communication about glucose data. We designed a brief, HCP-delivered intervention to enhance joint review of blood glucose (BG) data in adolescents with T1D; this intervention was developed and delivered prior to the wider spread availability and use of CGM in pediatric patients with T1D.²⁵ A proof-of-concept pilot was completed with 30 adolescents (M age=13.67±1.20 yrs; 67% non-Hispanic White; M A1c=8.87%±1.69) and a parent. *Checking In* content was delivered by HCPs during a routine T1D visit, using handouts to review the importance of frequent BG data review and a structure for joint review through “3 minute meetings” (3MMs) – meeting for 3 minutes, 3 times/week. Parents were encouraged to be supportive and actively model problem solving; content was reinforced by 2-3 text messages/week for 12 weeks. Of note, BG monitoring was the highest adolescent-endorsed conflict item and remembering to check BG levels was the highest parent-endorsed conflict item. Participants who adhered to 3MMs had increased BG monitoring frequency and trends in improved A1c and decreased T1D-related conflict from pre- to post-intervention. Adolescents and parents reported high satisfaction. Qualitative interviews conducted with the HCPs who delivered the pilot intervention found high satisfaction, with HCPs reporting parents and adolescents demonstrated enthusiasm for intervention content and reported more frequent glucose review post-intervention. HCPs reported interest helping sustain regular glucose review at home and requested tools to address parent-child conflict around glucose monitoring. *Brief interventions can improve family management of T1D. It is necessary to adapt this work to match current T1D technology needs; key intervention components found to be beneficial, including structured, routine review of glucose data and positive parent-child communication, are incorporated into the current intervention.*

CDCES-led problem-solving with glucose data. Drs. Streisand and Monaghan) have two ongoing trials utilizing CDCES as interventionists. Dr. Monaghan is evaluating a behavioral intervention promoting readiness for transition to adult T1D care for adolescents and young adults (AYA) with T1D. This trial has enrolled 45 AYA with T1D to date (M age=20.5 ±1.2 yrs; 62.2% female; 48.9% non-Hispanic White, 31.1% Black/African American, 11.1% Hispanic, 6.7% more than one race; 31.1% public insurance; M A1c=8.24±1.8%). For this intervention, participants complete a CDCES-led telemedicine session to discuss glucose data review and managing glucose trends.²⁴ Dr. Streisand is analyzing of the First STEPS (R01DK102561) trial, a stepped-care intervention that enrolled 157 parents of young children with T1D (M child age=4.5±1.6 yrs; 90% mothers; 62% non-Hispanic white).⁹⁰ As one intervention step, participants meet with a CDCES in person or via telemedicine to review glucose data and discuss pattern management. Data across both studies find high satisfaction with CDCES sessions, and CDCESs demonstrate high fidelity to the study protocol. *These intervention trials highlight our experience: (1) enrolling racially and ethnically diverse samples of youth with T1D and parents; (2) training CDCES for a behavioral intervention; and (3) conducting CDCES-led glucose data review as part of a behavioral intervention.*

Peer Parent Consultants. Dr. Streisand’s Newly-Diagnosed Pilot Trial⁶⁹ and First STEPS trial⁹⁰ (R01DK102561; N=157; PI: Streisand; Co-I: Monaghan) provided access to trained peer parents as a behavioral intervention component for parents of young children (<7) newly diagnosed with T1D. More than 35 parents of youth with T1D were trained to serve as “coaches” (the terminology used in Dr. Streisand’s studies), using a standardized training program developed by Dr. Streisand and her team encompassing best practices.²⁶ Coaches attended a 4-hour training, completed monthly fidelity checks, and were retrained as necessary—working with 1-4 participants/time x 9 months (99% participants had at least 1 contact with their coach; 77% had contact with their coach through month 9). Coach-parent dyads were matched on demographic characteristics as possible. Coaches communicated with their participants in-person, by telephone, or by email/text messaging; the most discussed topics were daily management of T1D and parent-child adjustment. Coaches received consistently high satisfaction ratings from parents. This experience can be adapted to recruit and train peer parent consultants to serve as an additional resource for parents and adolescents initiating CGM technology. *Our team has extensive experience training peer parents to provide direct support in a research context, with established procedures for training, tracking intervention contacts, and providing tailored support.*

Use of a Hybrid Closed Loop Insulin Delivery System in a High Risk Type 1 Diabetes Population. Dr. Brynn Marks (Pediatric Endocrinologist) is initiating an industry-funded trial to assess the efficacy of automatic insulin delivery on youth who statistically are the least likely to access these technologies through routine clinical care (non-Hispanic Black youth, ages 6-21, Medicaid insurance, A1c >10%, using insulin regimens that do not involve carbohydrate counting). As part of this trial, Dr. Marks has developed educational materials targeted for this patient population. Participants are followed over 6 months to assess changes in CGM time in range and participant, parent-reported quality of life, and diabetes treatment satisfaction. Qualitative interviews will be conducted upon study completion to better understand barriers in accessing diabetes technologies and parent-child interactions with regards to diabetes technology use. *Our study team has the expertise in diabetes technology, recruitment of diverse populations, and development of age-appropriate, culturally appropriate educational materials.*

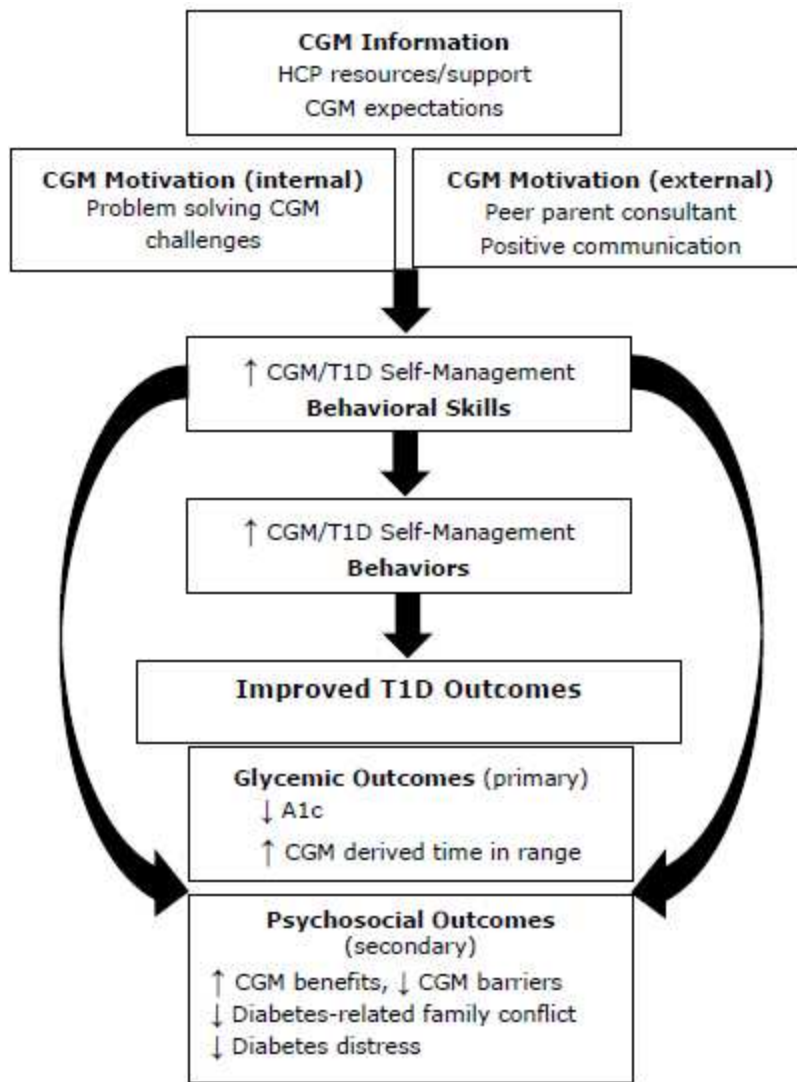


Figure 2: Intervention Mechanisms as Guided by the IMB Framework

Approximately 50% of patients in this age group currently use CGM, leaving approximately 240 patients in this age group who are not yet using CGM. We also anticipate significant increases in CGM initiation among youth diagnosed with T1D in the coming years. The patient population is 52% female and 42% non-Hispanic White, 30% Black/African American, and 11% Hispanic; over 40% of patients have medical assistance. *CNH is well-positioned to provide an adequate population of potential participants preparing for CGM initiation, including youth from backgrounds traditionally underrepresented in T1D technology research.*

2. Study Design. We propose to develop and pilot the proposed intervention in a small randomized controlled trial (RCT). We have evaluated individual components of the behavioral intervention in our prior work. Grounded by a validated self-management framework,⁷⁶ with intervention content directly informed by the Information-Motivation-Behavioral Skills framework⁷⁷ (see Figure 2), we utilized findings from our preliminary work promoting joint, supportive parent-adolescent glucose data review, CDCES-led problem solving with glucose data, and peer parent consultation to match advances in glucose monitoring technology and address health disparities in technology use. Results will inform feasible intervention components with potential to disrupt the decline in A1c typically seen across adolescence and enhance understanding of the needs and CGM experiences of diverse adolescents, with applicability to future technologies. Applying this systematic approach,⁹¹ results will lay the groundwork for a future multi-site RCT.

2.a.Setting. The Child and Adolescent Diabetes Program at Children's National Hospital (CNH) sees over 1850 patients with diabetes across the Washington, D.C region; 8 pediatric endocrinologists/ diabetologists and four nurse practitioners care for all patients with T1D. Patients are seen once every 3-4 months for routine care. CGM training is completed with a CDCES at the time of CGM initiation. There are currently **484 active patients** with T1D between 10-15 years old, with an average of 65-70 young adolescents newly diagnosed each year.

2.b.Participants. A sample of 65 adolescents ages 10-15 years who are new to CGM within the last 3 months or wear CGM less than 75% of the time and a primary caregiver (i.e. parent) will be enrolled. Early adolescence was targeted to reflect the critical developmental period when shared responsibility for T1D care is recommended yet glycemic control deteriorates. We expect to recruit equal numbers of male and female adolescents diagnosed with T1D ≥ 6 months, using any insulin regimen (e.g. insulin pump; injections) who are new to CGM within the last 3 months or wear CGM less than 75% of the time. Participants close to 6 months post-diagnosis may be in the honeymoon period, yet recent research demonstrates that the honeymoon period ends, on average, approximately 5 months post diagnosis.⁹² We will obtain documentation from the medical chart regarding the HCP's evaluation of honeymoon status and use the insulin dose-adjusted A1c to ensure that we are accounting for the honeymoon period.^{93,94} Allowing for participant enrollment ≥ 6 months post-diagnosis also will provide some preliminary insight into the timing of intervention delivery and the potential to impact the trajectory of glycemic control in young adolescents with T1D closer to disease onset.

Inclusion Criteria	Exclusion Criteria
- Adolescent ages 10-15 and a primary caregiver - T1D for ≥ 6 mos - New to CGM (within last 3 mos) OR CGM wear time <75% - Fluent in English or Spanish	- Other major chronic illness (e.g. cancer) - Major psychiatric disorder - Pervasive developmental disorder or cognitive limitations

We will enroll 65 young adolescents and a parent for participation. Our recent studies have recruited samples comprising of >45% of participants identifying as Black/African American, Hispanic, Asian/Pacific Islander, or more than one race/ethnicity and >40% of participants with public insurance. For the current study, we will oversample youth from racial, ethnic, and income backgrounds historically underrepresented in T1D technology research (Black/African American youth, Hispanic youth, public insurance), ensuring a diverse sample with <50% self-identifying as non-Hispanic White or with private insurance. Participants must be able to adequately understand English or Spanish to participate; recruitment materials are available in both languages. Measures and recruitment materials are translated into Spanish to recruit Spanish speaking participants. Adolescents and parents will need access to an internet-enabled device (i.e. phone, computer, tablet) to participate in video conferencing sessions. Based on our experiences with telemedicine visits during COVID-19 and as many CGMs utilize a smart phone as a receiver,^{36,95-97} we do not anticipate this will be a barrier.

3. Procedure. At study onset, we will hold a study team meeting to review current CGM education materials, educational resources, and intervention content. We will invite two adolescent/parent dyads (non-participants) to the initial meeting. We will utilize a graphic designer to redesign current CGM resources and study materials that are visually appealing, accessible to individuals with lower health literacy, and reflective of a racially and ethnically diverse patient population. All resources will be created with the healthcare team and in conjunction with our study consultant (Dr. Agrawal); further, materials will be reviewed for health literacy and all materials will be a Fleishman's reading level of $\leq$ 8th grade. In addition, we will get feedback on the developmental level of intervention information. All materials are translated into Spanish. Research CDCES will complete 20 hours of training in intervention procedures, including optimizing CGM use and modeling problem-solving using CGM data (led by Dr. Majidi/Ms. Henderson; guided by Dr. Marks' curriculum on Technology Knowledge Optimization in Type 1 Diabetes^{98,99}) and addressing psychosocial challenges to CGM use, including parent-adolescent communication and conflict (led by Dr. Streisand).

3.a. HCP training. Prior to adolescent enrollment, HCPs will participate in an introductory meeting about the study. All HCPs also will participate in an interactive training and guided discussion related to health disparities in CGM technology. The training is quality improvement for all practitioners in the diabetes clinic with voluntary attendance. Additionally, the training will be incorporated into one of our weekly division meetings, and there is not an evaluation component attached to it. We will not keep record of who participates. The training will focus on three key areas: 1) current racial, ethnic, and socioeconomic disparities in diabetes technology; 2) potential unconscious bias in referrals/follow-up for diabetes technology and support; and 3) tailored information for HCPs practicing in the Washington DC metro area, including current technology coverage for the major private and public insurance companies, the current technology referral pathway, and updated resources in English and Spanish related to CGM onboarding. The training will be led by Dr. Shideh Majidi (Co-I) and Dr. Shivani Agarwal (Consultant). Dr. Marks recently led a presentation on Diversity and Inclusion in Diabetes Technology for DiabetesMine (<https://www.youtube.com/watch?v=zP5g4MQj9WM>), which provides an outline for the HCP training program. Further, Ms. Celia Henderson, diabetes technology trainer, will collate and electronically distribute updated quarterly metrics related to diabetes technology onboarding, including key patient demographics (presented in deidentified form in aggregate, including: race/ethnicity, age, insurance status). Provider feedback at regular intervals is a critical component of changing provider behavior, and the use of a technology dashboard is a low-burden, easily disseminable strategy to reinforce provider attention to diabetes technology referrals.^{81,100,101} The CNH diabetes team has expressed significant support for this project (see letter from Dr. Cogen, Medical Director of the CNH Child and Adolescent Diabetes Program, and Dr. Brynn Marks).

3.b. Peer parent consultant training. Prior to adolescent enrollment, we will recruit 4-6 peer parent consultants. All peer parent consultants will be parents of adolescents with T1D who have utilized CGM for at least 1 year. Peer parent consultants will be purposefully selected to represent parents from diverse racial and ethnic backgrounds to match the anticipated demographics of our enrolled study participants. They will be nominated by at least one member of the diabetes care team at Children's National Hospital. We will work with our health care team and prior research collaborators to identify parents who can serve in this role. Dr. Streisand has extensive experience with peer parent coaching and her work has identified qualities that are present in successful peer parents, including diabetes management experience, warmth, flexibility, open-mindedness, active listening skills, and strong communication skills. Dr. Streisand will lead 2-3 small group, in-person trainings for peer parent consultants and provide ongoing monthly oversight/supervision to all peer parents, following procedures we have used successfully in prior studies.²⁶ Additionally, peer parent consultants will be engaged to help build out website content to support the intervention constructs, including decision making tools related to diabetes devices (e.g. www.diabeteswise.org), video content from CNH patients and families on technology use, and our currently available diabetes education videos, including Dr. Marks' video on diabetes technology options. All peer parent consultants will receive incentives in appreciation for their time, with \$50 for the initial training, and then for each participant: \$10 per month for the first 2 months and \$50 once finished with their

participant and complete a short online questionnaire about their experiences (up to \$70 per participant). Peer parent consultants will also receive \$25 for completing a final survey at the end of the entire study and \$25 for completing a brief (20 min) interview with a member of the study team.

3.c. Adolescent and primary caregiver procedures. We aim to recruit ~3-4 participants/month for an 18 month recruitment window (Y1, Month 6 – Year 2, Month 12). This is highly feasible, given that 70 youth in our target age range are newly diagnosed each year, only ~50% of our current population currently use CGM, and many youth, particularly harder to reach youth, start CGM ≥ 6 months post-diagnosis or use CGM $< 75\%$ of the time. We will employ methods for enrolling subjects that have been evaluated and refined in our prior work, resulting in enrollment of ~65% of adolescents reached for recruitment.^{25,58,102} Participants who are new to CGM will be identified by their HCP as being recommended for CGM. We will enroll participants who are new to CGM within 3 months of CGM initiation. We will also use electronic medical records to identify participants who used CGM $< 75\%$ of the time in the past 90 days according to Dexcom Clarity Ambulator Glucose Profile. Participants can also self-report their CGM usage time to the study team.. Further, HCPs will distribute study flyers to potentially eligible participants at our Diabetes Self-Management Education (DSME) 2/3 education classes (~1 month post-diagnosis) and at the time of CGM referral; flyers will be available in PDF format so they can be distributed in person or via email for telemedicine diabetes visits. All study flyers will have a QR code with a link to a recruitment video in English and Spanish (see <https://youtu.be/75OuQLIZz3M> for a recruitment video we are using in a current study). Our prior studies have supported the feasibility of HCPs sharing information related to patient care and clinical research, and we have the full support of HCPs and CDCES to distribute study flyers to potentially eligible participants as a key recruitment strategy. We will conservatively plan for 15% attrition at follow-up to protect against overestimation.

3.d. Recruitment/enrollment. Adolescents and a primary caregiver will be sent an introductory email will be co-signed by the PI and Dr. Majidi. 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. Potential participants will be screened by phone by a member of the research team to determine eligibility; a primary caregiver will provide eligibility information. Interested adolescents and their parents will provide initial verbal consent/assent via phone. Trained research staff will obtain informed consent via telemedicine using structured scripts, reviewing the consent/assent forms via screen sharing and directing interested participants to REDCap,¹⁰³ a secure, web-based data management and survey tool, to provide consent. Once parents and adolescents have consented to participate, the family will receive unique links to access the surveys on REDCap¹⁰³ to complete the T0 (baseline) assessment. REDCap can be accessed just by clicking on a personalized link from any web browser on a computer, tablet, or mobile device. Participants also can opt to complete consent on paper and return via mail/email or in person. Consent forms will include a description of study procedures, including that: (a) information collected will be confidential and not released to adolescents, caregivers, or HCPs, (b) participants will receive modest compensation (e.g., gift cards) for completing the study, (c) study withdrawal can occur at any time, and (d) data can be destroyed at any time upon request. The baseline assessment is expected to take 30 minutes (adolescent: 30 mins; parent: 30 mins). Blood glucose data will be downloaded and relevant information extracted from the medical record. All participants will be given an A1c kit from CoreMedica to obtain a current A1c.

3.e.Orientation and Randomization. Following baseline completion, all participants will complete a brief orientation session with a study team member via video-conferencing. This session will elicit anticipated or current benefits and burdens associated with CGM, current diabetes management practices, and psychosocial challenges (e.g. conflictual topics).

*One on one or small group instruction	* Monthly assessment of CGM challenges
*Features of CGM device (event, insulin-dosing, and food logs)	* Problem solving model to address CGM barriers (alarms, cost, data sharing)
*Personalized alarm thresholds, data share features, sensor insertion and adhesion	* Supportive parent-child communication around glucose data; conflict resolution
*Using software (e.g. Clarity); accessing and interpreting CGM data reports	* Routine joint review of CGM data reports at home (weekly check-in)
*Managing hypo- and hyperglycemia	

Following the orientation session, adolescent/parent dyads will be randomly assigned to one of two groups: immediate intervention (n=30) or delayed intervention (n=30). All participants will proceed with standard CGM education and onboarding at baseline per clinical care procedures. The immediate intervention group will be connected with a peer parent consultant and participate in 3 CDCES-led sessions. The delayed intervention group will receive no intervention beyond standard CGM education and onboarding for the first 6 months post-randomization; they will receive the study intervention, including the three CDCES sessions and access to a peer parent consultant, 6 months post-randomization. This study design maximizes use of the small sample, allowing for a standard care comparison group with no intervention over the first 6 months with additional data on intervention feasibility, acceptability, and timing

through the evaluation of the delayed intervention group. The study statistician Dr. Bost will use a computer-generated randomized sequence stratified by age (10-12 or 13-15) and participant race/ethnicity (non-Hispanic white vs. other self-reported race/ethnicity) for treatment assignment, with block randomization (groups of 6) to ensure balance over time.

Standard care consists of routine CGM education and related T1D care and services (e.g. education; nutrition); all patients using CGM meet with a CDCES at CGM initiation for education. CGM education consists of a 90 minute session conducted in person or via telehealth to initiate using the device. Additional CDCES education and contact (e.g. email via patient portal) will be tracked for both groups during the study. To increase retention, we will use strategies employed in our other projects including contacting the adolescent/parent by text to remind them about the data collection.

3.f. Intervention. Adolescent/parent dyads in the intervention group will be immediately connected with a peer parent consultant, with the first contact occurring within 2 weeks of randomization, and given access to the study website. All participants will have at least one contact with a peer parent consultant during the first month of the intervention by telephone or videoconferencing to discuss CGM experiences and answer questions. Adolescents and a parent will complete three intervention sessions (1 per month) together with a research CDCES. Each session will take approximately 30 minutes and will be completed via Zoom video conferencing, a secure telemedicine platform supported by CNH. Prior to each session, adolescents and parents will complete a tailored assessment of CGM benefits and burdens so that session content can be tailored to individual challenges. The first CDCES session will review expectations and goals related to CGM use and features. The CDCES will emphasize the importance of developmentally-appropriate parental involvement in T1D care, introduce diabetes problem solving, and review steps to conduct a joint parent-adolescent weekly review using the Ambulatory Glucose Profile (Check-In). The second session will review and problem-solve CGM challenges, elicit feedback from weekly Check-Ins and decrease conflict through communication skills training (e.g. active listening, joining language) and conflict resolution (e.g. attention to tone; taking a break; setting realistic expectations; praising steps towards goal). The third session will apply a problem-solving model to address remaining CGM challenges, review tailored strategies for communication and conflict resolution, and lead the adolescent and parent in guided problem-solving using CGM data (e.g. how to identify trends in glucose data; make dose adjustments). Any changes will be documented in the medical chart.

	Session 1	Session 2	Session 3
Topics	- Review of CGM expectations and challenges - Developmentally-appropriate parent involvement in T1D care - Problem-solving model - Conducting a joint weekly data review (Check-In)	- Review of CGM challenges - Communication-skills training for glucose discussions - Conflict resolution	- Review of CGM challenges - Review of communication and conflict resolution - Guided problem solving using CGM data
Access to peer parent consultant and study website			

3.g.Follow-Up Assessment. Immediately post-intervention (T1: 3 months post-randomization) and again 3 and 6 months later (T2: 6 months post-randomization; T3: 12 months post-randomization), all adolescents and parents in the immediate intervention or delayed intervention group will complete follow-up health outcome and psychosocial measures. After T2 (6 months post-randomization), the delayed intervention group will receive the

behavioral intervention, including 3 CDCES-led sessions and a peer parent consultant. If youth have discontinued CGM, the intervention content will be tailored to focus on CGM challenges, communication-skills training for glucose discussions, and guided problem solving using blood glucose data. The follow-up periods mirror recommended frequency for T1D medical visits. A1c data will be extracted from the medical chart; participants also will have the option to complete home A1c evaluation using the CoreMedica test kit to obtain A1c values. Adolescents will send reports with the most recent 14 days of CGM data. Follow-up questionnaires are expected to take 20 minutes (adolescent: 20 min; parent: 20 min), and can be administered online or in person at a clinic visit.

3.h.Measures. Biometric data, including A1c values, CGM data, and other clinical data (e.g. severe hypoglycemia; diabetic ketoacidosis), and adolescent- and parent-report measures will be collected at T0 (baseline) and three follow-up points. We will develop a study-specific satisfaction survey to evaluate participant experience with the intervention. We also will develop a baseline questionnaire assessing CGM expectations and understanding, guided by the CGM education curriculum developed by Dr. Marks.⁹⁸ As this is a pilot study, strong emphasis is placed on feasibility and acceptability assessments.

Primary and secondary outcomes will be evaluated at T0 and 3 follow-up timepoints (T1-T3). The frequency of assessment aligns with standard clinical follow-up visits and will provide essential information about participant experiences using CGM. The 6- month follow-up period is the primary timepoint for study analyses. This allows for comparison of the treatment group (immediate intervention) with a standard care comparison group. Given the proposal's commitment to health equity and the inclusion of participants from diverse racial, ethnic, and family income backgrounds underrepresented in T1D technology research, we felt it was essential to offer the opportunity to receive intervention content to all participants. Thus, the standard care group will receive the intervention at 6-months post-randomization, allowing for an additional evaluation of the intervention's feasibility and acceptability in this group.

Hemoglobin A1c is a widely accepted measure of glycemic control and represents average glucose over the preceding 6-12 weeks.¹⁰⁴ A1c values are obtained at all in-person clinic visits, with assays conducted with a DCA 2000+ analyzer.¹⁰⁵ Additionally, participants have the option of a home A1c kit from CoreMedica. Our site has an active contract with CoreMedica, with established research procedures to maintain confidentiality and ensure efficient data collection for research. 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,¹⁰⁶ data will be transformed to identify number of measurements and percent time spent in target glucose range (70-180 mg/dL), hypoglycemia (<70 mg/dL), and hyperglycemia (≥180 mg/dL), mean glucose level, and coefficient of variation (CV) of glucose values during each 14-day period. We also will track the mean (M) number of days/week CGM was worn and the percentage of time CGM is active.

Perceived CGM benefits and burden will be assessed using the Benefits of CGM (BenCGM) and Burdens of CGM (BurCGM) questionnaires.²² We will track health care utilization and T1D related complications (e.g., hospitalizations, absences, severe hypoglycemia, DKA). Family conflict will be assessed using the Diabetes Family Conflict Scale-Revised (DFCS),¹⁰⁷ a 19-item scale that assesses parent and adolescent perceptions of disagreements related to T1D care. Diabetes Distress will be assessed using the Problem Areas in Diabetes scale (PAID), a self-report scale of parent and adolescent experiences of diabetes-specific burden.^{108,109} T1D management is expected to be a key moderator of the intervention impact on A1c and will be assessed using the Diabetes Management Questionnaire (DMQ), a self-report measure assessing the frequency of engagement in diabetes self-care behaviors (e.g., glucose monitoring, insulin adjustment) over the past month.¹¹⁰ All measures have demonstrated high reliability and validity in adolescents and adults.^{111,112}

	Domain	Measure	Description*	T0 BL	T1 3 m	T2 6 m	T3 12 m
	Demographic	History or Brief Update	Medical, developmental, and family history P	X	X	X	X
	Health Care Utilization (HCU)	HCU from Electronic Health Record (EHR)	Health care utilization and complications EHR	X	X	X	X
PRIMARY OUTCOMES							
Clinical Outcomes	Health Outcomes	Hemoglobin A1c	Glycemic control EHR/A1c kits	X	X	X	X
		CGM indicators	Glycemic variability (% time in range; % hypoglycemia; % hyperglycemia; CV of glucose values; mean glucose value) A	X	X	X	X
SECONDARY OUTCOMES							
Psychosocial Outcomes	CGM Experience	BurCGM/BenCGM	Perceived burdens and benefits related to CGM use A P	X	X	X	X

	Diabetes-Related Family Functioning	DFCS	Diabetes-related family conflict A P	X	X	X	X
	Diabetes Distress	PAID	Perceived stress and burden of T1D care A P	X	X	X	X
MODERATOR							
Self-care Behaviors	Adherence	DMQ	Adherence to diabetes care regimen A P	X	X	X	X

***A** indicates that the outcome will be measured in adolescents; **P** indicates that the outcome is measured in parents; **EHR** indicates that the outcome will be obtained from the electronic health record

3.i.Incentives. Adolescent/parent dyads will receive incentives of increasing value for questionnaire completion (T0: \$20; T1: \$30; T2: \$40; T3: \$50). Adolescents with a CGM receiver will also receive \$10 for sending CGM reports or providing online access to CGM profiles (e.g. via Dexcom CLARITY) at each time point. Adolescents will receive \$10 for completing the remote A1c kit at each time point. We will conduct 1-on-1 interviews with a subset of adolescents and parents (n=30 each) at study completion; each participant completing the interview will receive \$10 (total maximum compensation per dyad=\$200).

3.j.Training & Fidelity Checks. The CDCES research interventionist will complete 20 hours of training on intervention content and delivery. Drs. Streisand and Majidi review recordings of the first 2 dyads, allowing for feedback regarding intervention delivery. All intervention sessions will be recorded, with 20% subject to ongoing fidelity checks by Drs. Streisand and Majidi to ensure fidelity to the intervention manual. Further, the research CDCES will meet with Drs. Streisand and Majidi on a quarterly basis to review best practices for engaging participants with intervention content and working with families from diverse racial/ethnic and socioeconomic backgrounds. Dr. Agarwal will join one meeting/year to discuss cultural considerations for diabetes technology education. Participant adherence to weekly joint data reviews will be measured via self-report. Other indices of treatment utilization (i.e., dose) include adolescent and parent reported use of strategies (e.g. problem-solving, praise) and use of CGM features.

3.k.Qualitative Evaluation. Qualitative interviews will be completed with a purposeful sample (n=30 adolescents; 30 parents across both immediate and delayed intervention groups) to gain insight into experiences with the intervention, including satisfaction, perceived impact, and ease of adhering to study components, and challenges associated with parent-adolescent interactions around CGM onboarding and data. Interviews offer key feedback on intervention applicability, translatability, and strengths/weaknesses and identify opportunities for refinement. Interview guides will include standard, open-ended questions to ensure that similar areas of content are queried across participants, providing more focus than a conversation but allowing for adaptability. Additionally, caregiver participants may be invited to participate in a 2nd qualitative interview focusing on their experience using CGM throughout the 12 month study period.

4. Data Analyses. Dr. Bost will lead statistical analyses. Sample size was determined by feasibility considerations and prior experiences with similar studies. The proposed sample of 65 dyads will be sufficient to assess magnitude and variability of the intervention's effect at 6 months post-randomization, using a delayed intervention group with no intervention in the initial 6 months post-randomization as the standard care sample, in improving clinical and psychosocial outcomes. Based on clinical sample and prior studies, our expected Mean $\pm$ -SD of A1c at baseline is 8.8% $\pm$ 1.7%. Thus, a 1:1 study with 65 dyads and 15% attrition rate will result in a precise estimate of intervention's efficacy compared to standard care, measured by difference in Mean A1c between arms, with standard error of 0.3% before any adjustments. Estimating effect size and sampling variability in this study is a critical step in sample size and power determination of a future RCT to inform feasibility and health impacts.

Aim 1. *Evaluate the feasibility and acceptability of the CGM support intervention.* The primary focus of feasibility and acceptability assessments include descriptive information on participant recruitment and retention, engagement, and satisfaction. We will track recruitment, enrollment, participation, and retention through a CONSORT table for the immediate and delayed intervention groups. Supported by HCP referrals and electronic medical records, we also can track the number of patients given information about the study and all communication related to CGM uptake and use as documented in the medical chart. Feasibility benchmarks include: recruitment (>60% of reached/eligible participants), CGM initiation, (>80%), sessions attended (>80%), parent consultant contacts (>80% with ≥ 1 contact), and retention (>85%). In addition, feasibility encompasses demographic characteristics of the enrolled sample, with enrollment of <50% non-Hispanic white patients and overall increased uptake of CGM among youth with historically lower use of T1D technology, including Black/African American youth, Hispanic youth, and youth with public insurance. For participants lost to attrition, baseline characteristics and team feedback will help determine how recruitment rates may be improved.

Construct	Measure	Interval
Recruitment Feasibility/ Acceptability	# referred from HCPs per month # screened per month # enrolled per month % eligible who enroll	Study initiation through recruitment completion (18 mos)
Intervention Feasibility	##/% sessions attended # contacts with parent consultant	Weekly during active intervention periods
Intervention Acceptability	Adolescent/parent satisfaction ratings Adolescent/parent qualitative interview HCP qualitative interview	Post-intervention follow-up periods
Intervention Fidelity	Parent consultant report of contacts (type of contact, topics discussed, duration of contact) % fidelity of CDCES sessions to treatment manual	Monthly during active intervention periods
Retention Feasibility/ Acceptability	% who complete CGM initiation % who are on CGM at 9-month follow-up % complete follow-up assessments	Post-intervention follow-up periods
Assessment Feasibility	% participants with missing A1c data % participants with missing CGM data % participants with missing psychosocial data	All assessment timepoints

Acceptability is assessed through evaluation of post-intervention satisfaction surveys overall and by group condition (immediate vs. delayed intervention). Acceptability will be determined by a high level of satisfaction, perceived utility of the intervention content, and perceived benefit from participation (>80% reporting that they were satisfied and perceived utility and benefit). Acceptability also will be examined by demographic characteristics, including age, race/ethnicity, and insurance status.

Aim 2. *Evaluate preliminary impact on T1D outcomes.* Primary clinical outcomes are A1c and CGM statistics (e.g. time in range; standardized number of

measurements of hypo- or hyperglycemia; mean glucose level). Secondary outcomes include adolescent and parent total scores on CGM Burdens and Benefits (BurCGM; BenCGM), Diabetes Family Conflict Scale (DFCS), and Problem Areas in Diabetes Scale (PAID). We will make several attempts to minimize missing values on all outcomes and document possible reason for missingness. Our analyses also will handle missing outcome values using multiple imputation methods and generating 15 imputed datasets given all measured baseline characteristics before carrying out analyses using library miceadds in R.¹¹³ The resulting effect size estimates and standard errors will account for sampling variability and variability due to missingness.

For Hypothesis 2.1 and Hypothesis 2.2 examining clinical and psychosocial outcomes, we will compare the Immediate Intervention arm to the Delayed Intervention arm at 6 months using unadjusted and adjusted analyses. In a randomized study, we expect unadjusted analyses to estimate effect size accurately and adjusted analyses to increase precision of these estimates. Unadjusted univariate analyses for A1c, CGM, and psychosocial (continuous) measures will compare the two arms at T1 and T2 (3- and 6-months post-randomization) using 95% confidence interval (CI) for mean difference. If there are departures from normality (e.g. variance increases with mean) for CGM statistics, we will report the 95% CI of the rate ratio using exact methods. In univariate analyses for group comparisons, we will compare the T0 (baseline) measure with the T2 measure (6 months post-randomization) using a paired t-test. In multivariate analyses, we will quantify the impact of the intervention on clinical outcomes with mixed effect models and report model-based 95% CIs for pre/post intervention effect for the immediate intervention group as compared to standard care (delayed intervention) at T2. We also can conduct similar univariate and multivariate models for within pre-post subject comparisons. These models take advantage of the longitudinal measures of each outcome pre- and post – intervention. In these models, the dependent variable will be primary outcome post-baseline, the independent variables will include an indicator of whether the measurements was taken pre or post intervention, the first measurement in the study pre-intervention, a linear trend for time post-intervention, and a random effect for participant to adjust for correlation of measures within the same participant. For CGM outcomes, which are counts or rates, we will report the 95% CI of the rate ratio using exact methods and fit a multivariable regression after log transformation or use a Poisson mixed effect regression accounting for overdispersion.

For Hypothesis 2.3, we will examine effect modification of the interventions on each outcome by different baseline characteristics including age, race, sex, insurance, and modality (e.g., pump vs. injection) and changes in adolescent- and parent-reported T1D treatment adherence (DMQ total score). We will summarize the mean outcome for different subgroups defined by each characteristic. We will compare association between change in an outcomes pre- and post intervention with age, race, sex, insurance, regimen, and T1D adherence using independent t-test. A p-value of > 0.10 will indicate possible effect modification. We will add those characteristics that show (univariate) association with intervention on a particular outcome (p-value > 0.10) to multivariable models and assess interaction of characteristic with intervention.

Aim 3. *Examine CGM experiences.* Qualitative coding will evaluate adolescent and parent themes related to intervention experience and CGM use. Interviews will be transcribed and coded for content by Dr. Streisand. Coding, sorting, and integration of the major themes will be accomplished as outlined by Charmaz,¹¹⁴ and supported by the use of contextual software Atlas.ti. Thematic prevalence will be determined by the proportion

of interviews to which a code is applied.¹²³ Adolescent and parent report will be integrated to provide a rich, detailed evaluation of intervention components and impact. To further evaluate associations of race/ethnicity, insurance, and intervention experience, we will investigate associations among key demographic characteristics with intervention engagement (i.e. session attendance; peer parent consultant contact) by reporting 95% exact CIs for differences in proportions for dichotomous baseline characteristics.

5. Potential Pitfalls and Future Directions. The study is limited by the setting in which it is conducted, including initial CGM education and procedures specific to CNH. It is expected that results of this pilot work will inform a future evaluation of a multi-site CGM support intervention to further evaluate the efficacy of behavioral content related to CGM use. The study targets young adolescents and a parent to capture the developmental age when T1D responsibility is shared yet adolescents begin to demonstrate resistance to or underuse of CGM; it also places a strong emphasis on evaluation of the intervention with racially, ethnically, and economically diverse adolescents, a population which has been historically underrepresented in T1D technology research and may experience unique barriers to CGM uptake and use. If CGM is discontinued during the trial, we will utilize blood glucose data during guided problem-solving and identify new T1D self-management goals as needed. The T1D technology landscape is evolving and it is likely that new technologies will emerge during the course of intervention delivery.³⁶ However, the processes of glucose data review, problem-solving technology challenges, and positive parent-adolescent communication remain relevant for new diabetes technologies. Dr. Majidi (Co-I) is an expert in diabetes technology and will work with the study team to adapt materials for HCPs as needed and guide any minor modifications needed for intervention materials. This intervention also provides an opportunity for more frequent engagement during a period of transition that may be particularly stressful (i.e. starting a new technology; within the first year of T1D diagnosis). Participants with significant issues related to diabetes distress will be referred for psychology support; referrals will be documented to identify families which may benefit from more intensive support than provided through this intervention. The CDCES-delivered format paired with accessible, low-cost modes of delivery (telemedicine, leveraging existing ambulatory glucose profiles, HCP dashboard) offers strong potential for impact and translatability. If successful, the logical next step is a larger multi-site randomized trial to more fully evaluate the program's efficacy and longer-term impact on glycemic outcomes. Further, there is opportunity for clinically meaningful change in access to and sustained use of CGM technologies among all adolescents with T1D. The findings of this pilot work will initiate a trajectory of research responsive to the needs of young adolescents related to new diabetes technologies with significant potential to improve health outcomes and clinical diabetes education and care.

**Research on Optimizing the Use of Technology With
Education (ROUTE-T1D)**

NCT05564481

DOCUMENT #2: Informed Consent Form (last approved by
CNH IRB on April 12th, 2024)



Place Barcode Label Here

CHILDREN'S NATIONAL MEDICAL CENTER

Center for Translational Research
111 Michigan Avenue, NW
Washington, DC 20010
(202) 476-5000

Consent/Parental Permission to Participate in a Clinical Research Study and Authorization to Use Protected Health Information

STUDY TITLE:	ROUTE-T1D: Research on Optimizing the Use of Technology with Education
PRINCIPAL INVESTIGATOR:	Randi Streisand, PhD, CDE

Throughout this document, “You” always refers to the person (you or your child) who takes part in the study.

SUMMARY AND KEY INFORMATION

We are inviting you to be part of a research study at Children's National Medical Center (Children's National). **Taking part in this study is your choice.** You can choose to take part or you can choose not to take part in this study. You also can change your mind about participating at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To help you decide if you would like to participate, we want you to know why we are doing the study, what you will be expected to do, and the possible risks and benefits of being in the study. This form has information to help you make your choice about whether or not to participate.

The purpose of this research study is to learn more about how youth with type 1 diabetes (T1D) and their families manage diabetes when using diabetes technologies such as continuous glucose monitors (CGM). We are interested in learning whether you would benefit from a new program to help families feel more comfortable using a CGM to help manage diabetes care. As a parent of an adolescent with type 1 diabetes starting CGM, we want to know more about that process from you, since you are experiencing it.



Participation in this study includes completion of study questionnaires, talking with the study team by secure video-conferencing (Zoom) three times, and talking with a peer parent coach. You and your child will each complete separate questionnaires. We also will collect information from your child's medical records at this visit and at future clinic visits that occur within 12 months of when you enroll in the study. We also will ask to download your blood glucose meter data and/or CGM data at the study visits or any clinic visits you have when you are enrolled.

There are some risks to participating in this study. Some questions will ask about your child's diabetes management and emotions. Sometimes thinking and talking about these subjects causes people to become upset. In addition, there is a risk that your personal information could be shared. You will not benefit directly from taking part in this study. The things we learn from you might help other adolescents with type 1 diabetes and their families in the future.

Your participation in this study is voluntary, meaning that if you do not want to participate, the only other choice would be to not participate. If you choose not to participate, that will not affect your relationship with Children's National Hospital or your right to health care or other services that you receive.

If you are interested in learning more about this study, please continue reading below. The rest of this form gives you more important information you need to know about the study before you decide if you want to participate. The study doctor or a member of the research team will talk to you about the study and answer all of your questions. We encourage you to discuss this study with your family and anyone else you trust before making your decision. It's important that you have as much information as you need and that all your questions are answered.

Your participation in this research is voluntary.

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to be in the study or withdraw from the study later. This means that:

- You do not have to join the study.
- You may change your mind and stop being in the study at any time.
- We will tell you if we make any important changes to the study or if there are any important new findings so that you can decide if you still want to be in the study.

Purpose of the Research

The purpose of this research study is to learn more about how youth with type 1 diabetes (T1D) and their families manage diabetes using diabetes technologies such as continuous glucose monitors (CGM). We are interested in learning whether you would



benefit from a new program to help families feel more comfortable using a CGM to help manage diabetes care. As a parent of an adolescent patient, we want to know more about that process from you, since you are experiencing it.

We are inviting you to participate in this study because you are the parent of an adolescent who is currently being treated for T1D at Children's National.

Dr. Randi Streisand is in charge of this research study. She is called the Principal Investigator (PI).

How many people will be enrolled in this research study?

This study will enroll up to 60 young adolescents with T1D and a primary caregiver. Adolescents are eligible to participate in this research study if they are between the ages of 10-15, have been diagnosed with T1D for at least six months, and have an expressed interest in, and a provider-referral for, CGM. Adolescents will be recruited with a primary caregiver, and both the adolescent and the primary caregiver must agree to participate in the study to be eligible.

What will happen in this research study?

If you agree to be in the study and meet the requirements, you will be asked to complete questionnaires and talk with the study team by secure video-conferencing (Zoom) three times. You also will have access to a parent coach, a trained peer who is the parent of an adolescent with T1D using CGM and is willing to serve as a resource. The study will take place at home (by internet or phone) and at Children's National Hospital.

This study may take place at clinic, and a research staff member can meet with you at a clinic visit to review the study. If you prefer, a research staff member also can talk with you over the phone or secure videoconferencing (Zoom) about this study and you can then complete study procedures online from the location of your choice (e.g. at home).

Questionnaires: You will be asked to fill out questionnaires. They will be emailed to you (on a secure web survey) by a member of the research team. These questionnaires will be sent to you (if participating) about every 3 months for a year. The questionnaires will ask you about how you manage diabetes. It will take about 20-25 minutes to fill out the questionnaires.

Visit 1: Research staff will meet with you in person or by secure video-conferencing to review the study timeline. We will also talk about your child's current diabetes care. We will explain what will happen during the study in detail. We will also talk about the best ways to reach you and your family so that we can keep in touch with you.



We will also collect information from your child's medical records. This includes weight, height, A1C, and/or other lab results. At this visit and any following clinic visits, if you cannot obtain a lab-drawn A1c value (e.g. you have a telemedicine appointment), the study team will mail you a self-collection A1c kit. If there is no clinic setting A1c value recorded in your child's medical record in the prior three months, we will send your research A1c value to you via email and we will also inform your Children's National health care provider of the A1c value. We will also ask to download/record your child's blood glucose meter data and your continuous glucose monitoring data (if applicable) during each visit. Glucose data will be collected in ways consistent with usual clinical care.

After the orientation visit, you and your child will be randomly assigned to one of two groups – either the immediate intervention group or the delayed intervention group. There is a 50% chance that you will be assigned to the immediate intervention group and receive the new program we are researching in this study right away, and a 50% chance you will be assigned to the delayed intervention group and receive the new program 6 months after being in the study. All participants, regardless of group, will receive usual diabetes care, including standard CGM education.

Phone/Video Calls: If you are in the immediate intervention group, you will begin the enhanced CGM education program after your first visit with our study team. If you are in the delayed intervention group, you will begin the enhanced CGM education program after 6 months of being in the study. The program includes three sessions with a member of the research team who is a certified diabetes care and education specialist. The sessions will take about 30 minutes. They will take place either over the phone or by video-conferencing (e.g. Zoom) and involve you and your child. During the sessions, we will talk with you about CGM expectations, challenges, and communication. Program sessions may be audio recorded to ensure that we are delivering the study information in a consistent way. You will also get connected to a peer parent coach to discuss (at least 1x month) CGM experience and answer any questions you may have. If you need to reach our study team, please call the study coordinator, Emma Straton, at 202-476-5360, or the main investigator, Randi Streisand, PhD, at 202-476-2730. You will also be able to access study information and resources for diabetes management on our secure study website.

Approximately 3, 6, and 12 months later: You and your child will be asked to complete an additional set of questionnaires and we will collect your child's 14-day glucose data in the same way your child's doctor usually collects it. Each questionnaire will take about 20 minutes. Additionally, if you cannot obtain a lab-drawn A1c value (e.g. you have a telemedicine appointment), the study team will mail you a self-collection A1c kit. Similar to earlier, if there is no clinic setting A1c value recorded in your child's medical record in the prior three months, we will send your research A1c value to you via email and we will also inform your Children's National health care provider of the A1c value.



Regardless of which group you are in, you may also be invited to participate in two interviews with a member of the research team. The first interview is to get your feedback on things you liked and didn't like about the program. The second interview will focus on your experiences with using a CGM throughout your enrollment in the study. Each interview should last 20 minutes. They will be just like having a conversation, and there are no right or wrong answers.

If you choose to participate in the interviews, we will ask if you are willing to have the interview audio recorded. All interviews will be audio recorded so we can later hear your answers and conversations with the certified diabetes care and education specialist and ensure that our team is sharing information in the same way. We won't ask you to say your name or any other information that can identify you for the audio recordings. No one other than members of the research team will listen to the audio recordings, and all of the tapes will be kept in a safe place that only the researchers will use. After we have finished looking at the data, the audio recordings will no longer be used and we will get rid of them. You can still participate in the study if you do not want your medical visit or interview to be audio recorded or if you do not want to share your glucose data with our team.

I give my consent to have the program sessions be audio recorded as part of study protocol.

☐ Yes ☐ No

Print Name: _____

Signature: _____

I give my consent to be audio recorded during the interview as a part of study protocol.

☐ Yes ☐ No

Print Name: _____

Signature: _____

I understand that I may have the opportunity to speak with a parent coach who also has a child with Type 1 diabetes who uses a CGM. I understand that only my first name, telephone number, and email address will be shared with this individual. All other study and medical records will be kept confidential. I understand that if I am not willing to share this information with a parent coach, then I will not be eligible to take part in this research study.

I give my consent to provide my name, phone number, email and child's age to a parent coach.

☐ Yes ☐ No

Print Name: _____



Signature: _____

How long will my participation in the research study last?

Participation in this study will last about 12 months. If you or your child decides to stop being in the study, please let us know. Your participation in this study is voluntary, so you can change your mind at any time. When answering the questionnaires, you do not have to answer a question if you do not know the answer, feel uncomfortable with the question, or simply choose not to answer. If you change your mind about participating while you are completing the interview or questionnaires, the interview/questionnaires will be stopped and those records will not be used for the study and we will get rid of them. You can also change your mind about audio recording at any time. There will be no penalty or changes to your child's medical care if you decide to stop participating in the study.

What are the risks and possible discomforts from being in this research study?

Some questions will ask about your child's diabetes management and emotions. Sometimes thinking and talking about these subjects causes people to become upset. If you become upset, the study staff will give you names of people you can contact to help you deal with these issues. Also, if you agree to have your sessions audio recorded, you can also ask to turn off the recorder at any time during the visit if you feel uncomfortable discussing any information on tape.

In addition, there is a risk that your personal information could be shared. However, steps will be taken throughout the study to protect your privacy and keep your information confidential.

What are the possible benefits from being in this research study?

You will not benefit directly from taking part in this study. The things we learn from you might help other adolescents with type 1 diabetes and their families in the future.

What kinds of information will the study collect? Will any information be shared with me?

This study collects your responses to survey measures, and information from your child's medical record. Your responses will not be shared with anyone outside of the research team.

How will you protect my privacy if I take part in this study? Who will see the information that I give you?



Only study staff will know your name if you decide to participate in the study. Your name will be linked to an identification number, which will be used on your records.

Information passed on the internet will use a secure web-based system (REDCap) and will not include any identifying information. We will maintain a separate file to be able to link your survey responses with the medical record data we collect and destroy that link once the data are collected. We will keep all the records private on secured computers that only study staff use and have access to. Your information will not be given to anyone unless we have your permission in writing or if the law requires it. While no one's information can be guaranteed to be private, the team will work to protect all participant information.

During the interview and program sessions, we will not ask you to say your name or any other identifying information for the recording. A participant number will be assigned to you and the recording will be labeled with that number only. All identifying information such as your name or birthday will be removed from written transcriptions of the audio recording. Audio recordings will be stored on a secure computer network and only the research team will have access to these.

Your medical record is private but just like any medical record, there are some exceptions under state and federal law. The federal government can review the study records and medical records to make sure we are following the law and protecting the adolescents in the study. There are some government agencies or other groups that may check records that identify you without your permission. They might review the records of this study and your medical records to make sure we are following the law and protecting the children in the study. The agencies or groups who might see these records are the Office for Human Research Protections, Department of Health and Human Services, and the Institutional Review Board of Children's National Hospital (the ethics board that reviewed and approved this research study). The federal government can review the study records and medical records to make sure we are following the law and protecting the children in the study. One exception is, if you report the intention to harm yourself or others or if there is any evidence suggesting child abuse or neglect, we must report this as required by regulations. The result of this research may be presented at meetings or in publications. You will not be identified.

Identifiers might be removed from the private information/biospecimens and the de-identified information/biospecimens COULD BE used for future research or distributed to other investigators for future research without additional subject consent.

Certificate of Confidentiality

CoC will be issued as a term and condition of award

Sometimes people tell us some very personal information about themselves when they participate in a study and it becomes part of their research record. To help us protect



your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

- With this Certificate, the investigators cannot be forced (for example, by a court order or subpoena) to give information that may identify you in any federal, state or local civil or criminal court, or in any administrative, legislative, or other proceedings.
- It is important that you know that a Certificate of Confidentiality does not stop you or a member of your family from voluntarily giving information to others about yourself or your taking part in this research. You should also know that if an insurer or employer learns about your participation and you give them permission to receive research information about you, we cannot use the Certificate of Confidentiality to keep your information private from them. This means that you must also actively protect your own privacy.

Finally, it is important that you know that we are not prevented from taking steps to prevent serious harm to you or to others. If we learn that you or someone else is harming you or others around you, we may be required by law to report this to the police or a social services agency to get emergency help if it is needed

What other choices do I have if I don't want to take part in the study?

Your participation in this study is voluntary, meaning that if you do not want to participate, the only other choice would be to not participate. If you choose not to participate, that will not affect your relationship with Children's National Hospital or your right to health care or other services that you receive.

Will it cost me anything to take part in the study?

There are no costs for your participation in this study.

Will I be paid for taking part in this study?

You and your child will receive a small monetary incentive for participating in this study. After you and your child complete the first set of questionnaires, your family will receive \$20; your family will receive \$30 for completing the second set of questionnaires; your family will receive \$40 for completing the third set of questionnaires; and \$50 for completing the final set of questionnaires. Your child will receive \$10 each time for completing a self-collection A1c kit.

Your family will also receive \$10 for sending CGM reports or providing access to their blood glucose numbers. If you do participate one or both of the interviews, your family will receive \$10 for each completed interview.



All incentives will be on a ClinCard (prepaid debit card). ClinCard follows laws, like HIPAA, which protect your identifiable information. As you and your child continue throughout the study, money will be added to the card. You can use your ClinCard at an ATM or bank to get cash, or at any store to make a purchase. There is a fee for using the card at an ATM machine and there may be other fees, like monthly fees.

The study team will give you a ClinCard and forms with more information about how to use it and about specific ClinCard user fees. The Internal Revenue Service requires that any monetary payments totaling \$600 or more in a calendar year must be reported for tax purposes.

ClinicalTrials.gov

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Dr. Randi Streisand, Ph.D., and her research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

- Information that identifies you such as name, address, telephone number, date of birth, Social Security number, and other details about you
- Information that relates to your health or medical condition from your medical records
- Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as physical exams, blood and urine tests, x-rays and other tests, and any other medical information we learn from you about your health history and family history
- Laboratory results obtained on specimens collected from you (blood, urine, tissue)



- Questionnaires or surveys you complete
- Interviews conducted with you by members of the research team
- Audio/ video recordings
- Information about financial circumstances and educational level

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study
- Government agencies that have the right to see or review your PHI including, but not limited to:
 - The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP)
 - The Food and Drug Administration
- Children's National Medical Center Institutional Review Board
- Children's National Medical Center Institutional Quality Assurance Program
- Other staff in the Human Research Protections Program at Children's National Medical Center

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

Storage of PHI in a Database:

We would like to store personal health information collected from you in this study in a database for future research. The database is maintained by Dr. Randi Streisand, Ph.D., in the Department of Psychology.

Please indicate your approval of any or all of the following by checking a box next to each statement and initialing your choice:

- My personal health information may be stored in the above named database for future analysis related to this study.
☐ Yes ☐ No Initials _____
- My personal health information may be stored in the above named database for future analysis related to "Youth and family functioning, knowledge, and technology perceptions among adolescents with T1D using continuous glucose monitoring (CGM)".



☐ Yes ☐ No Initials _____

- My personal health information may be stored in the above named database. Researchers may contact me to request my authorization for future studies that are not related to this study or the disease named above.

☐ Yes ☐ No Initials _____

- My personal health information may be stored without any of my identifying information for use in other studies of other diseases.

☐ Yes ☐ No Initials _____

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name, address, telephone, or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and revoke this Authorization.

- If you revoke the Authorization, you must send a written letter to the Principal Investigator to inform her of your decision.

Randi Streisand, Ph.D.
Children's National Medical Center
Center for Translational Research
111 Michigan Avenue, N.W.
Washington, DC 20010-2970

- If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
- If you revoke this Authorization, your PHI may still be used and disclosed if you should have an adverse event (unexpected side effect).



- If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study.

You will not be allowed to review the information collected for this research study until after the study is completed. If you are not allowed to review your information during participation in the study, when the study is over you will have the right to access the information.

This Authorization expires at the completion of the study.

If you have not already received a Notice of Privacy Practices from Children's National Medical Center, you may request a copy and will be given one. If you have any questions or concerns about your privacy rights, you may contact the Children's Hospital Privacy Officer at 202-476-6464.

Whom can I call if I have questions about this research study?

We want you to ask questions about any part of this research study at any time.

- For questions about the study or the information in this informed consent/parental permission document, call the Principal Investigator, Randi Streisand, PhD, at (202) 476-2730.

Whom can I call if I have questions or concerns about my rights as a research study participant?

The Children's National Office for the Protection of Human Subjects is available to talk with you about:

- Your rights as a research participant
- Your concerns about the research
- A complaint about the research

This is the administration office for the Institutional Review Board, which is a group of doctors, nurses, and non-medical people who review research studies for safety and the protection of people who participate in research. You can call the Office for the Protection of Human Subjects at 301-565-8447.

Children's National has a research participant and family advocate. The advocate is here to answer your questions or concerns about taking part in this research. The advocate does not work for the doctors who are doing this research and is not paid by the researchers. The advocate is here only to help and protect you during any research.



You may contact the research advocate at any time. This can be done before you decide to take part in the research, during the study, or even after you finish the study. You can contact the research advocate at 202-476-5586 or by email at

RSA@childrensnational.org. In urgent situations the research advocate and pediatric ethics program team can be reached at the pager number: 202-259-2082.

CONSENT/PARENTAL PERMISSION:

- I am the study participant or I am authorized to act on behalf of the participant.
- I have read this consent form or had it read to me.
- I have been invited to take part in a research study. I was told why the research is being done and how long my participation in the study is expected to last. I was told about what will happen in the study and if there are any procedures or drugs that are experimental.
- I was told that taking part in this research is voluntary. I also was told that I can decide not to take part or stop being in it at any time without any penalty to me or any change to the quality of care I receive at Children's National.
- I was told about the risks and possible discomforts of taking part in this research study. I was also informed if there are any possible benefits to me if I am in this study.
- I have been given the chance to ask questions about the study, and my questions have been answered. If I have questions later, I can ask one of the people listed in this form.
- I agree to take part in this research study.
- I will receive a signed copy of this Informed Consent/Parental Permission form to keep.

Signature of Parent(s)/Guardian(s) for participant under the age of 18 years

Printed Name of Participant: _____

Printed Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____

Date and Time: _____ a.m. / p.m. (circle one)



Signature of adult participant (18 years of age and older)

Printed Name of Participant: _____

Signature of Participant: _____

Date and Time: _____ a.m. / p.m. (circle one)

AFFIDAVIT OF PERSON OBTAINING CONSENT / PARENTAL PERMISSION:

I certify that I have explained to the above individual(s) the nature and purpose of the study, possible risks, and potential benefits associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Person Obtaining Consent: _____

Research Role: _____

Signature: _____

Date and Time: _____ a.m. / p.m. (circle one)

AFFIDAVIT OF PERSON OBTAINING ASSENT FROM A 7-11 YEAR-OLD CHILD:

- I have explained all aspects of the research study to the child participant to the best of his/her ability to understand.



- I have answered all of the child participant's questions relating to the research study.
- I believe the child participant's decision to enroll is voluntary.
- The study doctors and study staff agree to respect the child participant's physical or emotional dissent at any time during this research study when that dissent pertains to anything being done solely for the purpose of the research.

Printed Name of Person Obtaining Assent: _____

Research Role: _____

Signature: _____

Date and Time: _____ a.m. / p.m. (circle one)

