Supporting Parents of Young Children with Type 1 Diabetes in Closed-Loop System

Version 1.2

October 27, 2017

Synopsis of study protocol
This is study seeks to evaluate interventions to improve glucose control and adherence of young children and their families using a hybrid closed loop system in the home environment throughout the day and night.

We will enroll patients who are in the follow-up/continuation phase of the IRB and FDA approved Medtronic CEP302 study (IDE# G150247**,** NCT02660827). Subjects in this study are using the Medtronic 670G hybrid closed loop insulin delivery system, but have completed the trial period of the protocol.

This protocol is the addition of an educational/behavioral intervention(described below) designed to optimize their use of the hybrid closed loop system for their diabetes control. This is not a device intervention, and no IDE is required (since all subjects aree enrolled in the Medtornic CEP302 study).

This adaptive study design employs the possibility of subsequent randomizations if pre-designated targets are not reached. All participants will be ages 2-6 years old and in the continuation phase of the Medtronic CEP 302 Trial using the Medtronic MiniMed 670G pump with Guardian 3 sensor. All subjects will receive the same standardized education on using the pump with hybrid closed loop capabilities and continuous glucose monitoring (CGM) during the initial Medtronic CEP 302 trial phase. A review session will also take place as they enter the extension phase of the study which is the beginning of this study. Their uploaded data will be reviewed every two weeks and if they are not meeting adherence (≥ 70% of the time in closed-loop) and glycemic target goals (≥ 65% of sensor values between 70 - 180 mg/dL), they will be randomized to six interventions: 1) reduce psychological distress, 2) reduce worries about hypoglycemia, 3) education and understanding of developmental and technologic demands for using hybrid closed loop this age group, 4) understanding and modification of carbohydrate to insulin ratios, set point and in depth nutritional education, and interventions 5) and 6) will be minimal interventions with a text message providing information on how they are doing at meeting their targets. All these interventions will be compared to a minimal intervention (text of their results compared to target goals). We will examine group differences over a 3-month period on health and psychological outcomes at baseline and after three months.

Objectives: The objective of this study is to assess several remote interventions with families in the extension phase of the 670G toddler study to determine which interventions are most effective in improving their time in target (70-180 mg/dl) and their adherence in maintaining closed-loop control (at least 70% of the time in closed-loop).

Sample Size:

- We anticipate enrolling at least 4 subjects at each of the current sites, and would like to expand the number of sites to include Yale, and the University of South Florida. Each of these sites is scheduled to enroll at least 4 toddlers, and some will enroll up to 8. We therefore anticipate being able to enroll at least 30 subjects. A sample size of 26 subjects should allow for a statistically significant result with a power of 0.9 and a p of 0.05. Enrollment of 30 subjects would allow for a 10% drop out rate. See Biostatistics and Data Analysis section.

Sample size and power calculations were conducted with consideration of a clinically meaningful change in the primary outcome – percent time in target range – and the feasibility of enrolling participants from the continuation phase of the 670G trial. Each site has the potential to enroll up to 8 toddlers, and we expect that 70 to 80% would opt for the continuation phase and to be enrolled in the proposed study.

The primary outcome is the percent change in the amount of time spent in the target glucose range from baseline (prior to automated glucose control) to study completion. Data from our CGM study with toddlers (NIDDK funded DP3; Buckingham PI) show that of the sixteen 2-6 year-olds in the study, they achieve on average only 45% time in 70-180 mg/dL target range (standard deviation = 15%). Our hypothesized change will be a 10% improvement in time spent in target range. There is sufficient power) to detect this change in a sample size of 26. Another aspect of calculating power in this study is the actual number of participants exposed to the planned interventions after a glucose "failure." Over 90% of the participants in our DP3 toddler study experienced a glucose failure of less than 60% time in target range. Further, the table below shows the results of glucose failures from the DirectNet cohort of toddlers using CGM (Ped Diabetes 13:301-7, 2012).

Table 1. Expected Failure Rates

	Months						
	0	1	2	3	4	5	6
Glucose Failure (not having at least 65% of readings in the 70-180 mg/dL range)	-	70%	70%	70%	70%	75%	75%

Study Procedures

Participants will be recruited at 5 centers: Stanford University, the Barbara Davis Center for Diabetes, University of Colorado (referred to as Denver), Yale University, Indiana University, and University of South Florida. We expect to enroll 40 families total and attempt to have roughly equal enrollment at each site (ie. 4 to 8 at each site). Only families who have completed the Medtronic CEP 302 Trial and opt to participate in the continuation phase will be eligible for this study. Study staff will approach potential participants to explain the study, determine eligibility, and obtain informed consent.

The study design is adaptive, specifically a SMART (sequential multiple assignment randomization trial). A SMART is an adaptive study design that allows for multiple assessments and based on the results of those assessments, a menu of interventions can be deployed. To ensure that there is no bias when interventions are delivered, and to have a test of whether those who receive the intervention fare better (or worse) from those who do not receive the intervention, a randomization strategy is used. The decision to use a SMART was primarily made because this is what happens clinically – a child (and family) start on a system with a certain dose of education and when problems arise, the clinical team offers interventions to optimize their use of the system. The SMART allows us to test which interventions are best for this patient population that presents many unique challenges for diabetes management and coordinated care from the team.

All participants will complete a *checkpoint* visit every 2 weeks for the duration of 3 months. At each checkpoint in the study (weeks 2, 4, 6, 8, and 10), data from the preceding 2 weeks will be reviewed to determine if there have been "failures." Data will be available through pump uploads and by asking caregiver participants the frequency of wearing the devices. Objective data will guide determination of failures. We are defining failure in the following ways:

1) Adherence Failure: defined as using the hybrid closed loop "Auto Mode" less than 70% during a week
2) Glucose Failure: defined as less than 65% time spent in glucose range of 70 - 180 mg/dL.

If subjects pass both the adherence and glucose targets, no intervention is required. If there is an Adherence Failure, they will be eligible for an adherence intervention. The adherence interventions

will be randomized by order and the sequence of interventions will depend on whether a previous intervention has been administered. The participant may receive a minimum of zero adherence interventions over the 3 month period to a maximum of 5 adherence interventions during the 3 month period. A similar sequence of interventions will occur if patients experience a Glucose Failure. Finally, if subjects have both an Adherence Failure and a Glucose Failure at a checkpoint, they will enter the adherence intervention pathway. They will continue on this path until they have completed all three possible interventions. After this time, if they continue to failure both adherence and glucose targets, they will enter the glucose target intervention pathway. We decided that an adherence failure trumps a glucose failure because using the Auto Mode function is critical to opening the door to achieving glucose targets.

The figure below shows the possibilities at each 2-week checkpoint.

Figure 1. Potential interventions at 2 week monthly visit

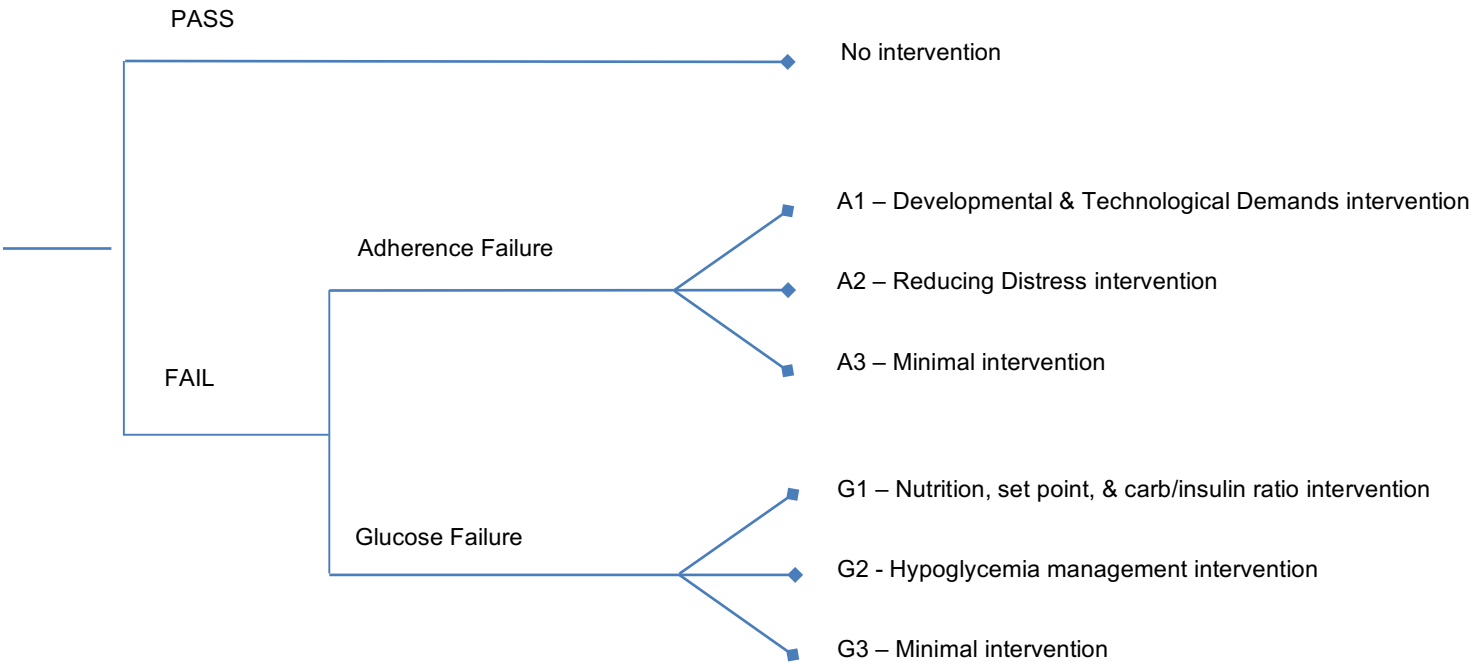

Figure 1 above graphically depicts the treatment scheme for participants in the SMART. Below, the conditions and possible scenarios are described in more detail. As a reminder, there are five checkpoints (2, 4, 6, 8, and 10 weeks). At each checkpoint, here are the possible scenarios. A = adherence; G = glucose range; and R = randomization below:

1. If 1st A failure, R to A1, A2, or A3
2. If 2nd A failure (ie., there was a previous A failure), and a history of A3, R to A1 or A2
3. If 2nd A failure, with history of (respectively) A1(A2) give A2(A1).
4. If A success, 1st G failure, R to G1,G2,G3
5. If A success, 2nd G failure, w/ history of G3, R to G1,G2
6. If A success, 2nd G failure, w/history of (respectively) G1(G2) give G2(G1).
7. All else, no treatment.

As noted above, an Adherence Failure is defined as use of Auto Mode for less than 70% of the time at a checkpoint. A Glucose Failure is defined as spending less than 65% of the time in the 70 - 180 mg/dL range at a checkpoint. Also note that the final visit at 3 months is the end of the study and no interventions are offered at that study visit.

Study Group

All participants will be using the Medtronic MiniMed 670G pump with Guardian 3 continuous glucose monitor. All participants will be given the same systematic review on the use of these devices and hybrid closed loop function. This review session will take approximately 30 minutes. A person trained in delivering education about this pump and sensor will deliver the education at the first visit. This individual will be available to assist with questions from participating families.

Behavioral Interventions

The table below lists the interventions, their targets, and how each intervention will be utilized as supports for parents of young children with T1D using diabetes devices. Of note, these interventions are delivered when there are adherence or glucose failures and are intended to be delivered online or over the phone.

Intervention Name	Intervention Goal	Frequency / Dose	Interventionist
Developmental & Technological Demands	Provide education on using diabetes technology in various settings and formats in this age group, and increase ability for real-time problem-solving. Identify and troubleshoot barriers to keeping young children in Auto Mode	Two ≤30 minute sessions delivered over a one-week period.	CDE, medical personnel, or psychologist on study team, with advanced training on the use of the Medtronic 670G pump and experience in diabetes, behavior, young children, and parenting.
Distress Reduction	Identify and reduce parent distress symptoms and worries. Provide strategies for obtaining social support.	Two ≤30 minute sessions delivered over a oneweek period.	PHD psychologist with advanced training and experience in diabetes, behavior, young children, and parenting.
Nutrition, Set Point, & Carb/Insulin Ratio	Provide education on a variety of properties of food and how they affect blood glucose levels. Optimize the use of carbohydrate to Insulin ratios, insulin duration of action, and use of temporary target glucose set point in the 670G pump and the Quick bolus feature to gain better glycemic control	Two ≤30 minute sessions delivered over a one-week period.	CDE or medical personnel with advanced training in nutrition, diabetes and experience in the use of the Medtronic MiniMed 670G pump.
Hypoglycemia management	Focus on hypoglycemia management to avoid hyperglycemia, review fear of hypoglycemia	Two ≤30 minute sessions delivered over a one-week period.	CDE, medical personnel, or psychologist on study team, with advanced training and experience in diabetes, behavior, young children, and parenting.
Minimal Intervention	A short communication detailing the percentage of time spent in range and in Auto Mode and if the goals have been met	An email or text message sent weekly during the two-week period	CDE or medical personnel on study team

Optimize Adherence Interventions

Below are brief descriptions of the interventions.

Developmental and Technological Demands Intervention

There are no existing interventions that target the uptake and promotion of diabetes technology for parents of young children with T1D. Further, no interventions provide education and skill-building on how to use these devices and technologies across multiple settings (e.g., school, home, social activities) and by multiple formats (e.g., direct monitoring vs. remote monitoring). Becoming more comfortable with using these devices (specifically the Medtronic 670G pump and Guardian 3 sensor) in multiple settings should help to promote adherence to device use. We will continue to take advantage of several important themes. First, those individuals with more comfort with technology in general (e.g., smartphones and computers), are more comfortable and better equipped when using specific technology for managing health. Second, mobile technologies (apps and text messaging, for example) and programs that support the use of diabetes technologies are effective in increasing adherence to management tasks. The third theme and necessary component of this intervention will be to teach a brief 3-step rubric for solving problems: 1) identify the problem, 2) chose a solution decided on by the parent and interventionist, and 3) monitor for results at the next session. These sessions will specifically address some of the difficulties with keeping a child in Auto Mode. They will cover the most common reasons for getting kicked out of Auto Mode and discuss strategies to maximize the time spent in Auto Mode. The Developmental and Technological Demands intervention will include two ≈30-minute sessions.

Distress Reduction Intervention

Many parents of young children with T1D express worries, fears, concerns, and distress over many aspects of diabetes management. The Distress Reduction intervention targets 1) the identification of and reduction of parent anxiety/depressive symptoms (general and diabetes-specific) and 2) increasing access to and attainment of social support. It will also be delivered in two ≈30-minute sessions online (or over the phone if online is not available). Multi-media approaches will also be used in this session. We recognize this dose of an intervention is not intended to completely remove all parent fears and worries, nor will it fully connect them to a network of support. However, it is intended to reduce fears/worries and provide avenues for obtaining support that *do enough* to help them maintain adherence diabetes devices.

Glucose Targets Interventions

Below are brief descriptions of the interventions. Each intervention will be recorded using Blue Jeans to capture the content delivered and duration of the intervention.

Nutrition, Set point, and carbohydrate/Insulin Intervention and insulin duration of action

These sessions will focus on how different factors affect blood glucose levels. Education on how combinations of proteins, fats and carbohydrates can be used to extend the release of glucose into the body will be discussed. We will also provide training on adjusting carbohydrate to insulin ratios to achieve better glycemic control. In addition we will address the target glucose set point of the 670G pump and how this can be changed during periods of activity to modulate insulin delivery. We will also review and potentially intervene with the duration of insulin action as an adjustable parameter to be either more aggressive or less aggressive with correction doses. The duration of action can be modified to allow more aggressive correction bolus, or to decrease correction doses if there is a risk of hypoglycemia. For young children for whom insulin is given immediately after eating (because the amount of food they will eat is unknown), the Quick bolus may be an option. Each session will last up to 30 minutes and be delivered online or over the phone.

Issues with Hypoglycemia

These sessions will primarily focus on parental concerns about hypoglycemia. In this age group we believe the major focus will be on fear of hypoglycemia, but we will also provide education and support on safely reducing hyperglycemia. Since many of these families may have previously used the Dexcom share with remote monitoring, we will discuss how they may or may not be using the Dexcom Share for remote monitoring since this feature is not available on the 670G pump. We will review their fears and the child's past severe hypoglycemic events, and what they have read and heard from friends and support groups. We will teach parents the links between fears/worries and diabetes behaviors (e.g., fear may lead to hyper vigilance which in turn causes more stress and burnout). We will provide behavioral strategies for monitoring for hypoglycemia (and hyperglycemia) at regular intervals, steps to problem solve unexpected high and low blood sugars, and basic efforts at sleep hygiene. These sessions have the same format (two ≈ 30-minute sessions delivered online or over the phone).

Minimal Intervention

The randomization to minimal intervention will be present in both the Adherence arm and Glucose arm. In this intervention the parent will receive either an email or text message that details what percentage of the prior two weeks spent in Auto Mode, percentage of time below, within, or above target glucose range, and whether they met the study goals for these areas. If they have concerns about their management, they are of course instructed to contact their study coordinator or study PI.

Study Visits and Measurements

In person study visits for all participants will occur at baseline (0 weeks) and 12 weeks. These are the pre and post assessments that include all measures in table 2 below. Briefer assessments (or checkpoints) are completed at 2 weeks intervals. These visits should be within ±1 week of the scheduled visit. Any behavioral interventions delivered will be done remotely and will not require an in-person visit. All of the questionnaires will be completed online via RedCap.

Table 2. Timeline and Components of Study Visits and Checkpoints

Visit/Checkpoint	1	2	3	4	5	6	7
Study Time:	0	2w	4w	6w	8w	10w	12w
In-person or remote	In-person	Phone	Phone	Phone	Phone	Phone	In-person
History (medical and demographic)	X						
Review of using Medtronic MiniMed 670G pump and Guardian 3 Sensor	X						X
Adverse Events such as severe hypoglycemia		X	X	X	X	X	X
670G uploads	X	X	X	X	X	X	X
HbA1c	X						X
Full Psychosocial Questionnaires	X						X

Checkpoint for Adherence and Glucose Failures		X	X	X	X	X	X

Table 3. Assessment battery completed by Parents

Measure	Construct Measured / Relevant Points	Number of Items / Time to Complete
Psychosocial Outcomes		
Parents' Diabetes Distress	The Problem Areas in Diabetes, Pediatric version (PAID-P). The PAID-P is a validated tool used to assess parental burden related to diabetes management. The Parent Diabetes Distress Scale (PDDS). This is a validated tool to assess how diabetes care impacts on parents' quality of life.	18 items. 5-10 minutes to complete. 21 items, 2 – 3 minutes to complete.
Parents' Psychological Distress	The PHQ-8 and the State-Trait Anxiety Inventory will be used to assess depressive and anxiety symptoms. These symptoms represent the general construct of psychological distress.	8 items on PHQ-8 (5 minutes) and 40 items on STAI (10 minutes)
Parents' Sleep Quality	An abbreviated version of the Pittsburgh Sleep quality Index, a validated tool for assessing self-reported sleep quantity and quality, will be developed for this project.	10 items, 2 – 3 minutes to complete.
Parents' Hypoglycemic Fear	The Hypoglycemic Fear Survey-Parents (HFS-P) is a validated tool to assess parents' anxiety and behavior concerning possible hypoglycemia.	18 items, 5 – 10 minutes to complete
Parents' Hypoglycemic Confidence	A new version of the Hypoglycemic Confidence Questionnaire, modified for use by parents, will be developed for this project.	8 items, 2 – 3 minutes to complete
Health-related quality of life	Parents will complete the diabetes specific version of the Pediatric Quality of Life Inventory (PedsQL) to provide a report of their perception of the child's quality of life. This cuts across social, emotional, academic, and health domains.	23 items. 5-10 minutes to complete.
Satisfaction with Glucose Monitoring	The Glucose Monitoring System Satisfaction Survey (GMSS-T1D) is a validated tool used to assess treatment satisfaction with glucose monitoring devices and its impact on quality of life and other patient-reported outcomes.	15 items. 5-10 minutes to complete.

Use and Comfort with Technology	Objective questions documenting the frequency of use and types of technologies used. Both general (e.g., smartphone) and diabetes-specific (e.g., trend program).	23 items. 5 minutes to complete.
Demographic and Family Data	Parents will complete a questionnaire on the family's structure, racial and ethnic background, indicators of socioeconomic status, insurance status (public vs. private), and other essential characteristics.	5 minutes
Behavioral Outcomes		
Diabetes management behaviors	Amount of time spent in Auto Mode; blood glucose monitoring frequency (by meter download); adherence to pump boluses;	Download (no time burden for participants)
Health care utilization	Number of visits and calls to the diabetes care team	Tracking by interview (10 minutes to complete)

Table 4. Measures obtained from child

Health Outcomes		
HbA1c measurement	Participants will provide a small fingerstick sample of blood (capillary) during their routine clinic visit. This will be done using the DCA in clinic or local lab method.	Gold standard measure of glycemic control
Glycemic excursion measures	Time in range (70 to 180 mg/dL); percent below 70 and 60 mg/dL as indicators of hypoglycemia, and above 180 and 250 mg/dL as indicators of hyperglycemia; additional indices of variability including standard deviation will also be calculated	

In addition, parents will be asked to complete a brief online survey (< 10 minutes) at the following intervals since randomization – 4, 8, and 12 weeks. These online surveys will consist of the Diabetes Distress Scale (3 items), PHQ-8 (8 items), and the short form of the STAI (10 items). All surveys can be completed online via RedCap.

Schedule

Stanford IRB approval will be in March, 2017. Upon entering the extension phase of the toddler 670G study subjects will be recruited for this study. We anticipate this will begin occur between July through August of 2017. The study will have a 3 month duration so we anticipate completing the study in September through December of 2017.

Biostatistics and Data Analysis

This is a pilot and feasibility study aimed at determining preliminary efficacy of interventions to optimize the use of the 670G hybrid closed-loop in toddlers. It will allow assessment of the effect of specific interventions on improving use of the system and improving glucose control. In addition, collection of these data will allow us to determine personnel demands and timing of interventions worth pursuing in a larger clinical trial. Our team has extensive experience in database design and implementation, use of web-based assessment, data management, and data analysis. We will utilize the RedCap survey system to format all measures in to electronic form for completion online or in-person via computer or iPads. Data collected from participants will be housed on the RedCap server, which is encrypted and HIPAA-compliant, with secure access for unique study IDs assigned to each participant. RedCap survey data is then ready for download by study staff and will be imported to SAS 9.3 for data cleaning and analysis.

Sample size and power calculations were conducted with consideration of a clinically meaningful change in the primary outcome – percent time in target range – and the feasibility of enrolling participants from the continuation trial. Each site has the potential to enroll 4 to 8 subjects in the primary study, and we expect that 70 to 80% would opt for the continuation phase and to be enrolled in the proposed study.

The primary effect we are interested in is percent change in the amount of time spent in the target glucose range from baseline to study completion. Data from our CGM study with toddlers (NIDDK funded DP3; Buckingham PI) show that of the sixteen 2-6 year-olds in the study they achieve, on average, only 45% time in 70-180 mg/dL target range (standard deviation = 15%). Our hypothesized change will be a 10% improvement in time spent in target range. There is sufficient power (0.9) to detect this change in a sample size of 26. Another aspect of calculating power in this study is the actual number of participants exposed to the planned interventions after a glucose "failure." Over 90% of the participants in our DP3 toddler study experienced a glucose failure of less than 60% time in target range. Further, the table below shows the results of glucose failures from the DirectNet cohort of toddlers using CGM (Ped Diabetes 13:301-7, 2012).

Table 1. Expected Failure Rates

	Months						
	0	1	2	3	4	5	6
Glucose Failure (not having at least 65% of readings in the 70-180 mg/dL range)	-	70%	70%	70%	70%	75%	75%

The SMART design of our proposed study allows for randomization to one of 3 conditions when there is a glucose failure (2 interventions and 1 control). Because of this, participants can contribute to more than one comparison which increases power. This makes the SMART design very efficient, particularly when examining multiple treatment strategies, which is what clinicians do in these cases. Our primary outcome will be Glucose Failure, which we expect 80-90% of participants to experience. With 27 participants available for randomization after a Glucose Failure and each subject assigned at least once to each of the three intervention groups, there is only 73% power to detect a difference of 10% change in time spent in range for a given intervention. In other words, going from 45% time spent in range at baseline to 55% time spent in range at study completion; an outcome of 10% change. Thus, while the percent change in the sample from baseline to the end of the continuation phase does appear to be adequately powered for the group, the testing of individual interventions is underpowered. We will proceed with caution when estimating likely effect sizes for each intervention based on the results of the planned analyses.

Our primary outcome will be tested in two ways. First, by using latent growth curve models to compare change in response to treatment strategies, we can examine outcomes from checkpoint to checkpoint. For example, we can test percent change in time spent in range from week 2 to 4 and determine which intervention is associated with promotion of change during that time period. Because more than three time points are available in this study, nonlinear trajectories will also be examined. Second, we will also examine the treatment effect using separate individual trajectory models for the primary outcome across the entire 3 months of the study. These analyses will inform more precise sample size considerations based on observed effect sizes for a larger efficacy trial conducted after this proposed research is completed.

Study population

The patient population is children with type 1 diabetes and their parents who are actively enrolled in the IRB and FDA approved Medtronic CEP302 study (IDE# G150247**,** NCT02660827**)** . Parents (18 years and older) will provide informed consent for their own participation and parental permission for their child to participate. We will enroll and randomize 40 families.

Eligibility criteria

To be eligible for the study, a child must meet the following criteria:

1. Enrollment in the continuation phase of the Medtronic CEP 302 study
Ages 2 to <7.0 years of age

Expected duration of the study participation

Duration of study participation is expected to be three months.

Start Date: As early as September, 2017.

End Date: As late as September, 2018

Adverse Event Reporting and Safety Monitoring

Overview of Safety Monitoring

All participants will have glucose data reviewed at planned intervals for study adherence. All of the other medical monitoring of these subjects are done as part of the IRB and FDA approved Medtronic CEP302 study (IDE# G150247**,** NCT02660827)

Definition of Adverse Event

Adverse event reporting and definitions for these research participants will be defined and carried out via the IRB and FDA approved Medtronic CEP302 study (IDE# G150247**,** NCT02660827), as these encompass all the inherent risks of Type 1 Diabetes, insulin pump use, and continuous glucose sensor use.

Recording of adverse events

Reportable adverse events and serious adverse events are defined and carried out in accordance with the IRB and FDA approved Medtronic CEP302 study (IDE# G150247**,** NCT02660827

Data and safety monitoring

Data and safety monitoring will be carried out in accordance with the IRB and FDA approved Medtronic CEP302 study (IDE# G150247**,** NCT02660827. There is no additional safety monitoring due to the educational intervention described here.

Potential risks and side effects

Loss of confidentiality is a potential risk, and is protected by the safeguards discussed above.

Psychological and human factors testing may make study participants uncomfortable. Subjects are free to withdraw from the study at any time. A psychologist or a health care professional will be available to help them with their stress or anxieties.

Distress or discomfort experienced by participants as they complete surveys is not considered an adverse event. However, we have trained psychologists on staff who will be available to address any distress or discomfort and initiate referrals if requested.

Adequacy of protection against risks

Recruitment and informed consent

All minorities will be encouraged to participate. Economically and educationally disadvantaged people, parents who are employed at the clinical center (Stanford, the University of Colorado, Indiana University, Yale University, and University of South Florida) will be eligible to enroll their child in this study if they meet all the study criteria.

Participation will be voluntary and all participants must provide consent prior to inclusion in this research study. The primary investigator at each of the participating clinical sites, or one of their designees, will explain the nature, purpose, expected duration, and risks of study participation to each eligible family. The primary investigator at each site, or one of their designees, will also obtain consent and authorization for the release of personal information.

Protections against risk

All protocols and consent documents will be approved by the local IRB at each clinical site.

Study stopping criteria

Individual subjects will be removed from the study if they are removed from the CEP302 study

Miscellaneous Considerations

Benefits

It is expected that this protocol will yield knowledge about the impact of closed-loop insulin pump on families with young children with type 1 diabetes. The introduction of a closed-loop system might allay parents' fears, ease their sense of diabetes-related distress and foreboding, and impact glycemic variables, however there is no guarantee of any benefit from participating in this research study.

Subject compensation

There will be no cost to the subjects to participate in this research study. Parents will receive $50 for each of two surveys, completed at the enrollment and final visits. In total, a family can receive $100 for completion of the study.

Subject withdrawal

Participation in the study is voluntary, and a subject may withdraw at any time. The investigator may withdraw a subject who is not complying with the protocol. For subjects who withdraw, their data will be used up until the time of withdrawal.

Confidentiality

For security and confidentiality purposes, subjects will be assigned an identifier that will be used instead of their name. De-identified subject information may also be provided to research sites involved in the study.

Level of risk
This research proposal in children is consistent with 21 CFR 50.51 - Clinical investigations involving not involving greater than minimal risk

Devices

There are no study devices other than those used in the IRB and FDA approved Medtronic CEP302 study (IDE# G150247**,** NCT02660827)