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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-34857
Status: Approved
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Approval Period: 3/1/2019 - 2/29/2020

Section Aa: Title & PI

A1. Main Title

PROMOTING RESILIENCE IN YOUTH WITH TYPE 1 DIABETES: PILOT OF A STRENGTHS-BASED FAMILY INTERVENTION TO IMPROVE DIABETES OUTCOMES

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

A6a. Institution(s) where work will be performed:

TCH: Texas Children's Hospital

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
Yes

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

The incidence of pediatric T1D in the United States is growing, with a projected prevalence of nearly 600,000 youth under age 20 diagnosed by 2050. The demanding diabetes management regimen requires constant vigilance and many complex management behaviors throughout the day and night, including frequent blood glucose monitoring, precise calculations of insulin doses, multiple insulin administrations via injections or an insulin pump, and attention to nutrition and physical activity. During adolescence, the responsibility for diabetes management begins to gradually shift from parents to youth. Declines in adherence to the diabetes regimen and in glycemic control are common, and parents and teens report increasing diabetes-related distress and family conflict during this period. Extended periods of out-of-range glycemic control raise the risk for health complications in young adulthood. Across pediatric diabetes care centers, there is a growing emphasis on preparing youth for successful transition to adult diabetes care, a primary goal of which is to equip adolescents with the skills and confidence for effective, independent self-management.

Decades of clinical diabetes research have identified contributors to suboptimal diabetes management and glycemic control in adolescence. Risk factors include depressive symptoms, ¿diabetes burnout¿ and distress, poor health-related quality of life, diabetes-related family conflict, and parental diabetes burden. Additionally, glycemic disparities across racial and economic groups are difficult to modify and leave many youth at risk for poor outcomes. There is also a growing interest in identifying protective factors associated with good diabetes outcomes. The emerging field of ¿Diabetes Resilience¿ focuses on adaptive behaviors that promote high quality of life, good treatment adherence, and in-range glycemic control despite the challenges and risks associated with having and managing T1D. Protective behavioral skills include effective problem-solving, adaptive coping, and constructive communication. Similarly, the ongoing involvement of parents in adolescents¿ diabetes management is protective, provided it is supportive, collaborative, and responsive to youths¿ changing developmental needs.

Empirically supported behavioral diabetes interventions include Behavioral Family Systems Therapy for Diabetes, Family Teamwork, Diabetes Coping Skills Training, and Multisystemic Therapy for Diabetes. These interventions have resulted in improved self-management skills, adherence, and glycemic control, and the involvement of parents in these interventions

highlights the central role of families in effective diabetes management in adolescence. However, the clinical impact of these interventions has been modest and benefits have been difficult to maintain. Most existing interventions aim to minimize the deleterious impact of risk factors and prevent poor diabetes outcomes by teaching new skills to address specific diabetes problems or challenges. Fewer aim to promote resilience and optimal diabetes outcomes by explicitly identifying, reinforcing, and building upon youths¿ and families¿ existing skills and strengths. Two recent behavioral diabetes interventions emphasize the positive aspects of youths¿ diabetes management. De Wit et al. and Viner et al. focused on issues that youth reported were currently going well in relation to their T1D. Both studies may be classified as ¿monitoring plus feedback¿ interventions, in that youth completed questionnaires (monitoring) about positive aspects of their diabetes management (i.e., health-related quality of life, diabetes self-efficacy) and received feedback from health care providers about their responses. Improvements in quality of life and glycemic control were reported and suggest that strengths-based ¿monitoring plus feedback¿ interventions hold potential for enhancing critical diabetes outcomes. This represents a promising next step for further development and evaluation of family-centered, resilience-oriented diabetes interventions that can complement and extend the impact of existing approaches on the clinical and behavioral outcomes of adolescents with T1D.

Limitations of traditional research interventions include that they are often time- and resource-intensive and require delivery by specialized highly trained interventionists. With rising healthcare costs and tighter margins for healthcare delivery systems, brief yet cost-effective interventions that make use of existing resources and clinical infrastructure are needed. There is increasing demand for patient- and family-centered care that focuses on value and quality, and that is accountable to both clinical and patient satisfaction outcomes. Thus, the next generation of behavioral diabetes interventions must not only improve glycemic and behavioral outcomes, but also demonstrate respect for patients and families, strengthen patient-provider relationships, and increase the value of healthcare delivery.

Section D: Purpose and Objectives

The purpose of the current proposed study is to pilot test a newly developed strengths-based clinical intervention delivered by diabetes care providers in the context of routine ambulatory diabetes care, designed to promote resilience and support diabetes management among adolescents with T1D and their families. The emphasis of the intervention is shifting the tone of clinical encounters for diabetes care to emphasize and reinforce youths¿ and families¿ current strengths and positive diabetes management behaviors. Youth with T1D are seen routinely in clinic every 3-4 months, and this intervention will occur at two consecutive clinic visits. The intervention consists of: (A) assessing youth and family diabetes strengths and adherence prior to each visit, and (B) training diabetes care providers to tailor their clinical encounters around reinforcing each patient and family¿s unique ¿diabetes strengths profile¿ generated from the strengths and adherence assessments. With its foundation in the Diabetes Resilience Model this intervention focuses on building diabetes resilience by strengthening existing protective behaviors of youth and families and by establishing supportive, patient-centered processes within the healthcare system.

The specific aims of the proposed pilot study are to: Aim 1: Assess the feasibility and acceptability of this strengths-based family intervention. Hypothesis 1A: The intervention will be feasible to conduct in the context of an ambulatory diabetes care clinic and adolescents, families, and providers will report the intervention to be highly acceptable.

Aim 2: Evaluate preliminary intervention impact on clinical outcomes, behavioral diabetes management, and patient satisfaction. Hypothesis 2A: Diabetes regimen adherence will increase and glycemic control will improve (i.e., HbA1c will decrease) from pre- to post-intervention (4-month intervention period). Hypothesis 2B: Adolescents and families will report decreased conflict, decreased diabetes burden, increased diabetes resilience, and increased satisfaction with diabetes care from pre- to post-intervention.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Adult (18-64 yrs), Child (3-12 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:

Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Potentially eligible participants will be identified by reviewing scheduled appointments for participating diabetes care providers 6-8 weeks in advance. All patients of these providers will be screened for eligibility criteria, and potentially eligible families will be mailed an informational letter about the study. The informational letter will also include a copy of the consent form and an addressed stamped envelope for the family to return the signed consent if they choose to enroll in the study. A study phone number and email address will be provided for families to contact should they wish to opt-out of being recruited for the study. For potential participants who do not opt-out after receiving the letter, three-four weeks prior to the scheduled clinic appointment, study staff will call each family to describe the study, answer questions, and obtain informed consent.To obtain verbal consent, study staff will speak with at least one parent/legal guardian and with the adolescent. If available by telephone, a second parent/legal guardian will also be invited to participate. Families will be asked to also provide written consent on the consent form that was mailed to them, and to return it via fax, scan/email, or with the enclosed stamped envelope. Verbal consent and documentation of written consent are necessary because participants will be asked to complete questionnaires at home via web-survey prior to the study visit. If a second parent/caregiver has not provided consent or completed baseline questionnaires via web, but is present at the clinic visit, and if he/she wishes to participate, he/she will provide written consent and will have an opportunity to complete questionnaires at that time. Study staff will meet with families in a secluded and relatively private area of the waiting room ¿ or, if available, in a private consultation room in the clinic space. The study staff member will provide the family with a duplicate copy of the consent and assent forms for their records. To protect confidentiality, a study ID number will be assigned to the participant and all subsequent data collection will be labeled with this ID number and no other identifiable information. Risks to privacy and confidentiality will be minimized through these study procedures and study staff will be trained in appropriate skills related to recruitment, obtaining informed consent, and data collection and management to avoid undue influence or coercion and to protect confidentiality.

To recruit diabetes care providers to participate, the PI will make a research presentation to the TCH Diabetes Service faculty to inform them about the study and the opportunity to volunteer to participate. Provider participation will be entirely voluntary.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This pilot study is a single-arm design without a control group. All participants will receive the intervention and will complete baseline and follow-up data. For the purpose of assessing intervention feasibility and acceptability, this design permits more participants to be exposed to the intervention in less time than alternative designs with a wait-list or crossover condition or control group. This will increase the ability to assess participant and provider perceptions about the intervention, to obtain valuable feedback that will help refine the intervention, and to detect any pre-post changes in study outcomes. Following pilot data collection, external funding (NIH R mechanism) will be sought to conduct a full-scale randomized controlled trial of the intervention compared to an educational, attention-control, or treatment-as-usual condition.

Inclusion Criteria:

Adolescents and families: Ninety adolescents between the ages of 12-17 years diagnosed with T1D and followed at the TCH Diabetes Care Center will be enrolled in the pilot study. At least one parent of each adolescent, self-identified as the primary caregiver most involved in diabetes care, will also be enrolled. When present, secondary caregivers involved in diabetes management will be invited (not required) to participate. Eligibility criteria will include: (1) T1D diagnosis for at least 12 months, to allow ample opportunity for adjustment to diabetes management, and (2) fluency in written and spoken English because assessment measures are not available in other languages.

Diabetes care providers: Five diabetes care providers in the TCH Diabetes Care Center (main hospital and/or satellites) will be enrolled as ¿Resilience Promotion Providers¿ to deliver the feedback intervention. Eligibility criteria will include: (1) Caseload of at least 20 adolescents with T1D, and (2) willing to participate in 2 training sessions, deliver the intervention to enrolled participants, and complete questionnaires.

Exclusion Criteria:

Adolescents and families: Presence of a serious mental illness or developmental disability in youth or parent that would impede participation would exclude eligibility.

F2. Procedure

BASELINE & FOLLOW-UP OUTCOME ASSESSMENTS: Following enrollment in the study, adolescents and parents will be e-mailed a link to complete the baseline assessment battery via secure web-survey. Participants will be encouraged to complete the battery at home prior to their next clinic appointment; for anyone unable to do so, a tablet computer will be available in the waiting room before the appointment. The assessment battery administered prior to the intervention visit will also be administered at follow-up to evaluate pre-post change.

Adolescent will self-report on the frequency of 12 resilience-promoting behaviors via the Diabetes Resilience Measure for Adolescents (DRM-A). The DRM-A is a self-report assessment of positive behaviors related to diabetes resilience for youth with T1D, such as perceived competence to manage the demanding T1D regimen, to adapt to the unpredictability of diabetes, and to seek help and support with diabetes challenges. This measure requires less than 5 minutes to complete. The DRM-A will be administered in the baseline and follow-up assessment batteries, and will also be administered as part of the intervention (See below).

Parents will rate adolescents¿ adherence to the diabetes regimen using the 24-item Diabetes Self-Management Profile Self-Report (DSMP-SR). The version appropriate to the adolescents¿ current diabetes regimen (conventional or intensive insulin regimen) will be administered. The DMSP-SR was developed to be minimally burdensome compared to adherence interviews and has demonstrated satisfactory psychometric properties.The DSMP-SR will be administered in the baseline and follow-up assessment batteries, and will also be administered as part of the intervention (See below).

The following measures will be administered only as part of the baseline and follow-up assessment batteries. Adolescents will also complete the youth-report version of the DSMP-SR at baseline and follow-up to assess their perceptions of adherence. Behavioral outcomes include diabetes-related burden and family conflict. Burden will be assessed via the Problem Areas in Diabetes measures for adolescents (PAID-T) and parents (PAID-PR). The PAID-T has 26 items and the PAID-PR has 18 items, and both demonstrate good psychometric properties. Parents and youth will also complete the Diabetes Family Conflict Scale Revised (DFCS-R), a 19 item scale with good reliability and validity. To assess healthcare satisfaction, parents will complete three subscales of the Pediatric Quality of Life Inventory Healthcare Satisfaction Generic Module (PedsQL-HS), assessing their satisfaction with communication, inclusion of family, and how well the patient¿s emotional needs are addressed during the clinical encounter (13 items). Adolescents will rate their overall satisfaction with the patient-provider relationship on a 1-10 scale single item developed for this study, as there is no validated youth-report measure of satisfaction with care.

Clinical diabetes outcomes including glycemic control (HbA1c) and blood glucose monitoring frequency will be collected as part of routine care at each of the two study visits via blood assay and glucometer download, respectively.

INTERVENTION: This intervention will be delivered at two consecutive ambulatory diabetes clinic appointments (typically scheduled 3-4 months apart). Prior to each appointment, youth and parents will each complete one intervention assessment questionnaire online (DRM-A and DSMP-SR, respectively - described above). The first intervention assessment will be included within the baseline outcome assessment battery described above; for the second study visit, it will be a single survey. For each intervention assessment, the adolescent will be asked to rate specific diabetes strengths, and the parent(s) will be asked to rate behavioral adherence to various diabetes management tasks. They will also be asked to indicate one positive behavior item that they wish to discuss with their diabetes care provider. A report (referred to as ¿diabetes strengths profile¿) will be printed for the diabetes care provider, generated from the completed intervention assessments, which will highlight the top-rated positive behaviors from each questionnaire and the positive behavior items flagged for discussion. Diabetes care providers will be trained to review the diabetes strengths profiles with the adolescent and family during their clinical encounter, and to provide feedback that reinforces and builds upon the positive behaviors.

At follow-up, all participating participants and providers will be asked to complete a brief survey about their experiences in the study and requesting any feedback and recommendations to improve intervention delivery or content. The provider will also be asked about their experiences with integrating the intervention into routine care, perceptions of intervention feasibility, and impact on clinic flow.

PROVIDER TRAINING: Five diabetes care providers who volunteer to participate in this study will be trained to provide

positive feedback to participating adolescents and families based on their unique ¿diabetes strengths profile.¿ Training will consist of (1) a two-hour training session with the Principal Investigator (PI) prior to participant enrollment, including instruction in the intervention protocol, demonstration, and role-play; and (2) a one-hour booster session with the PI, midway through the study period, including protocol review and role-play. The PI will also be available on an as-needed basis to answer questions and troubleshoot challenges that arise. Intervention fidelity will be assessed in two ways: (1) after each intervention visit, providers will document which components of the intervention were delivered, and (2) the PI will observe live a random sample of 10% of each provider¿s intervention visits with participating families.

Providers will complete a brief survey immediately following each clinical encounter with a participating family. They will be asked to rate their satisfaction with the patient-provider relationship on a 1-10 scale single item developed for this study. They will also document intervention fidelity by indicating whether and to what degree they discussed the items on the family¿s diabetes strengths profile.

INCENTIVES: To encourage completion of all outcome assessments, modest financial incentives will be offered at each data collection point. Adolescents and parents will each receive $10 for completing the baseline and follow-up assessment batteries ($40/family total). To encourage adolescents to bring their glucometers to the study visits, they will receive an additional $5/visit if they bring their meter and provide it for download ($10/family total). Parents will also receive $12 to cover parking and transportation expenses at each of the two study visits ($24/family total). Because the strengths questionnaires completed prior to each diabetes clinic appointment are a part of the intervention itself, no incentive will be offered for their completion so as not to coerce participant engagement in the intervention. Per family, the maximum incentive received for participation in this study will be $74.

The participant/family will be paid for participating in this study in cash, check or with a Clincard. Payments will be loaded onto the ClinCard within 24-48 hours of visit completion, and payment confirmations will be sent via text. The participant/family will be able to use ClinCard at any location that accepts MasterCard to make purchases and to obtain cash. During the consent process, the participant and family will be provided handouts (attached in section S) that explain how to activate and use the funds loaded on ClinCard.

To encourage diabetes care providers participate in the study, small tokens of appreciation will be given to providers in appreciation and recognition of their contributions to this research study. Providers will also be invited to co-author scholarly products that result from this research.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 90 Worldwide: 90

Please indicate why you chose the sample size proposed:

This sample size will permit an ample number of families to experience the intervention and to give feedback that will permit us to refine the protocol for future research. Because gathering preliminary data on change in outcomes from pre- to post-intervention is the secondary aim of this pilot study, the sample is not powered for robust change analyses. However, trends can be identified from a sample of this size, which will inform future power analyses for a larger sample randomized controlled (intervention) trial.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Aim 1: Feasibility and Acceptability. To evaluate the primary aims of this pilot study ¿ feasibility and acceptability of the intervention ¿ descriptive statistics (e.g., frequencies, means and standard deviations, medians and interquartile ranges) summarizing participant and provider ratings will be calculated.

Aim 2: Preliminary Outcomes. Because gathering preliminary data on change in outcomes from pre- to post-intervention is the secondary aim of this pilot study, the sample is not powered for robust change analyses. To explore change pre- to post-intervention, paired t-tests will be conducted for each outcome, comparing scores at baseline to follow-up. Change scores will be examined in relation to potential demographic or clinical covariates to explore whether individual, family, or provider characteristics need to be considered in the future refinement and evaluation of this intervention.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

This study entails only minimal risk or discomfort, given the nature of the task to complete a small number of behavioral

measures and participate in conversation with the diabetes care provider, all of which primarily emphasize positive attributes and behaviors. Nevertheless, potential risks include the possibility of emotional distress upon questionnaire completion or intervention participation, and risks to privacy and confidentiality. Regarding the possibility of emotional distress, some questions on the surveys may make participants feel uncomfortable. Research staff will be trained to tell participants that any items that are upsetting may be skipped. Regarding potential risks to privacy and confidentiality, all study data will be stored securely and identified by a number and not with identifiable personal information. Study staff will be trained and supervised to protect patient privacy in accordance with and HIPAA Privacy Rule. Completion of all required CITI modules will be a prerequisite of study staff activity.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

There are no direct benefits to individuals that will necessarily result from this study. However, adolescent and parent participants may have a pleasant experience or benefit from completing questionnaires or participating in an intervention that emphasizes positive aspects of themselves/their children. Participating providers may benefit from learning new clinical approaches that emphasize positive behaviors in their patients.

Describe potential benefit(s) to society of the planned work.

The ultimate goal of this line of research is to increase the research and clinical communities¿ emphasis on the positive, prosocial aspects of youth with diabetes and their families. It is hoped that this increased emphasis will influence care delivery and self-management behaviors in such a way that results in an improvement in patient-centered care and ultimately impact children¿s quality of life and their diabetes management and control.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

Yes, the potential benefits of this research outweigh the possible risks. The potential risks are minimal, and the possible discomfort is unlikely to have short- or long-term impact on participants¿ health or well-being. A psychologist will be available to all participants to discuss any discomfort that arises. On the other hand, the benefits to individuals and society have the potential to have a lasting impact on a vulnerable group of individuals in a growing population of youth with diabetes.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Potentially eligible participants will be identified by reviewing scheduled appointments for participating diabetes care providers 6-8 weeks in advance. All patients of these providers will be screened for eligibility criteria, and potentially eligible

families will be mailed an informational letter about the study that outlines what participation in the study will entail. The informational letter will also include a copy of the consent form and an addressed stamped envelope for the family to return the signed consent if they choose to enroll in the study.

Three-four weeks prior to the scheduled clinic appointment, study staff will call each family to describe the study, answer questions, and obtain consent. To obtain verbal consent, study staff will speak with at least one parent/legal guardian and with the adolescent. If available by telephone, a second parent/legal guardian will also be invited to participate. During this phone call, staff will review the informed consent documents that were mailed with the informational letter, and will ensure that the family understands what is involved in study participation. Families will be asked to also provide written consent on the consent form that was mailed to them, and to return it via fax, scan/email, or with the enclosed stamped envelope.

When potential participants cannot be reached by telephone for study information and informed consent prior to their first clinic visit, the research coordinator will meet the family in person at the visit. At that "meet and greet" visit, the coordinator will describe the study and answer the family's questions. Consistent with the telephone procedures currently being used, this "meet & greet" process will offer families an opportunity to (a) opt-out of being recruited for the study or (b) go through the informed consent process described above. Families may then provide written consent or decline participation. Consenting families will then be enrolled in the study and will be e-mailed the link to complete the pre-intervention questionnaires online prior to their next diabetes clinic visit (e.g., 3 months later). If a second parent/caregiver has not provided consent or completed baseline questionnaires via web, but is present at the clinic visit, and if he/she wishes to participate, he/she will meet with study staff prior to the clinic appointment to learn about the study and to provide written consent and will have an opportunity to complete questionnaires at that time.

To recruit diabetes care providers to participate, the PI will make a research presentation to the TCH Diabetes Service faculty to inform them about the study and the opportunity to volunteer to participate.

For any potential participants who decline to participate in the study, research staff will invite them to share their reasons for choosing not to participate. These reasons will be documented without being linked to any personal health information, and will be reported in scholarly works resulting from this research.

Research Staff Sahar Eshtehardi is a study staff who will oversee and conduct all study activities including identifying eligible participants, preparing recruitment and study participation materials, conducting study visits, data collection, and data entry and management. Viena Cao is a volunteer who will be helping to identify eligible participants, to prepare recruitment and study participation materials, and to assist with data management and entry. Wendy Levy is a study staff member who will assist with conducting study intervention visits, collecting data, and giving participant incentives.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?

Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
No

At what institution will the physical research data be kept?
Baylor College of Medicine

How will such physical research data be secured?
All research data that is collected electronically will be entered in password-protected database and stored on a secure server, accessible only by the PI and study staff. Any research data collected via pencil and paper materials will be entered onto the same secure database and all hard copies will be stored in a locked filing cabinet in a locked office, accessible only to the PI and study staff. All study data (hard copies and electronic files) will be coded by being labeled with a study number and not with identifiable personal information. The only document linking participant names and IDs will be the signed consent/assent forms, and will be stored separately from study data and will be appropriately secured and accessible only to the PI and study staff.

At what institution will the electronic research data be kept?
Baylor College of Medicine

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
N/A

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.

N/A

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

There will be no research-related costs to participants, families, or insurers.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

74

Distribution Plan:

Participants will receive study payments in cash, check or with a Clincard. To encourage completion of all outcome assessments, modest financial incentives will be offered at each data collection point. Youth and parents will each receive $10 for completing the baseline and follow-up assessment batteries ($40/family total). Youth will receive an additional $5/visit if they bring their glucometer and provide it for download ($10 total). Parents will also receive $12 for parking/transportation expenses at each study visit ($24/family total). Because the strengths questionnaires completed prior to each diabetes clinic appointment are a part of the intervention, no incentive will be offered so as not to coerce participant engagement in the intervention. To recognize diabetes care providers who participate in the study, they will be provided with a personalized stethoscope and will be invited to co-author scholarly products that result from this research.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug that is not approved by the FDA?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

None