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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-37311
Status: Approved
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Approval Period: 2/18/2020 - 2/4/2021

Section Aa: Title & PI

A1. Main Title

DIABETES STRENGTHS MHEALTH APP FOR PARENTS OF TEENS WITH TYPE 1 DIABETES

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:

Organization: NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

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

TCH: Texas Children's Hospital, Clinic

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

A9. ClinicalTrails.gov Registration

Does this trial meet the definition of an Applicable Clinical Trial and require registration on ClinicalTrials.gov?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT02877680

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Type 1 diabetes (T1D) is among the most common chronic conditions of childhood and its management is complex and relentless: tasks include frequent daily blood glucose monitoring, insulin calculation and administration, and careful attention to nutrition and physical activity. Worsening diabetes management and glycemic control are common during adolescence, as responsibility begins to shift from parents to youth. Supportive parent involvement promotes optimal diabetes outcomes, yet family diabetes-related conflict is common and is a risk factor for poor clinical, behavioral, and glycemic outcomes. Negative interactions stemming from parents¿ frustration and fears about the consequences of poor glycemic control can interfere with positive family teamwork and cooperative diabetes problem-solving. Parents¿ worries can heighten their attention to adolescents¿ diabetes-related ¿misbehavior,¿ making it difficult to identify or attend to what youth are doing well for their diabetes management, which is essential to reinforce desired management behaviors.

Interventions to reduce family conflict and build teamwork for T1D management are efficacious, yet effect sizes are modest and for many youth adherence and glycemic control remain suboptimal. Relatively few interventions promote good outcomes by explicitly reinforcing youth and family strengths, or positive diabetes management behaviors (e.g., expressing confidence or optimism, seeking assistance when needed, accessing social supports). Strengths-based family interventions are needed that can foster positive parent-adolescent interactions around diabetes and promote optimal quality of life, treatment adherence, and glycemic control.

Behavioral mobile health (mHealth) technologies are gaining popularity, with growing evidence of their feasibility and impact in T1D. These tools are well-suited for real-time, ecologically valid behavioral assessment and intervention, as they can both collect data and deliver brief interventions in the context of everyday health management. For youth with T1D, mHealth tools for adherence assessment and intervention have shown promising results. Behavioral mHealth technologies have great potential to measure and provide timely feedback on adolescent and parent diabetes management strengths.

Section D: Purpose and Objectives

The purpose of the proposed study is to develop and evaluate the feasibility of a strengths-based behavioral mHealth intervention for parents of adolescents with T1D, delivered via smartphone app. This intervention will use an app for strengths monitoring-plus-feedback to promote optimal diabetes outcomes by helping parents recognize and reinforce what their adolescents are doing well for T1D management. Intervention components will include (A) monitoring by the app, intermittently prompting parents to report when their adolescents engage in strength behaviors (e.g., asking an adult for help with insulin calculation, managing a difficult diabetes-related problem); (B) feedback to parents by providing personalized graphs or charts of the adolescents¿ most frequent strength behaviors; and (C) feedback to adolescents by teaching and encouraging parents to reinforce their adolescents¿ diabetes strength behaviors. This intervention aims to increase parents¿ awareness of the diabetes actions adolescents are doing well, to reinforce desired behaviors, and to facilitate positive

family interactions, all in the context of everyday T1D management. The ultimate goal is to improve glycemic outcomes by enhancing these protective behavioral and family processes.

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?
For Phase 1, parents and adolescents will be invited to participate in the qualitative interview portion of the study via advertisements in diabetes clinics and local diabetes association newsletters/social media. The advertisements will include contact information for study staff, and families will initiate contact if they are interested in learning more about the study or participating. If sufficient recruitment is not achieved via advertisements, letters will be sent to potentially eligible youth/families seen in the TCH diabetes clinic using the process described below (phase 2). Study staff will speak with all potential participants by telephone to confirm eligibility, describe the study protocol and risks in detail, ensure understanding of the protocol and answer questions. At the time of the qualitative interview, participants will sign all required informed consent and assent forms and will receive a copy of the signed forms for their records. If any interviews are conducted by telephone, consent documents will be mailed/faxed/emailed, signed by consenting participants, and returned to study staff before the interviews take place.

For Phase 2, study staff will review upcoming scheduled appointments in the diabetes care center, and will screen the electronic medical records of scheduled patients for inclusion and exclusion criteria. Potentially eligible families will be sent an informational letter about the study, including instructions to contact study staff to learn more about the study or to opt-out of being contacted about the study. For families who do not opt-out, study staff will meet with them at the next scheduled diabetes clinic visit to confirm eligibility, describe the study protocol and risks in detail, and answer questions. This conversation will be conducted in a private or quiet/secluded area to protect privacy. Families who choose to participate after this process will sign all required informed consent and assent forms and will receive a copy of the signed forms for their records.

In both phases, potential participants will be assured that participation is voluntary and the decision to participate or not will not impact their health care in any way. They will also be assured that all study participation will be confidential and their responses will not be shared with their care team. Study staff will describe the study at a developmentally appropriate level and will ensure participant understanding of the protocol before obtaining written consent. 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.

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.
Phase 1: Two rounds of qualitative interviews will be conducted with n=10 adolescent and parent dyads, and n=5 providers to inform the app design and intervention details in preparation for the pilot intervention study in Phase 2. There will be no group assignment - all enrolled participants in phase 1 will participate in the interviews.

Phase 2: A two-group randomized design will be used to conduct the pilot intervention trial with n=82 adolescent-parent dyads. Participating families will be enrolled and randomized 2:1 to Group A-Intervention or B-Control (A=54, B=28). During the 3-month period, group A will receive the intervention while B serves as the control and receives usual care. Data collection will occur at baseline and approx 3 months (the 2nd data collection will occur at the subsequent diabetes clinic visit, which usually occur approximately every 3-4 months)

Inclusion Criteria:

Families will be eligible for both phases of the study if: 1) adolescent is between the ages of 12-17 years at enrollment; 2) receives treatment for T1D at Texas Children¿s Hospital (TCH); 3) T1D diagnosis of at least 6 months; 4) parent and adolescent exhibit fluency in reading/speaking English; & 5) parent has mobile device with a data plan.

Providers will be eligible for phase 1 if he/she:1) provides treatment to adolescents (12 - 17 years old) with T1D, & 2) provides T1D treatment at one of the TCH diabetes clinics.

Exclusion Criteria:

Families will be excluded from both phases of the study if there is a serious medical, cognitive, or mental health comorbidity in parent or adolescent that would preclude ability to provide informed consent or participate in data collection or intervention. Families will be excluded from Phase 2 if they participated in Phase 1 or if they have participated in another intervention study in the previous 6 months prior to enrollment.

Providers will be excluded from Phase 1 if he/she is primarily a researcher or only providing treatment to non-T1D patients.

F2. Procedure

The study will be conducted in two phases.

(PHASE 1) During Phase 1, 10 adolescents and their parent and 5 pediatric diabetes providers will be invited to participate. Families will be informed about the study and invited to participate via advertisements in diabetes clinics and local diabetes association newsletters. The advertisements will include contact information for study staff, and families will initiate contact if they are interested in learning more about the study or participating. If sufficient recruitment is not achieved through advertisements, letters will be sent to potentially eligible youth/families through the process described in phase 2. To recruit diabetes care providers, the investigator will make a research presentation to the TCH diabetes service, and will invite diabetes providers who treat adolescents to participate in qualitative interviews. Interested providers will be asked to contact the PI for more information or to participate. Study staff will speak with all potential participants by telephone (or in person for local providers) to confirm eligibility, describe the study protocol and risks in detail, and answer questions. Adolescents, parents, and providers who choose to participate after this process will schedule a time to participate in the qualitative interview. At the time of the interview, participants will sign all required informed consent and assent forms and will receive a copy of the signed forms for their records, all in accordance with the IRB protocol.

Study staff will conduct semi-structured interviews about participants¿ perspectives on adolescent and family strengths for diabetes management and preferences for an mHealth intervention. All interviews will last less than one hour. Parents will complete a brief demographic questionnaire and will provide consent for study staff to review the patient's medical chart to document the birth date, date of diagnosis, current insulin regimen, and most recently hemoglobin A1c value. Provider interviews will relate to their observations of strength behaviors and communication in families of teens with type 1 diabetes, and on their suggestions to make the app clinically relevant. Families may have the option to use the app for 1 week and subsequently be interviewed about their experiences, usability concerns, and suggestions, which will be used to refine the app for the second phase: intervention pilot study. Additionally, families may have the option to participate in the production of a brief scripted video that will be used during the phase 2 as part of the app (intervention). Participating in the video production would include: attending a 2-3 hour scripted filming session and signing separate media release forms.

The interviews will be conducted in person (in private meeting space) or over the telephone, whichever is most convenient for the family. The qualitative interviews will be audio-recorded and transcribed verbatim by medical transcriptionists for qualitative coding and analysis. The responses will inform the development of a prototype of the app in partnership with collaborators at Northwestern University BIT Core (app developers).

Incentives will be distributed to participants following completion of each study visit, as outlined in section L.

(PHASE 2) For Phase 2, study staff will review upcoming scheduled appointments in the diabetes care center, and will screen the electronic medical records of scheduled patients for inclusion and exclusion criteria. Potentially eligible families will be sent an informational letter about the study, including instructions to contact study staff to learn more about the study or to opt-out of being contacted about the study. For families who do not opt-out, study staff will meet with them at the next scheduled diabetes clinic visit to confirm eligibility, describe the study protocol and risks in detail, and answer questions. Families who meet eligibility requirements and agree to participate will sign all required informed consent and assent forms and will receive a copy of the signed forms for their records.

During Phase 2, following consent and enrollment at the baseline clinic visit (V1), 82 adolescent-parent dyads will individually complete a questionnaire battery and will provide blood glucose meter for the staff to download data. They will also provide consent for study staff to review the patient's medical chart to document birth date, date of diagnosis, current insulin regimen, diabetes-related ER visits or hospitalizations, and most recent hemoglobin A1C - for the next 12 months.

Families will then be randomized using a 2:1 ratio to Group A or B (A=54, B=28). Group A will begin the intervention immediately. Research staff will provide verbal and written instruction on how to install and use the mobile phone app and will instruct families to begin using the app that day. Group B will be the control group for the entirety of the study and will receive usual care. At the V2 clinic visit (approx. month 3, or at the time of the next diabetes clinic visit), participants in Group A will stop using the app, and both groups will complete the questionnaire battery/provide meter for download again. At this time, Group A will provide qualitative feedback about their experiences and recommendations to improve the intervention. To assess the process of the intervention¿s impact, adolescents and parents in both groups will each provide biweekly ratings (via email, text message, or telephone) of their parent-adolescent relationship quality throughout the full study period (V1-V2).

Incentives will be distributed to participants following completion of each time point, as outlined in section L.

ASSESSMENTS:

(1) Questionnaire Battery (completed by adolescents and parents during Phase 2 at baseline, and 3 months)

- Diabetes Strengths: Measured by the Diabetes Strengths & Resilience Measure, a 12-item measure of strengths including perceived mastery over T1D management demands and accessing social and family support for T1D needs. There are 2 versions of this measure depending on age. Youth-report only.

- Quality of Life: Measured by the MIND-Youth Questionnaire, a 33-item measure of diabetes-specific health-related QOL. Youth-report only.

- Family Impact of Diabetes: Measured by the PedsQL Family Impact Module, a 38-item measure of the impact of parenting a child with a chronic medical condition on family activities and parent QOL. Also measured by the Diabetes Family Impact Scale, a 15-item measure of the impact of diabetes on family members' activities. Parent-report only.

- Adherence to Diabetes Regimen: Measured by the Diabetes Self-Management Profile Self-Report, a 24-item measure of adolescents' adherence to the diabetes regimen. Participants will use the version appropriate to the youth¿s insulin regimen (conventional or intensive) and the respondent (youth or parent reporter).

- Diabetes Burden: Measured by the Problem Areas in Diabetes measures for adolescents (PAID-T) and parents (PAID-PR): Both measure diabetes-specific burden. The PAID-T has 26 items and PAID-PR has 18 items.

- Family Conflict: Measured by the Diabetes Family Conflict Scale Revised, a 19-item scale of family conflict surrounding diabetes issues. Parents and teens will complete this measure.

-Family Communication: Measured by the Helping for Health Inventory (HHI), a 15-item questionnaire assessing perceptions of parental help around the teen's diabetes management. Parent- and teen-report versions will be completed.

(2) Diabetes Management and Control Measures (Study staff will collect data for these measures during Phase 2 at baseline and 3 months)

- Blood glucose meter downloads will be conducted by study staff to assess the frequency of blood glucose monitoring over the previous 14 days. Documentation of glucometer data will include every blood glucose value over the previous 14 days and the date/timestamp. Data that cannot be collected in person (e.g., meter not brought to clinic) will be collected via email, fax, or phone.

- Glycemic control measured by glycosylated hemoglobin A1c will be extracted from the medical record. A1c values are obtained in the course of routine clinical care in the TCH diabetes clinics.

(3) Intervention Process Measure (Study staff will collect ratings biweekly via email, telephone, or text message, during Phase 2)

- Parents and adolescents will each rate their relationship quality in relation to diabetes management using 3 items adapted from the Parent-Youth Relationship Index of the National Longitudinal Study of Youth-1997.

(4) Intervention Satisfaction and Feedback (Study staff will collect data for these measures following the intervention periods in both phases. - - Participants will complete the USE Questionnaire, a 32-item measure of the users¿ perceived usefulness of, satisfaction with, and ease of use of a particular technology.

- Semi-structured interviews with parents and adolescents in the intervention group will be conducted to contextualize survey responses, discuss user perspectives on the app (e.g., intrusiveness of prompts, clarity/relevance of response options, usefulness and appeal of strength behavior feedback charts), and obtain suggestions for improvement. The interviews will be conducted in person (in private meeting space) or over the telephone, whichever is most convenient for the family. The qualitative interviews will be audio-recorded and transcribed verbatim by medical transcriptionists for qualitative coding and analysis. The responses will inform future expansion of this study.

Section G: Sample Size/Data Analysis

G1. Sample Size

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

Local: 112 Worldwide: 112

Please indicate why you chose the sample size proposed:

The purpose of this study is to develop and evaluate the feasibility of a strengths-based behavioral mHealth intervention for parents of adolescents with T1D, delivered via a smartphone app. In order to adequately capture the variability of experiences and preferences among adolescents with diabetes and their families, we propose to enroll a total of 97 participants, in the following way:

PHASE 1: 10 adolescent-parent dyads, 5 diabetes care providers PHASE 2: 82 adolescent-parent dyads

This sample size should be sufficiently large to conduct the qualitative and quantitative analyses to address the study aims and research questions. To allow for possible attrition or other loss of enrolled participants, we have added an additional 15% to our sample size estimate: 97 + 15 = 112

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?

Qualitative Data (PHASES 1 and 2): Audio recordings will be transcribed verbatim by a medical transcription company and errors will be corrected prior to analysis. Thematic analysis will be used to analyze the qualitative data. Two coders will independently code and analyze the transcripts, and will discuss discrepancies to reach a joint coding resolution. The research team will meet throughout the coding and analysis process to discuss emerging themes and patterns. To protect confidentiality, transcripts will be coded by participant number not names.

Quantitative Data (PHASE 2) : Intervention feasibility will be determined if the upper bound of the 95% exact, binomial confidence interval (CI) is greater than or equal to 95% for downloading the app and greater than or equal to 70% for using the app at least twice per week. Acceptability will be measured as the proportion of participants who rate the intervention as acceptable (somewhat to very much) with 95% exact, binomial CIs (upper bound should be greater than or equal to 80%).

The primary analysis of glycemic and behavioral outcomes will be to compare the change in response (V1 vs. V2) between groups using an independent, two-sample t-test. Equal variances will be assumed, unless the F test rejects the null hypothesis of equality. Quantile-quantile plots, stratified by group, will be used to test for approximate normality, and data transformations (e.g., natural logarithm) will be used if needed. All outcome measures will be independently compared between groups, and no adjustments for multiple hypothesis tests will be made in this pilot study. A general linear mixed model will also be used to compare groups and will allow for the use of all available data, including incomplete observations. The model will assume an unstructured matrix of correlated error terms to account for repeated observations. Statistical significance will be assessed at the 0.05 level for all hypothesis tests. A total sample size of n=82 with complete data would be required to detect an effect size of 0.75 with 80% power using an independent, two-sample t-test assuming alpha=0.05. This sample size will also have >95% probability of generating binomial confidence intervals with half-widths <=0.20. Therefore, this study will plan to enroll n=82 (54 intervention, 28 control) in the pilot intervention trial (Phase 2) to allow for a 20% attrition rate.

Data from the second intervention period (V2) will be exploratory. A similar analysis will be used including independent, two-sample t-tests and general linear mixed models. Maintenance or drop-off of intervention engagement past three months will be observed for group A. Descriptive analyses of pre-post outcomes for both groups during the 3-month study period (V1-V2) will maximize this pilot sample's data to estimate trends and receive additional qualitative feedback.

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:

The risks associated with this study are relatively minor, as the protocol does not involve any medical procedures and the study procedures and intervention do not include any treatment or advice related to medical care of diabetes or treatment of psychological conditions. No study procedures or questions will

assess risk for depression. The questionnaire batteries for adolescents and parents include measures assessing disease burden and family conflict related to diabetes, which may be upsetting for participants to complete. Participants will be informed that they may skip any questions that they find uncomfortable or that they prefer not to answer. If participants express any distress related to completing questionnaires, the PI (a licensed clinical psychologist) and study staff will be available to discuss concerns and make referrals to mental health professionals as needed.

Although this proposal is designed as a strengths-based approach to supporting positive parent-adolescent interactions, it is possible that participants could experience some distress related to the intervention. Efforts will be made to minimize or prevent risks through the process of informed consent and through the initial parent training around effective monitoring and praise at the start of the intervention. Throughout the course of the intervention, study staff will be in frequent touch with participants (adolescents and parents) to collect the biweekly intervention process ratings - staff will discuss any concerning responses or trends that emerge in these ratings with the study PI to monitor for unanticipated problems and adapt the protocol as needed to reduce these risks.

It is also possible that participants in both conditions will experience diabetes-related medical deteriorations. Participation in this study will not impact participants' access to their usual diabetes care provided through Texas Children's Hospital diabetes care centers. Any medical questions that participants ask during the course of the study will be referred to the medical team, with whom the PI and study team are well integrated. The medical director Co-I on this study will also be available at monthly meetings or on a as-needed basis to address any medical or health-related risks that arise during the course of the study.

As with any study, there are risks associated with loss of confidentiality. To minimize these risks, all efforts will be made to fully comply with federal and HIPAA regulations to avoid disclosure of protected health information (PHI). Study staff will be carefully trained and supervised to adhere to regulations and reduce risks to confidentiality, including completion of required training modules (e.g., responsible conduct of research).

The study collaborators at Northwestern University who are creating the app (BIT Core) will have access to a small amount of personal information, including parents' mobile phone numbers, parents' email addresses, and the first names of the parent and adolescent, to administer and personalize the app software. If parents choose to send text messages to their adolescent through the app, the adolescents' mobile phone number will also be stored in the app software. Parent responses to study-related messages about recent strength behaviors the adolescent has completed will be stored in the software, and may reference health-related information (such as mentioning the use of an insulin pump), but there will be no collection of medical information (such as blood glucose values) through the app. The BIT Core faculty and staff are fully trained in the responsible conduct of research and will follow established, HIPAA-compliant research protocols used in numerous other research studies to protect the strict confidentiality of all study data and will not release any participant information to any other parties.

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.

The purpose of the proposed study is to develop and evaluate the feasibility, acceptability, and initial impact of a pilot behavioral mobile health (mHealth) intervention for parents of adolescents with type 1 diabetes. Based on participant input and feedback in the first phase of the study, qualitative phase of the study, the intervention will use a smartphone app to teach parents strategies to identify and reinforce strength behaviors their adolescents engage in related to diabetes management, and will prompt parents to monitor and reinforce these behaviors throughout the day. Supportive parent involvement in adolescents¿ diabetes management is known to improve family relationships, treatment adherence, quality of life, and glycemic control, and therefore it is hypothesized that adolescents and parents in this study will experience similar benefits. Participants in Phase 1 of the study may enjoy the process of contributing to developing a research intervention and having their input heard. In the Phase 2, parents may benefit from learning strengths-based parenting strategies, and adolescents may appreciate having their positive behavior recognized.

Diabetes care providers who participate in Phase 1 will have the opportunity to be recognized in or contribute to academic works resulting from this research after the study has been completed.

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

Behavioral interventions have demonstrated an impact on family relationships related to diabetes management, quality of life, adherence, and glycemic control, however for many youth and families, daily management demands remain a struggle and glycemic control remains suboptimal. The proposed study aims to evaluate whether a novel behavioral intervention, designed in collaboration with families and delivered via an engaging, inexpensive, and low-burden smartphone app, can enhance these important outcomes and promote resilience in adolescents with type 1 diabetes. The results will optimally lead to dissemination of a useful and engaging intervention for families of adolescents and will inform future behavioral mHealth interventions for this population.

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 risk are minimal, and the possible emotional distress is unlikely to have short- or long-term impact on participants' health or well-being. However, 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.

For Phase 1, parents and adolescents will be invited to participate in the qualitative interview portion of the study via advertisements in clinic and local diabetes organizations or via an informational letter. The materials will include instructions on how to contact study staff to learn more about the study or to opt-out of being contacted about the study. If sufficient recruitment is not attained through advertisements, letters to clinic patients will be sent, using the process described below in Phase 2. Diabetes care providers will be invited to participate following a research presentation made to the faculty of the Texas Children¿s Hospital diabetes care center, and they will be asked to contact the PI for more information or to participate. Study staff will speak with all potential participants by telephone (or in person for local providers) to confirm eligibility, describe the study protocol and risks in detail, and answer questions. Adolescents, parents, and providers who choose to participate after this process will schedule a time to participate in the qualitative interview. At the time of the interview, parents will sign two informed consent forms - one for their participation and another for their adolescent's participation. Adolescents will sign an assent form. Providers participating in the interview will also sign a consent form. All participants will receive a copy of the signed forms for their records. In addition to consenting for participation in the qualitative interviews portion of phase 1, families will also consent to having the option to also participate in a one-week beta-testing of the intervention app and to participate in filming a video that will be used in the app. Families who consent to phase 1 are not required to participate in either of these activities, they are optional.

For Phase 2, study staff will review upcoming scheduled appointments in the diabetes care center, and will screen the electronic medical records of scheduled patients for inclusion and exclusion criteria. Variables to be extracted from the electronic medical records include: patient name, MRN, date of birth, date diagnosed with T1D, English fluency, presence of serious medical, cognitive, or mental health comorbidity, and participation in other intervention studies during the previous six month period. See Attachments (Section S) regarding use of waiver of consent for the screening process.

Potentially eligible families will be sent an informational letter about the study, including instructions to contact study staff to learn more about the study or to opt-out of being contacted about the study. For families who do not opt-out, study staff will meet with them at the next scheduled diabetes clinic visit to confirm eligibility, describe the study protocol and risks in detail, and answer questions. Those who pass screening will sign all required informed consent forms. Parents will sign two informed consent forms - one for their participation and another for their adolescent's participation. Adolescents will sign an assent form. All participants will receive a copy of the signed forms for their records.

For all participants, originals of the signed consent and assent forms will be stored in locked filing cabinets accessible only by trained study staff and agencies/individuals with legal rights or authority to inspect the records. No study procedures will occur until after signed informed consent and assent are obtained. Any adolescent who turns 18 during the course of the study will be asked to sign informed consent documents as an adult.

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 #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

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 a password-protected database and stored on a secure server, accessible only by the PI and study staff. All research data that is 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 forms, and will be stored separately from study data and will be appropriately secured and accessible only to the PI.

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 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:
256

Distribution Plan:
PHASE 1: - $25/person x2 visits = $100 - Parking $13/family per visit (x2 visits) = $26 - For those agreeing to beta-test the app: Data use: $10 - For those agreeing to participate in filming the video to be used in the app: $50 - Max compensation/family = $186

Providers will not receive financial incentives, but will be recognized in scholarly works from this study.

PHASE 2: - $25/person x2 visits = $100 - Parking $13/family per visit (x2 visits) = $26 - $5/visit for bringing all actively used glucometers to each visit (2 visits)= $10 - Bi-Weekly rating $5/person (2 people, up to 8*ratings) = $80 - Data Use: $10/mo of app use (up to 4*months) = $40 - Max compensation/family = $256

All participants in both phases: small (<$2 in value) gift item (silicone adhesive cell phone wallet) branded with the study logo for participant retention

A ClinCard will be used for reimbursement, unless it is not available, in which case, cash or check will be used.

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?

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