Diabetes Journey: An Adolescent Adherence Barriers Intervention Study Protocol

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CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

STUDY PROTOCOL

Study Title: Diabetes Journey: An Intervention to Improve Adherence Barriers for Adolescents with Type 1 Diabetes

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1. ABSTRACT

Type 1 diabetes (T1D) treatment adherence is complex and involves glucose monitoring, counting carbohydrates, and intensive insulin delivery via injections or insulin pump in response to food intake, exercise, and illness to achieve near-normal blood glucose levels. Evidence demonstrates that adhering to T1D treatment is challenging, especially during adolescence. Non-adherence leads to suboptimal glycemic levels that severely compromise health and quality of life. Suboptimal adherence to T1D treatment regimen is common in >50% of adolescents and directly related to suboptimal glycemic control, increased risk of hospitalizations for diabetic ketoacidosis, and decreased health-related quality of life (HRQOL). The maximum benefits of current diabetes technology are limited by the knowledge, skills, adherence barriers, and non-adherence behaviors.[10-14] Ultimately, adolescents have to overcome these barriers in order to benefit from technological advances. Thus, there is a clear need for behaviorally focused interventions to identify and reduce adherence barriers. The overall objective of this study is to identify adolescents with elevated adherence barriers and provide novel tailored mHealth intervention (Diabetes Journey) targeting these barriers. The pilot randomized controlled clinical trial will examine feasibility, acceptability and preliminary efficacy of Diabetes Journey versus enhanced standard of care (control group) in approximately 190 adolescents with type 1 diabetes. Primary and secondary outcomes include adherence barriers, adherence, health-related quality of life and A1C. Satisfaction and acceptability will also be examined. Mediators and moderators will include executive functioning, diabetes distress, family conflict, depressive symptoms, fear of hypoglycemia and sleep.

2. PURPOSE OF STUDY

The purpose of this study is to examine the feasibility, acceptability, and preliminary efficacy of a mHealth intervention addressing adherence barriers in adolescents with T1D, and to identify moderators that predict intervention responsiveness, as well as mediators of adherence barriers and adherence responsiveness.

3. BACKGROUND

Urgent Need to Improve T1D Adherence and Glycemic Control in Adolescents. Long-term T1D complications are related to both glycemic control and T1D duration. There is an urgent need to improve glycemic control for adolescents, given that 17% of youth ages 13-17 years with T1D have A1C values $\geq$9.5%,[2] which is much greater than A1C of <7.5% recommended by the American Diabetes Association.[6] Further, T1D is a lifelong chronic condition and establishing optimal adherence behaviors in adolescence can set the stage for positive outcomes in adulthood. Suboptimal adherence to the T1D treatment regimen is directly related to suboptimal glycemic control,[7,8] increased risk of hospitalizations for diabetic ketoacidosis,[9] and decreased health-related quality of life (HRQOL). Alarmingly, the average A1C of 9% in 13-17 year-olds is similar to the average A1C of 9.5% of youth from the Diabetes Control and Complications Trial more than 30 years ago,[1] suggesting that advances in diabetes technology such as blood glucose monitors, continuous glucose monitors, and insulin pumps, have not led to reductions in A1C and T1D complications. The maximum benefits of current diabetes technology are limited by the knowledge, skills, barriers, and non-adherence behaviors of the user of these technologies, especially insulin pumps.[10-14] Ultimately, adolescents have to use the technology for it to be beneficial and clearly there is a need for behaviorally-focused interventions to identify barriers and improve adherence behaviors.

Adolescence is often accompanied by desire for autonomy, feelings of invincibility, and decreased parental monitoring.[36] Adolescence is the only period of human development in which the primary causes of morbidity and mortality are behavioral (e.g., reckless driving) rather than disease-based.[37] Adolescents are motivated by novel experiences and predisposed to impulsive and risky behaviors due to an immature inhibitory control system (i.e., executive dysfunction).[38] This makes adolescents more likely to engage in behaviors that have immediate rewards (e.g., omitting blood glucose checks and insulin boluses when out with friends[15]) and less likely to be concerned about the negative consequences of their decisions for the future (e.g., blindness, amputation, cardiovascular disease).[18, 21] T1D non-adherence during adolescence is often attributed to family conflict,[16-19] and psychological conditions (e.g., depression).[20-23] These areas have frequently been targeted by existing interventions, with some success. In addition, stress (e.g., negative life events,[24] familial,[25] T1D burnout) and executive dysfunction (e.g., problem-solving, organizing/planning, working memory)[3] are known to negatively influence adherence behaviors. Unfortunately, these barriers have never been targeted in adherence interventions and represent an important opportunity to improve T1D outcomes. Fortunately, adherence barriers have been addressed in other chronic conditions with both statistically and clinically meaningful improvements (see C1d and C1e) underscoring the need for effective intervention in T1D. *If the aims of this R01 are achieved, adherence to the T1D treatment regimen and A1C will improve.*

Patient Reported Outcomes (PROs) are Recommended as a Part of Comprehensive T1D Care. Although A1C is recognized as the gold standard outcome in T1D, there is widespread recognition of its limitations[26] and the need for assessment of meaningful PROs to complement existing clinical metrics. Integrating PROs into T1D clinical care is key to: 1) designing interventions that are tailored to the needs of adolescents with T1D; and 2) enhancing collaboration between families and health care teams by expanding providers' focus beyond A1C to better address the broader impact of T1D.[27] However, obstacles (e.g., lack of personnel to administer and intervene when necessary, lack of referral resources) exist to systematic integration of PROs into routine clinical practice, which impedes the ability to provide tailored interventions to patients during routine clinical care. The integration of T1D-specific PROs into T1D clinical care, such as the Barriers to Diabetes Adherence scale and the PedsQL-Diabetes Module, is recommended.[27]

The Barriers to Diabetes Adherence scale comprises two subscales, including the Stress/Burnout and Time Pressure/Planning (executive dysfunction) subscales, that are associated with suboptimal adherence (*r=0.21, p<0.05*) and glycemic levels *(r=0.38, p<0.01*).[3] The magnitude of these relationships is similar in other validated measures of executive functioning, including the Diabetes Executive Functioning Scale, with correlations in the medium effect range (0.27-0.66).[28-31] Targeting executive dysfunction is essential because some children with T1D demonstrate significant deficits in learning and memory,[32] which can lead to adherence barriers , including stress[33] and poor planning skills,[34] and eventual non-adherence. In addition, severe hypoglycemia has been implicated in executive dysfunction in children.[35-38] Executive dysfunction is also associated with poor HRQOL (*rs= -0.24 to -0.32, ps<0.05*).[4] Specifically, deficits in the ability to problem-solve, initiate tasks, transition between activities, and hold information in one's memory negatively impacts HRQOL in adolescents with T1D.[4] Combined, these data suggest that stress/burnout and executive dysfunction may be critical PROs for clinic-based intervention that have not yet been addressed in pediatric T1D adherence interventions. *Thus, if the aims of this R01 are achieved, we will systematically integrate an extremely important PRO that negatively impacts adherence and A1C – adherence barriers.*

We are proposing a novel intervention, Diabetes Journey, which will focus on improving adherence barriers, specifically Stress/Burnout and Time Pressure/Planning. We hypothesize the intervention will also improve our secondary outcomes (i.e., adherence, glycemic levels, and HRQOL). We will explore whether depressive symptoms and family conflict moderate

intervention effectiveness. In addition, we will explore potential mediators (e.g., adolescent distress, executive functioning) of the relationship between barriers and adherence. Notably, the primary goal of the current proposal is to assess, intervene on, and improve adherence barriers, an important PRO that has been neglected in prior research yet shown to strongly influence health outcomes and HRQOL.

Critical Targets for Intervention Include Adherence Barriers via Mobile Health and Telemedicine. Although T1D interventions including multisystemic therapy,[39,40] problem-solving,[41] coping skills,[42] and behavioral systems therapy[43,44] yield small, but clinically meaningful effects on glycemic levels (0.44% reductions[5]), these effects are insufficient to prevent long-term T1D complications. Moreover, these small effects are likely due to lack of intervention integration into T1D clinical care and a mismatch between intervention targets and the difficulties that plague 1/3 of adolescents with T1D on a daily basis (e.g., stress, executive dysfunction).[3] Thus, we propose to measure and target adherence barriers for the current proposal.

Telemedicine and mHealth (mobile health) interventions have the potential to significantly improve T1D care and health outcomes in adolescents, yet there is a fundamental gap in the extant literature investigating the impact on pediatric T1D outcomes. mHealth tools are well-matched to the information consumption patterns of adolescents as approximately 90% have cell phones (73% smartphones), 90% of those with cell phones use text messaging,[45] and 91% access the internet on their mobile device (with a notable increase in use for minority youth).[45] Using telemedicine to deliver interventions with adolescents in routine T1D clinical care will increase access to adherence interventions, provide flexibility, and decrease burden (e.g., travel time, missed school). Moreover, it is well-known that there is a 17-year time lag for translating research into clinical practice.[46] By simultaneously testing the efficacy of our intervention and implementing our research into clinical practice,[47] "we can more rapidly translate our evidenced-based findings into clinical practice, and more effectively disseminate novel and impactful information to researchers and decision makers."

Overall Impact
If successful, the results of this study would have a large impact on pediatric T1D outcomes. Telemedicine and mHealth (mobile health) interventions have the potential to significantly improve T1D care and health outcomes in adolescents. Knowledge gained in this study has the potential to improve the treatment of pediatric T1D by reducing adherence barriers, enhancing adherence and T1D management skills that, consequently, would improve health outcomes (i.e., A1C) and quality of life in this population. Data elicited through the study will also allow us to modify the intervention to improve the generalizability and potential efficacy of the intervention for future trials.

4. STUDY DESIGN
We will conduct a pilot randomized clinical trial of adolescents with T1D and their caregivers (n=190) to evaluate the feasibility, acceptability and preliminary efficacy of an adherence barriers mHealth intervention for adolescents with T1D.

5. DURATION
Participants will be in the study for 6 months. The pilot randomized clinical trial will last approximately 48 months overall.

6. SELECTION & RECRUITMENT OF PARTICIPANTS
Study Participants
Study participants will include n=190 adolescents, ages 12-17, with T1D and their caregivers from Cincinnati Children's Hospital Medical Center (CCHMC), the University of Florida (UF) and the University of Colorado Barbara Davis Center for Diabetes (BDC). Adolescents and caregivers will be recruited during routine diabetes clinic visits and will meet the following inclusion/exclusion criteria:

Inclusion Criteria

- T1D diagnosis >1 year
- Adolescents with T1D ages 12-17
- Elevations on the Barriers to Diabetes Adherence questionnaire (scores of ≥ 2 of 5 for the Stress/Burnout and/or Time Pressure/Planning subscales) based on their previous clinic visit scores
- Ability to read/speak English (all measures are in English)

Exclusion Criteria

- Diagnosis of significant developmental disorders (e.g., autism spectrum disorder, moderate/severe developmental or intellectual disability)
- Comorbid medical diagnoses (e.g., cystic fibrosis) with the exception of endocrine disorders (e.g., Celiac disease, thyroid)

Recruitment Procedures

Potential participants meeting eligibility criteria will be identified by a trained research assistant in collaboration with the members of the Diabetes teams at each site. Specifically, patients will be pre-screened based on their scheduled appointments for inclusion/exclusion criteria. Elevations on the BDA is one of our inclusion criteria for study entry. At CCHMC and the University of Florida, BDA elevations will most often be identified by reviewing responses from the patient's clinic visit or through a screening process. For eligible participants who do not have a completed Barriers to Diabetes Adherence (BDA) measure, study coordinators may administer a screening BDA to determine further study eligibility, but only after informed consent/assent is obtained. If the participant does not have any elevations on the BDA, they will be deemed a screen-fail and will not participate in the Diabetes Journey intervention. If the participant completes the BDA at a later clinic visit and has elevations on the BDA that make them eligible for study participation, and study staff determine they still meet all other inclusion criteria, the participant may be re-consented for study participation at that time.

The University of Colorado Barbara Davis Center does not administer the BDA clinically. Thus, adolescents from the University of Colorado Barbara Davis Center who are eligible for Diabetes Journey will be identified through an ongoing study at the University of Colorado Barbara Davis Center (PI: Dr. Holly O'Donnell) in which participants in that study complete a variety of psychosocial questionnaires including the BDA; this approach is approved by the University of Colorado Multiple IRB. If participants are elevated on Stress and Burnout and/or Time Pressure and Planning, a trained research assistant will approach families about participating in Diabetes Journey.

At all sites, if potential participants are eligible, a trained research assistant will approach families with adolescents with T1D either during a routine diabetes follow-up clinic visit or via other recruitment methods (i.e., phone calls, recruitment letters). A thorough overview of the study will be provided, including study procedures, benefits, and risks. All questions will be addressed, and informed consent/assent will be obtained if the family agrees to participate.

Following written informed consent from the caregiver/legal guardian and adolescent assent, copies of informed consent/assent forms will be provided to participants at recruitment. Subsequently, handouts about diabetes device download will be provided and baseline assessment questionnaires will be completed via REDCap or by paper/pencil surveys. Recruitment materials, including flyers, scripts, etc. can be found in Appendices A, B, and H.

7. PROCESS OF OBTAINING CONSENT AND ASSENT

As noted above, once participants are identified as study eligible, they will be approached during or following their diabetes clinic visit and provided a description of the study (e.g., study procedures, benefits, risks) by a trained research coordinator. Due to restrictions in the wake of COVID-19, eligible participants may be mailed recruitment letters and/or called to assess

interest in the study. After addressing all questions from potential participants, informed consent/assent will be obtained by trained research staff. Consent/assent forms will be signed electronically using REDCap, a secure web-based interface supported by the CCHMC Division of Biomedical Informatics in compliance with HIPAA designed to protect PHI in the electronic transfer and storage of the consent/assent forms. Should technical issues arise with the REDCap interface, paper copies of consent forms may also be used. For all consent/assent visits, all pertinent aspects of consent/assent will be covered including study purpose, risks/benefits, confidentiality, and right to withdraw. Patients will be informed that their care at CCHMC or other collaborating study sites will not be affected by whether they choose to participate in the study. A copy of the assent/consent form will be provided to all participants.

For eligible participants who do not have a completed Barriers to Diabetes Adherence (BDA) measure upon recruitment, study coordinators may administer a screening BDA to determine further study eligibility, but only after informed consent/assent is obtained. If the participant does not have any elevations on the BDA, they will be deemed a screen-fail and will not participate in the Diabetes Journey intervention. If the participant completes the BDA at a later clinic visit and has elevations on the BDA that make them eligible for study participation, and study staff determine they still meet all other inclusion criteria, the participant may be re-consented for study participation at that time.

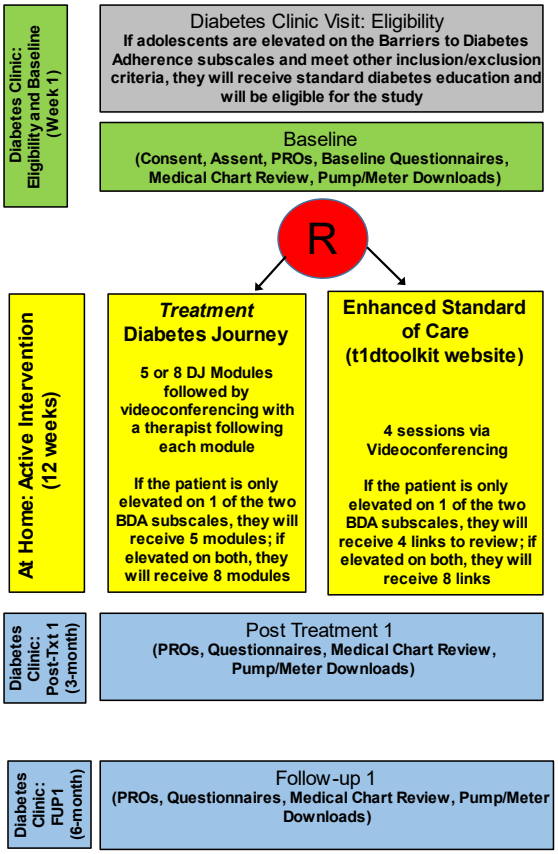
Participants recruited in-person will either complete the informed consent document via e-consent on a tablet/computer or via a paper/pencil form. For participants who decide to participate after the clinic visit, we will use telephonic electronic consent. Specifically, a member of the study team will provide a link to access the consent/assent form in REDCap via email or text message. A paper copy of the form may also be mailed if necessary. During the consent/assent call, research staff will ensure all questions are answered. In compliance with CCHMC SOP Number 41-1.6, study staff will sign and date accordingly, on the signature page of each form corresponding to the date the forms were received, not necessarily reviewed with the family. The method used to obtain participant consent/assent will also be written on the Informed Consent Process Note.

8. STUDY PROCEDURES

After participants provide informed consent/assent as noted above, baseline questionnaires will be completed via REDCap or by paper/pencil (see Table 1). All questionnaires will be hosted on REDCap, a secure web-based interface or stored in a secure cabinet. Some questionnaires are completed as a part of standard clinical care and thus may not be repeated, if unnecessary. Participants must provide an email address for the online questionnaires. If they do not have one, we will help them create one or we will text the link to their cellular phones. If participating caregivers and adolescents prefer to complete paper/pencil questionnaires, we will provide them.

During the visit or recruitment call, participants will be asked to share all blood glucose monitors, continuous glucose monitors, and/or insulin pumps data for the study via Tidepool (e.g., free software for diabetes devices downloads used clinically) when possible. If data is not shared during the clinic visit or while on the call with study staff, families will be given instructions about how to download diabetes device data to Tidepool remotely following their recruitment date. We will also offer a videoconference appointment to assist with the upload. Families will be provided with a username and password to access their Tidepool account. Research staff may contact participants via phone after their clinical visit if technical support is needed to complete remote download of diabetes device data from patients' blood glucose monitors, continuous glucose monitors, or pumps. If participants have difficulty with Tidepool, other software used as a part of routine clinical care (e.g., Glooko, Carelink, TConnect) may be used to download diabetes devices. Additionally, Tidepool experts at other sites may be consulted for further troubleshooting with Tidepool. All downloaded data will be de-identified, given a unique ID

Figure 7. RCT of Diabetes Journey



number, and password protected to ensure privacy. A medical chart review will also be conducted to gather information about hemoglobin A1C, data downloaded from devices, medications, comorbidities, hospitalizations, and time since diagnosis.

It is the goal for all participant families to complete their baseline visit prior to being randomized to intervention. This will include completion of questionnaires and download data from their T1D device. However, participating families may be randomized if the primary outcome measure (BDA) and a baseline A1C within 4 weeks of enrollment is available, at a minimum. Participants will have an opportunity to complete baseline questionnaires until the initiation of the first intervention session. Device downloads will not be required for randomization as these data can be retrieved from the medical record.

After completion of the required questionnaires and A1C at a minimum will be randomized to either: Diabetes Journey *or* Enhanced Standard of Care (Figure 1). Stratified block randomization with two strata and blocks of size 2 or 4 chosen randomly within each stratum will be used and stratification will be based on baseline A1C (i.e., ≥9% or <9%), site (i.e., CCHMC, the University of Colorado Barbara Davis Center or the University of Florida), and Barriers to Diabetes Adherence elevation type within the treatment arm (i.e., elevated on one or both of the subscales). The A1C criterion was selected because the average A1C in 13-17 year olds with T1D in the US is 9%, which will result in comparable sample sizes above and below 9%. In addition, although the American Diabetes Association recommends an A1C <7%, very few adolescents achieve this. Site was chosen as a stratification variable to ensure balance for any site-related differences. This randomization strategy will minimize imbalance of the number of participants across groups. The randomization list will be held by an individual independent of the study to reduce any potential biases. Participants will be notified of their randomization group within 3 business days of completion of baseline data and be provided with appropriate materials (e.g., log-in information or website information and links). Total treatment time is up to 12 weeks, which coincides with routine quarterly T1D clinic appointments. This also enables sufficient time for cancelled and/or rescheduled sessions that are likely to occur given adolescents' busy schedules.

Control Group (Enhanced Standard of Care)

Participants randomized to Enhanced Standard of Care will receive general education via the T1DToolkit website, as well as 4 Zoom sessions **(**e.g., Zoom for Healthcare; See Appendix C) with certified diabetes educators (CDEs) from either CCHMC or UF across 12-weeks. Notably, if technical difficulties arise, telephone sessions will be conducted and audio recorded. Content to address adherence barriers were modified and or newly developed for the Enhanced Standard of Care group via the T1DToolkit website. Depending on the participant's elevated score(s) on the Barriers to Diabetes Adherence scale, patients will receive information specifically addressing elevated scales of the BDA. Treatment fidelity will be assessed via audio recordings and completion of checklists, which will be reviewed weekly by Dr. Kichler with the CDEs who deliver this intervention.

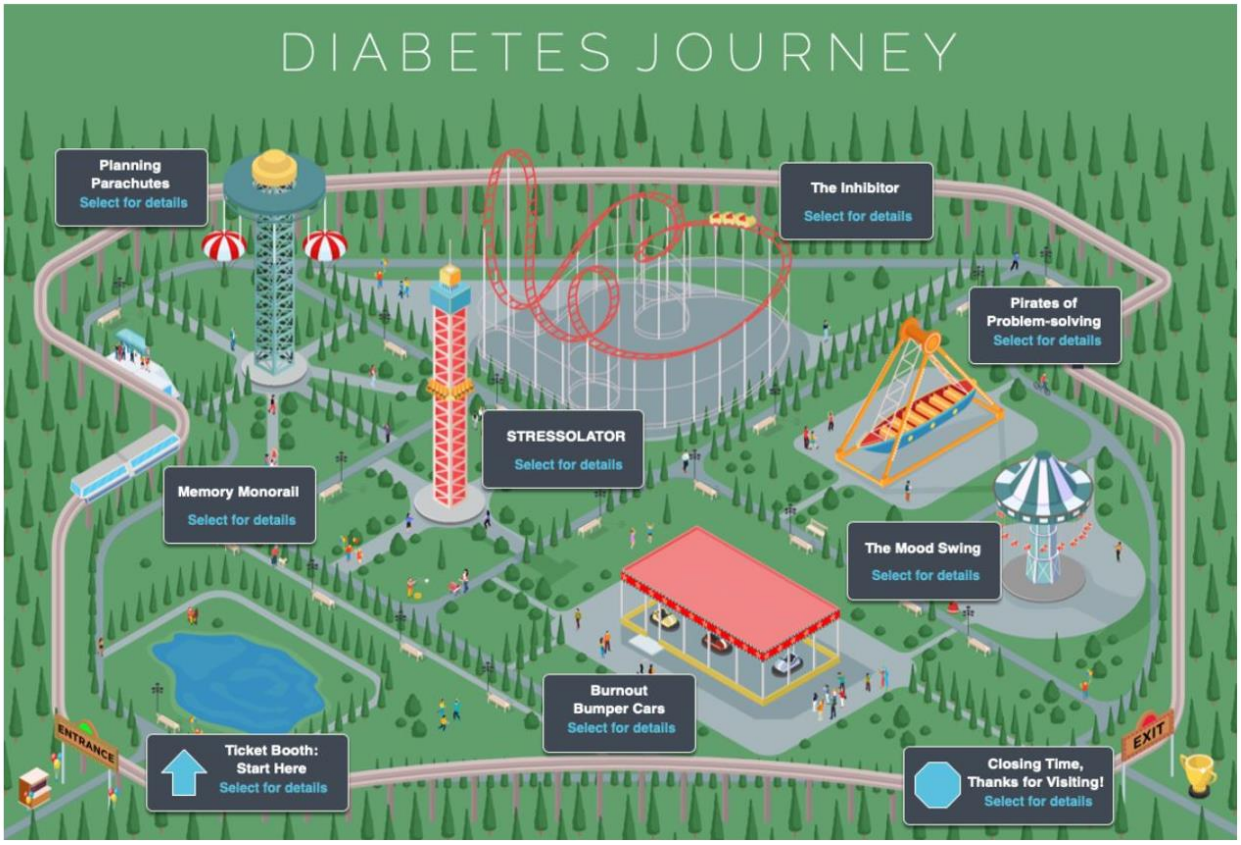
Modules	T1Dtoolkit.com links
Stress and Burnout	
Burnout	https://t1dtoolkit.org/for-teens-young-adults/burnout-2/
Sharing responsibility	https://t1dtoolkit.org/for-teens-young-adults/sharing-responsibility/
Strategies to Manage Pain	https://t1dtoolkit.org/uncategorized/strategies-to-manage-pain/
Building a Support Network	https://t1dtoolkit.org/uncategorized/building-a-support-network/
Time Pressure and Planning	
Setting Reminders	https://t1dtoolkit.org/for-teens-young-adults/setting-reminders/
Prioritizing and Planning	https://t1dtoolkit.org/for-teens-young-adults/14472/
Organization of Your Environment	https://t1dtoolkit.org/for-teens-young-adults/organizing-your-environment/
Eating on Your Own	https://t1dtoolkit.org/for-teens-young-adults/eating-on-your-own/

Treatment (Diabetes Journey)
All Diabetes Journey participants will first receive the mandatory Introduction and Problem-Solving Modules. Participants with elevations on only one subscale will then receive 4 additional modules based on their individual subscale elevations (5 modules total). If the participant is elevated on both Barriers to Diabetes Adherence subscales, they will receive all 8 modules. This will yield completion of 5 or 8 total modules and 5 or 8 HIPAA compliant video-sessions (e.g., Zoom for Healthcare; See Appendix C) with a therapist from CCHMC or UF. No therapists will be utilized from the University of Colorado Barbara Davis Center.

The primary foundational skill that will be taught is problem-solving, the first core module. As a part of Problem-Solving Module, an engaging and visually appealing video reviewing problem-solving skills will be viewed. The following approach to teach problem-solving skills will be used: 1) Define the problem (e.g., feeling stressed and cannot sleep resulting in high blood glucoses); 2) Teach the adolescent to generate several solutions (e.g., deep breathing before bed, listening to relaxing music, talking to a caregiver); 3) Evaluate the pros and cons of each potential solution; 4) Select one solution for implementation; and 5) Review detailed solution with specifics regarding who, when, where, and how the solution will be attempted. The therapist plays a critical role in helping apply problem-solving skills in daily life. Notably, if technical difficulties arise, telephone sessions will be conducted and audio recorded. If adolescents lack access to mobile devices, an iPad will be provided to the participant.

Session	Content	Diabetes Journey Modules
1	**Introduction and Problem Solving**	**Ticket Booth and Pirates of Problem-Solving**
	Stress and Burnout	
	Stress	Stressolator
	Diabetes Burnout	Burnout Bumper Cars
	Emotional Control	The Mood Swing
	Time Pressure and Planning	
	Planning	Planning Parachutes
	Working Memory	Memory Monorail
	Inhibition	The Inhibitor Roller Coaster
5 or 8	**Wrap-Up**	**Closing Time**

The images below illustrate the draft layout of Diabetes Journey and the modules that will be used. Treatment fidelity will be assessed via audio recordings of the sessions and completion of checklists, which will be reviewed weekly by the supervising licensed psychologist at each site or designee. Treatment sessions may be delivered by interventionists at CCHMC or the University of Florida.



Following the 12 week active intervention phase, participants will complete one follow-up visit as shown in Figure 1.

8.1 Data collection procedures and measures

Participants will complete a demographic questionnaire that provides general information about the child's age, history of T1D, and family information. Both adolescents and caregivers will complete questionnaires. All participants will have the same baseline, post-treatment (3-months from baseline) and follow-up study visits (6 months from baseline), which includes questionnaires, diabetes device downloads, and health outcomes through medical chart reviews. In light of COVID-19, the COVID-19 Exposure and Family Impact Survey (CEFIS) will be administered to adolescents and caregivers to determine the impact of COVID-19 on their functioning (see Appendices J and K). The medical chart review will include key patient medical characteristics (e.g., insulin regimen type, A1C, PROs collected during routine clinical care)

Sources of data for the current study will include: 1) adherence data downloaded from blood glucose meters, continuous glucose monitors, insulin pumps, and hybrid closed loop systems; 2) REDCap web-based questionnaires completed by adolescents and caregivers assessing demographics, barriers to T1D adherence, health-related quality of life, depressive symptoms, T1D distress, executive functioning, family conflict, and feasibility/acceptability of the Diabetes Journey intervention; and 3) mail, electronic-mail, and telephone contact with participants to coordinate study visits and maintain study retention (See Appendices D, F, and E for relevant materials). T1D devices will be downloaded to industry standard HIPAA compliant software and cloud-based programs, which is diabetes standard of care.

Construct Measured	Respondent	Stages and Time points			
	C= Caregiver; Y=Youth M= Med Chart Review D= Doctor/ Clinician	*Screening (may apply)*	*Baseline*	*Post Treatment (3-month post-txt)*	*Follow-up 1 (6-months post-txt)*
ORDER OF MEASURES (As applicable)					
Background Questionnaires	C		X		
Diabetes-Related Executive Functioning Scale (DREFS)	Y/C		X	X	X
Diabetes Family Conflict Scale (DFCS)	Y/C		X	X	X
Barriers to Diabetes Adherence: Stress/Burnout and Time Pressure/Planning subscales (BDA)	Y	X	X	X	X
Type 1 Diabetes and Life (T1DAL)	Y		X	X	X
Problem Area in Diabetes- Teen Version (PAID-T)	Y		X	X	X
Patient Health Questionnaire-8 (PHQ-8)	Y		X	X	X
University of Virginia- Low Blood Sugar Survey	Y		X	X	X
ASWS	Y		X	X	X
Pittsburg (PSQI)	Y		X	X	X
COVID-19 Exposure and Family Impact Surveys (CEFIS)	Y/C		X	X	X
Satisfaction and Acceptability Questionnaire	Y/C			X	X
Device Downloads	Y		X	X	X
Fingerstick Blood Sample	D		X	X	X
Medical Record/Patient Record	D		X	X	X

8.2 Sample Size Considerations and Power Analysis:

Sample size for this study is based on our preliminary work with this intervention in epilepsy (i.e., Epilepsy Journey), which found moderate to large effect sizes from baseline to 6-month follow-up, ranging from d = 0.55 to d = 0.93 for the Global Executive Composite Score, the composite measure of the Behavior Rating Inventory of Executive Function, which represented our barriers outcome of interest. Additionally, preliminary data on our primary outcomes collected at CCHMC from 2016-2017 (i.e., Stress/Burnout and Time Pressure/Planning subscales) show that our patients improve slightly over one year with Enhanced Standard of Care, corresponding to an effect size of d = 0.19. A Monte Carlo simulation in Mplus with n = 5000 replications was conducted assuming: 1) proper handling of missing data; 2) 25% attrition; 3) standardization of all analysis variables; 4) at least 30% of the error variance in our primary outcome (R^2 = 0.30) being explained by baseline barriers scores and covariates; 5) we will observe the smallest effect size from our preliminary work in the treatment group (i.e., d = 0.55); and 6) we will observe a small improvement in our control group (d = 0.19). **Recent interim analyses and meetings with our NIH program officer have yielded a change in our study design from a fully powered RCT to detect subgroup differences to a pilot RCT focused on feasibility, acceptability, satisfaction and preliminary efficacy differences between the control and treatment groups. These new analyses indicate the need for a total sample size of n=190 (n=95 in the control group and n=95 in the treatment group).**

9. POTENTIAL BENEFITS

No immediate or direct benefits to patients participating in this study are expected. However, it is our hope that participants will have reduced adherence barriers and learn better disease management skills. The information obtained from this study can ultimately be used to increase

knowledge in the scientific community about how to improve adherence barriers in youth with T1D.

10. POTENTIAL RISKS, DISCOMFORTS, INCONVENIENCES, & PRECAUTIONS

There are minimal potential risks/discomforts/inconveniences to participants in this study, no greater than those encountered in routine behavioral assessment and clinical care. There are no medical risks. All the questionnaires have been used in research, including our own, without any reported negative effects; however, it is possible that a small group may feel uncomfortable responding to questions. Participants may decline answering questions that cause them to feel uncomfortable and will be reminded of this prior to each study visit. Participants may also withdraw from the study at any time and will be informed of this right during the consent/assent process.

If a participant is distressed by any study procedures, the site PI or designee will be contacted immediately to assess the situation. The study PI or their designee will provide appropriate referrals and/or intervention. Safety procedures for suicidal ideation and reports of abuse/neglect are delineated in our safety monitoring committee plan (See Appendix E). In both cases and similar to above, the study PI or their designee at each site will be contacted immediately and he/she will assess the risk profile of the caregiver and/or adolescent participant with subsequent recommendations based on the level of risk. Further, the PHQ-8 assesses participants for depressive symptomology. Though the suicidal ideation item has been removed from this version (e.g. PHQ-8 not PHQ-9) for the purposes of the current study, a significant elevation on the PHQ-8 suggests the participant is experiencing significant depressive symptomology. The PHQ is given during routine diabetes clinic visits and data from the measure will be entered into REDCap when available. The diabetes clinical team addresses elevations on the PHQ during routine clinical care and thus if elevations are addressed during clinic, no further action will be taken by our research team. However, if the PHQ is only administered via the research protocol and there is an elevation on the PHQ, the following actions will be taken. REDCap is now programmed to send an alert if anyone scores $\geq$10 (considered moderate risk) on the PHQ. The alert will be sent to the site PI, supervising psychologist and coordinators. Results will also be communicated to the primary caregiver or adult participant within 3 business days of the elevation and appropriate referrals to outpatient mental health services will be provided, as necessary. In the instance a family is unable to be contacted within 3 business days despite several attempts, a letter (see Appendix P) will be sent to the address on file detailing this information. Additional details on these procedures are provided in Appendix E.

There is also the risk of possible loss of privacy of data or loss of confidentiality. These risks are inherent in all research studies, and a statement to this effect will be included in the informed consent/assent documents. Every effort will be made to ensure that all participant information will be kept confidential. A majority of this study is going to be conducted via Zoom sessions. Participants will access or receive information from several different sources including REDCap, Tidepool, Diabetes Journey site, T1Dtoolkit site, and Zoom for Healthcare. De-identified ID numbers will be used when possible for the sites. For example, enrolled participants will be assigned a secure login ID and password by the study staff to access measures via REDCap and/or to upload diabetes devices through Tidepool or other platforms. Each site will only be able to see their own site's participants in REDCap, with the exception of the lead site (CCHMC). Additionally, The University of Florida PI and her study team will manage the study for the University of Colorado Barbara Davis Center. They are all non-paid employees of the University of Colorado Barbara Davis Center and are authorized to have access to the University of Colorado Barbara Davis Center data. The University of Florida and University of Colorado Barbara Davis Center teams will meet weekly to review the study protocol, monitor recruitment and discuss other study related issues that may arise. Participants will be asked not to share their ID or password with anyone else. Use of Protected Health Information (PHI) on online measures will be minimized and participants will not be asked to enter their last name, date of birth, or medical record number on the online measures. When the study is complete,

the content of the site will be taken down. Setup is consistent with HIPAA guidelines and was designed to support projects that contain PHI and are subsequently subject to compliance with federal and state regulations regarding data of this type. Similarly, the Wordpress and T1Dtoolkit sites for the DJ modules will be linked to their study ID and there will be no identifying information listed in this site. Similarly, although Zoom for Healthcare is HIPAA compliant, participants will be required to login to the secured Zoom server for sessions and will be provided with the Zoom link to their email accounts. This information and protection of the participant's identity will be clarified in the informed consent and assent forms. We will provide each participant with a unique anonymous Tidepool username and password (See Appendix I). Finally, because interventionists can be from CCHMC or the University of Florida, participant information to conduct intervention sessions will be shared with the interventionist and appropriate supervisor in order to contact them.

To communicate study related information across sites, our team will be using Trello, a task management system that is frequently used by research teams. No identifying information will be entered into the Trello system; however, we will be tracking participants through the study procedures using their study ID.

Notably, the only place the study ID will be linked to the name and demographics is the participant database, which is password protected, individually, at each site by the research team. No other individuals outside of the IRB-approved research team from both sites will have access to this participant database.

11. RISK/BENEFIT ANALYSIS

There is minimal risk associated with study participation. If participants feel distressed as a result of their participation, they will be encouraged to discontinue. The PI and site PIs or their designee will be available to participants during study participation to assess for discomfort, safety, and risk, as needed. The minimal risks of this study do not outweigh the potential indirect benefits that may be gained through increasing knowledge about best practices for improving adherence barriers to treatment in adolescents with T1D.

12. DATA SAFETY AND MONITORING

This is a multisite observational study and is considered minimal risk. Safety monitoring will occur at the level of the multiple PIs due to the minimal risk nature of the study. See Appendix E for details of the NIDDK approved data safety and monitoring plan.

13. PRIVACY AND CONFIDENTIALITY

All study personnel have been trained in data safety and monitoring, privacy and confidentiality, minimizing risks related to loss of privacy and confidentiality. We will closely monitor performance of our research personnel to ensure the strictest standards. Additional information related to privacy and confidentiality is noted above in section 10.

***13.1 Data De-Identification*:** All data will be de-identified with the use of unique assigned study identifier codes. No other identifying data such as address, phone numbers, social security number, or zip code will be entered on electronic measures. Electronic data files (including downloads of data from REDCap measures) will only identify participants via study identifier codes and will be password protected. Electronic data files will be maintained on CCHMC hard drives.

Because this research study involves payment for participation, we are required by Internal Revenue Service (IRS) rules to collect and use participant's social security number (SSN) or taxpayer identification number (TIN) in order to track the amount of money that we pay them. Unless they have given specific permission for another use of their SSN or TIN related to this research study, we will only use their SSN or TIN to keep track of how much money we pay them and their SSN or TIN will not be used as part of this research study.

13.2 Data Storage and Management

Informed consent/assent documents and all electronically collected data will be maintained in REDCap, a secure web-based platform, and in a password protected electronic database on CCHMC hard drives. Device data downloaded from Tidepool (a HIPAA compliant website used routine for clinical care) will be kept in password protected electronic databases at CCHMC. CCHMC is the Primary Site and will manage all the final deidentified data. Paper informed consent/assent documents will be maintained in locked storage cabinets, if they are needed, and will be kept separate from participant data.

Trello (www.trello.com), a web-based project management tool, will be used to coordinate study-related tasks across sites. No identifiable patient information will be saved in this platform. Medical chart data will be collected by trained study staff at each site under the supervision of the PI or site PI. These risk protection methods have been effectively used by the PI and her collaborators for numerous studies.

Individual data will not be available to anyone not directly associated with the study. All study personnel have been trained in data safety and monitoring, privacy and confidentiality, minimizing risks related to loss of privacy and confidentiality. We will closely monitor performance of our research personnel to ensure the strictest standards. Study-related information will not be released without written permission of the participant.

14. COST OF PARTICIPATION

There are no costs for participation in this research study. Participants will be responsible for the usual costs of medical care.

15. PAYMENT FOR PARTICIPATION

Caregivers will be compensated for participation in the study in the form of a reloadable debit card (ClinCard). They will receive a handout that will explain how to use this card. A graduate incentive schedule will be as follows:

	Adolescents		**Caregivers**
	Questionnaires	*Device Download*	*Questionnaires*
Phase 2 (n=256)			
Baseline	$10	$10	$10
Post-treatment	$15	$10	$10
Follow-up	$20	$10	$10
TOTAL	**Up to $75**		**Up to $30**

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