Diabetes Journey: An Adolescent Adherence Barriers Intervention
Parental Permission Form

NCT04404556 Unique Protocol ID: 2020-0162

CCH IRB Approval Date: 6/20/23

TITLE OF RESEARCH STUDY: ***Diabetes Journey: An Intervention to Improve Adherence Barriers for Adolescents with Type 1 Diabetes***

Investigator:
XXXXXXX

Contact Info:
XXXXXXX
Phone: XXXXX

Funding: **National Institute of Health: R01DK121295**

Key Information:

The following is a short summary of this study to help you and your teen decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

The goal of this study is to help teens with Type 1 Diabetes (T1D) navigate any barriers that might make it harder for them to follow their diabetes regimen. Our research and clinical work has shown us that following a regular treatment everyday can be difficult for teens, especially when things get in the way, like stress and burnout. We have created an intervention to help teens called Diabetes Journey. Our study will use mobile health ("mHealth") technology (e.g., cell phone, tablet, or computer) to provide teens with different tools to help them better manage their diabetes. Because we are using mHealth, all the materials are web-based and all sessions with our diabetes educators and coaches will occur via telehealth Zoom for healthcare.

During the study, our goal is to recruit 190 teens (ages 12-17) with T1D at three diabetes sites across the country in order to help teens with T1D navigate barriers to their treatment regimen by using a mHealth intervention we have created. You and your teen will complete surveys at the time of enrollment (either paper/pencil or via a website). As part of the study, your teen will also be asked to download their pump/continuous glucose monitor/meter data to a website called Tidepool.

Teens will be in one of two groups. Group 1 will receive educational materials via a website and four sessions with a diabetes educator. Group 2 will log on to a special website with modules that were created to address particular barriers. The amount of modules your teen receives will be based on answers on the questionnaires they fill out. After your teen completes each module (up to 8), a diabetes coach will review the information and help them problem-solve ways to address things that get in the way of their diabetes management.

When teens are done with the intervention (up to 3 months), you and your teen will complete questionnaires again and upload diabetes device data to Tidepool. You will do this one more time 3 months after the intervention is completed, at which time your study participation will end. Your teen will participate in the intervention and you will be asked to complete surveys at 3 times during the study. The study diagram below shows you how the study will work.

Parents/Guardians: You have the option of having your teen join this research study. This is a parental permission form. It explains this research study. If you decide that your teen can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

<table>
<tr><td>Diabetes Clinic</td><td>First 4 Weeks  </td><td colspan="2">Survey (Parent = $10, Teen = $10) and Tidepool Upload (Teen = $10)  </td></tr>
<tr><td>At Home</td><td>Months 1-3</td><td>  
We will flip a coin and you go to Group 1 or Group 2</td><td>Group 1: Educational materials on webpages AND telemedicine sessions

Group 2: Diabetes Journey modules AND telemedicine sessions</td></tr>
<tr><td>Diabetes Clinic</td><td>Month 3</td><td colspan="2">  Survey (Parent = $10, Teen = $15) and Tidepool Upload (Teen= $10)</td></tr>
<tr><td>Diabetes Clinic</td><td>Month 6</td><td colspan="2">  Survey (Parent=$10, Teen= $20) and Tidepool Upload (Teen= $10)</td></tr>
</table>

Reason for the study:

The main reason for this research study is to help teens with T1D follow their diabetes regimen more consistently by overcoming barriers related to stress and planning/organization. Problems with diabetes regimen adherence (i.e., taking medication consistently as prescribed by a doctor) are common in teens with T1D and we need to better understand the strategies that are most helpful for teens to overcome difficulties with adherence. Our study will help us to learn more about how mobile health technology (mHealth) can be used to improve adherence among teens. You and your teen are being asked to be part of this study because your teen is between the ages of 12 years old and 17 years old, has been diagnosed with T1D for longer than 1 year, may have some difficulty with T1D management and is fluent in English.

Procedures:

You and your teen will be asked to complete a number of questionnaires about how they manage their T1D regimen and some background information. You will complete these via a website or paper and pencil. We will also review your teen's medical record to gather information about their T1D diagnosis and treatment plan. Teens will also be asked to upload their diabetes device data to a website called Tidepool. You will be provided instructions on how to do this and this can be done in clinic, if needed. If you experience difficulty uploading device data to Tidepool, other software used as a part of routine clinical care (e.g., Glooko, Carelink, TConnect) may be used to assess adherence to diabetes care. Study staff will work with your family and provide technical support as needed.

After you both complete questionnaires and upload diabetes device data to Tidepool, your teen

will be assigned to one of the two groups. Group 1 will receive educational materials via a website and four sessions with a diabetes educator. Group 2 will log on to a special website with modules that were created to address particular barriers. The amount of modules they receive will be based on answers on the questionnaires they fill out. After they complete each module (up to 8), a diabetes coach will review the information and help them problem-solve ways to address things that get in the way of their diabetes management. Coaches/diabetes educators for both Group 1 and Group 2 will be from Cincinnati Children's Hospital Medical Center or the University of Florida. The time they will receive this intervention is up to 3 months.

Throughout the study, your teen will continue to follow their diabetes regimen as prescribed.

After the intervention, you and your teen will complete questionnaires again and upload diabetes device data to Tidepool. This process will also occur at one more follow-up visit (3 months following the end of intervention).

- You each will be compensated every time you fill out study questionnaires.
- We expect you to be in the study for up to ~6 months altogether. The first 4 weeks are only to get information on how you take your insulin. The next 1-3 months are the intervention period and then you will complete measures again and download diabetes devices data to Tidepool. This will happen once (3 months following intervention) more.
- None of the research procedures are part of routine clinical care.
- You will be asked to complete questionnaires at least 3 different times.

More detailed information about the study procedures can be found under **"*(Detailed Procedures)*"**

Risks to Participate:

There are minimal risks to participants in this study. Study questionnaires have been used in research without any reported negative effects. You and your teen can refuse to answer questions for any reason. More detailed information about the risk can be found under "(Detailed Risks)"

Benefits to Participate:

There are no known benefits to you or your teen for taking part in this research. However, it is possible that your teen will learn more about ways to manage their diabetes regimen. The information that the researchers learn from this study will allow health care professionals to have a better understanding of how we can improve diabetes regimen adherence and disease management for teens with T1D in the future.

Other Options:

Participation in research is completely voluntary. Your and your teen's decision to participate or to not participate will not affect the care your teen receives. The alternative to participating in this research study is to not participate.

Cost to Participate:

Aside from time, there are no costs for participating in this research study. You will be responsible for the usual costs of your teen's medical care, but you will not be charged any additional costs for study participation.

Payment:

If you and your teen agree to take part in this research study, your teen will be compensated a total of up to $75 and you will be compensated a total of up to $30. You and your teen will complete questionnaires 3 times in the study and receive compensation once questionnaires have been completed (Baseline: Parent=$10, Teen=$10; Post-intervention: Parent=$10, Teen=$15, Follow-up 1: Parent= $10, Teen=$20). Your teen will also be compensated every time they download their meter/pump data to Tidepool (Baseline=$10, Post-Intervention=$10, Follow-up 1=$10). You each will receive payment for this study in the form of a reloadable debit card. We will give you and your teen a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's Hospital Medical Center (CCHMC) is required by the Internal Revenue Service (IRS) to collect and use your teen's social security number (SSN), as well as your SSN or taxpayer identification number (TIN) to track the amount of money that we pay. You and your teen will need to complete a Federal W-9 form for this income tax reporting. This form also requires your teen's Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your teen's study chart. If you and your teen move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	XXXXXX	Phone: XXXXX
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**XXXXX** **XXXXX**	Phone: XXXXXX XXXXXXX
• Your teen's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: XXXXXX

Total number of participants:

Out of 190 teens in the entire study, we expect about XXX teens from <YOUR SITE HERE> to participate in this research study. Cincinnati Children's Hospital Medical Center (CCHMC) is the Primary Site for the study, and data from other sites will be shared with minimal identifying information.

Detailed Procedures:

- If you and your teen decide to participate, you and your teen will be asked to complete study questionnaires. Your teen will also be asked to download their pump/continuous glucose monitor/meter information to Tidepool, a secure website for T1D patients. Teens will be provided with an anonymous ID and password for a free Tidepool account. If your family experiences difficulty uploading your device data to Tidepool, other software used as a part of routine clinical care (e.g., Glooko, Carelink, TConnect) may be used to assess adherence to diabetes care. Study staff will work with you and provide technical support as needed.
- After you and your teen complete the questionnaires and download diabetes device data to Tidepool, your teen will be placed into one of two groups.
- Which group your teen gets will be chosen by chance, like flipping a coin. Neither you, your teen nor the study doctor will choose what group they get. The intervention will last up to 3 months.
- Group 1 will receive access to an education website designed to teach them about T1D in teens and young adults. They will also have 4 Zoom (or phone) calls with certified diabetes educators across 12 weeks. Zoom for Healthcare is a HIPAA-compliant videoconferencing platform through which online sessions for the study will be conducted. Links to the sessions will be sent to your teen's email address, and they can join the session via Zoom on either a computer, tablet, or cell phone.
- Group 2 will log onto a special website with modules that were created to address particular barriers. The amount of modules your teen gets will be based on answers on the questionnaire they fill out. They will get up to 8 modules and have telehealth Zoom for healthcare sessions with a diabetes coach following completion of each module. Links to the sessions will be sent to your teen's email address, and he/she can join the session via Zoom on either a computer, tablet, or cell phone.
- After your teen has completed the intervention period, you and your teen will be asked to complete questionnaires two more times (immediately after the intervention, and 3 months later). Each of you will be compensated for completion of questionnaires with individual reloadable debit cards (ClinCard). Your teen will also be asked to download their diabetes device data to Tidepool at each of these time points, utilizing their original Tidepool ID and password. After each of these times they will be compensated an additional $10.

Change of Mind/Study Withdrawal:

You and your teen can leave the research at any time; it will not be held against you or affect your teen's care in any way.

If you or your teen decide to leave the research, contact the investigator so that the investigator can document you are no longer interested in participating in the study.

The person in charge of the research study or the sponsor can remove you and your teen from the research study without your approval. Possible reasons for removal include: the study doctor determines that it is in your teen's medical best interest, the study ended early for any reason, or new information becomes available.

If you or your teen withdraw permission to use and share your PHI, you and your teen would be withdrawing from participation in the research study. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Detailed Risks:

LESS COMMON, LESS SERIOUS
• Psychological risk: Discomfort filling out questionnaires (infrequent) or how they manage their diabetes. Questionnaires may also ask about sensitive information, such as about your child's mood. We will inform you if there are any concerns (infrequent) and provide additional information on resources available to your family, as needed. • Privacy risks: Loss of confidentiality (rare) • Unknown or unforeseen risks associated with study participation

If any of the procedures cause you or your teen to feel uncomfortable in any way, you will be encouraged to discontinue. The PI will meet with you and/or your teen to discuss concerns, and if appropriate, assist in making clinical referrals.

Another risk may be loss of confidentiality. Please see the section of this consent form entitled Privacy to learn steps that will be taken to reduce the risk of loss of confidentiality.

Finally, there may be unknown or unforeseen risks associated with study participation.

Privacy:

Efforts will be made to limit the use and disclosure of your and your teen's personal information, including research study and medical records, to people who have a need to review this information. Participation and results of research tests/procedures will be included in your teen's medical record. All information within your teen's medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you/your teen to the extent allowed by law.

We cannot promise complete privacy. Organizations that may inspect and copy your/your teen's information include the IRB and other representatives of this organization. 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 anonymous study ID. We will be using a WordPress portal for the education and barriers to diabetes adherence modules. These will only include your anonymous study ID; you will be given a unique ID and password to access this system. Tidepool, or if needed other clinical care device portals (e.g., Glooko, Carelink, TConnect) will be used to gather diabetes technology data, which is a HIPAA secure website.

Cincinnati Children's Hospital Medical Center, the Primary Investigator and Co- Investigators collaborating on the study will take the following precautionary measures to protect you and your teen's privacy and confidentiality and/or your teen's medical records. All participants' data will remain strictly confidential, as all information is coded with a unique number, rather than you or your teen's name or other identifying information. These files are stored in password-protected computer files or on password protected servers at <YOUR SITE HERE>. All study documents will be stored in a locked cabinet in the PI's secure lab area and only research staff

working on the project will have access to these secured files.

There are some limits to confidentiality for the research study. If a participant (teen and caregiver) reveals intent to harm themselves or others or actual harm (e.g., abuse, neglect, suicidal behaviors), we must disclose this information to ensure your and your teen's safety.

In addition, because the intervention is mHealth, we will need some identifying information (i.e., cell phone number, email address) to send you and your teen study questionnaires. We will make every effort to keep these confidential but cannot guarantee that they will be. Additionally, your coach/diabetes educator and the study team will need information to contact you during the intervention period.

The sponsor, monitors, auditors, and the IRB, will be granted direct access to your teen's medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your/your teen's name and other identifying information confidential.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you and your teen must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
<YOUR SITE HERE> will need to use and share your/your teen's PHI as part of this study.

This PHI will come from:

- Your teen's hospital medical records
- Your/your teen's research records
- The study questionnaires and pump/continuous glucose monitor/meter information

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, time of diagnosis, demographics

Who will share, receive and/or use your/your teen's protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you and your teen as part of this study
- Other individuals and organizations that need to use your/your teen's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The institutional review board at your site, as well as members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs, which serve as the IRB of record for the study.

How will you know that your PHI is not misused?
People that receive your/your teen's PHI as part of the research are generally limited in how they can use your/your teen's PHI. In addition, most people who receive your/your teen's PHI are also required by federal privacy laws to protect your/your teen's PHI. However, some people that may receive your/your teen's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You and your teen may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your/your teen's PHI would also include a withdrawal from participation in the research study. If you or your teen wish to withdraw permission to use and share PHI you and your teen need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you or your teen will be used or shared.

The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your and your teen's permission will expire at the end of the study.

Will your teen's other medical care be impacted?
By signing this document, you agree to participate in this research study and give permission to <YOUR SITE HERE> to use and share you/your teen's PHI for the purpose of this research study. If you refuse to sign this document you/your teen will not be able to participate in the study. However, you/your teen's rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES
The research team has discussed this study with you and your teen, and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you and your teen have had enough time to consider whether you should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____
Printed Name of Parent or Legally Authorized Representative

_____	_____
Signature of Parent or Legally Authorized Representative Allowing Teen and Caregiver Study Participation*	Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____	_____

Signature of Individual Obtaining Consent Date