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Study Protocol

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Discovery Diabetes: A Pilot Randomized Controlled Trial

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Discovery Diabetes:
A Pilot Randomized Controlled Trial

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1.0 Background

Adolescents and young adults (AYAs) with type 1 diabetes (T1D) face unique psychosocial barriers that hinder effective diabetes self-management (DSM), resulting in poor glycemic outcomes. Psychological burdens such as stress, burnout, stigma, and lack of social support contribute to inadequate DSM. These barriers contribute to poor glycemic outcomes, with only 17% of adolescents meeting the recommended HbA1c target of 7.0%. Current diabetes care practices often do not address these psychosocial challenges, resulting in a gap between clinical goals and actual outcomes. This study seeks to evaluate an intervention that integrates 1) clinical informatics-based data collection, 2) clinician-provided support, and 3) personalized mobile health communications to address these barriers.

2.0 Rationale and Specific Aims

The Discovery Program is a novel intervention designed to address these psychosocial barriers by integrating a hybrid model of care that combines completion of a patient reported measure in the patient portal (My Health at Vanderbilt, MHAV), in-clinic collaborative psychosocial goal setting with a nurse practitioner (NP), and between-visit personalized mobile health communications (digital stories and SMS messages). By leveraging clinical, in-person routine care clinic visits, and mobile resources, the intervention aims to improve DSM behaviors, alleviate psychosocial burdens, and ultimately enhance glycemic control in adolescents with T1D. The intervention will be evaluated within the context of routine care at the Eskind Pediatric Diabetes Clinic, a leading regional center for adolescent diabetes care at Vanderbilt University Medical Center.

2.1 <u>Specific Aim 1</u>: Assess the efficacy of the Discovery Program on primary and secondary outcomes in adolescents with T1D. Specifically, we will measure changes in glycemic control, barriers to diabetes adherence, problem-solving skills, diabetes distress, and diabetes self-management efficacy.

2.1.1 <u>Primary Outcome Measures</u>: **Change in glycemic control** (measured by HbA1c): Glycemic control will be assessed through changes in HbA1c levels assessed through routine care visits at baseline, 3 months, 6 months, and 9 months. We will also explore **CGM time in range (TIR)** as a secondary glycemic outcome, as approximately 70% of participants use CGM devices at baseline, 3 months, 6 months, and 9 months.

2.1.2 <u>Secondary Outcome Measures</u>: Change in diabetes distress (PAID-T); Change in barriers to adherence (BDA); Change in problem-solving skills (SPSI-R); Change in diabetes self-management efficacy (SCI).

2.2 <u>Specific Aim 2:</u> Evaluate the success of the intervention implementation and adolescent, parent and clinician satisfaction with the intervention and related

processes using self-report and interview methods at 3 and 6 months.

3.0 Inclusion/Exclusion Criteria

3.1 Inclusion Criteria

- **3.1.1** Adolescents (13-17 years) and young adults (aged 18-21 years),
- **3.1.2** Diagnosed with T1D for at least one year,
- **3.1.3** Access to a smartphone,
- **3.1.4** A My Health at Vanderbilt (MHAV) patient portal account,
- **3.1.5** Ability to read, speak, and understand English
- **3.1.6** An appointment with an NP in the Eskind Clinic within 7 months of initial contact

3.2 Exclusion Criteria

- **3.2.1** Diagnosis of type 2 diabetes
- **3.2.2** Any physical, cognitive, sensory or emotional condition precluding participation in the intervention (seeing/using a phone, hearing digital stories, answering questions).

4.0 Enrollment/Randomization

4.1 Study Recruitment Methods

All possible recruitment strategies have been developed in coordination with and the approval of the VU-VUSN liaison service (https://starbrite.app.vumc.org/research/development/vumcliaison) and the Vanderbilt Coordinating Center (VCC). See the recruitment methods Table 1 below.

Per VUMC policy, the only mechanism by which VUSN research staff will directly contact potential participants is after obtaining a completed written online REDCap form indicating that a parent/young adult wishes to be contacted. All other methods of recruitment that result in the online form completion are required to be carried out by a VUMC employee, either a clinician key study personnel on the project, the VCC or VUMC personnel, or distribution of flyers in the community by the local chapter of Breakthrough T1D (formerly JDRF).

Flow diagrams that illustrate the entire process from recruitment to the conclusion of participation are included in the appendix. These diagrams provide a clear visual representation of each step involved in the Discovery Diabetes RCT, ensuring transparency and ease of understanding.

Table 1. Recruitment Methods and Responsible Parties

	VCC or VUMC Staff	Eskind Clinic KSP	VICTR EHR Recruitment Staff	Break-through T1D staff	VUSN Research Staff
Send mailed letters home to parents and young adults with a QR code	X				
Send emails to parents/young adults to the Vanderbilt research distribution list with QR code					X
Call parents and young adults at home	X				
Send MHAV messages to parents of minors with VUSN phone number and link to the online form	X	X			
Send MHAV messages to adult patients including a VUSN phone number and link to the online form			X		
Distribute QR code to online form via flyers and handouts in clinic		X			X
Distribute interest cards for parents or young adults to complete in the Eskind Clinic (saved in lock box)		X			X
Respond to Completed Online Requests					X
Flyers distributed by Breakthrough T1D staff at events and meetings				X	X

4.1.1 Letters Home to Parents and Young Adults

Two separate letters will be used: one addressed to parents/guardians of eligible potential participants aged 13-17 and one to potential young adult participants aged 18-21. Letters will be mailed by the VCC staff hired by the research team. These letters will introduce the study, explain its purpose, and provide contact information for the study team for those interested in learning more. The letters clarify that recipients are under no obligation to respond or participate. Letters will contain a simple URL and QR code for parents and young adults to complete an online interest form. They will have the option to complete the online interest form or wait until a researcher contacts them. Copies of the letters are included in this application.

4.1.2 Vanderbilt Research Notification Distribution List

The email distribution list allows researchers to email IRB-approved participant recruitment announcements to the Vanderbilt community. Members of the distribution list have the option to subscribe/unsubscribe with each email. For recruitment via email, there will be a link directing the potential participants to the interest form in REDCap. After receiving the completed online form, researchers will contact the parent or young adult. They will have the option to complete online interest form, contact the research team via phone or email or wait until a researcher contacts them. A copy of the email message for the Research Notification Distribution List is included in this application.

4.1.3 Reporting Workbench

Recruiting Workbench Reports are available/viewable in eStar by VUMC KSP. These reports are developed using real-time data and can be customized to meet study-specific inclusion/exclusion criteria that are computable in the EHR. The reports often include additional variables to facilitate study team outreach, such as Research OK to Contact status, MHAV account status, contact information, next upcoming appointment in a specific clinic. While the report displays certain variables/data, it provides easy access to a patient's record for additional screening and confirmation of eligibility. Research team members with appropriate eStar access can view/run the reports as frequently as needed. We plan to use the results from our custom Recruiting Workbench report to facilitate outreach in the following way: 1) To have VUMC KSP send Direct To Patient Messages, as detailed below in recruiting strategy 4.3.1, and 2) To have the VICTR EHR Recruitment Support team send My Health at Vanderbilt (MHAV) recruitment requests, as detailed below in recruiting strategy 4.3.2. Recruitment outreach will be restricted to those patients marked as 'OK to Contact'.

4.1.4 MHAV Messages to Parents/Guardians of Minors

Only Key Study Personnel (KSP) who are VUMC employees will have access to send these messages directly to the parent/guardian accounts based on potentially eligible participants identified through the reporting workbench report. Clinician KSP and VCC/VUMC staff will use MHAV to send messages to the parents or guardians of potential minor participants (ages 13-17). The message will contain general study information, contact details, and instructions for parents to reach out directly to the study coordinator by phone or email for additional details or eligibility screening. The study team-managed MHAV Direct to Patient

Message is included in this application.

The appearance of the message in MHAV will display as "to Proxy" and will specify it is “for [patient name]” to make clear that the communication is intended for the parent/guardian on behalf of the minor participant.

Although the minor cannot directly access the message via their MHAV account, the message is linked to their medical record. Therefore, the message may be viewable if the patient or their representative were to request the medical record in the future. This information will be included in the recruitment plan to ensure transparency. By following this structured workflow, we aim to maintain compliance, protect participant privacy, and reduce the risk of accidental non-compliance in our study recruitment process.

Direct to Patient Messaging Workflow: To ensure compliance and prevent messaging the minor patient directly, KSP will follow a specific workflow:

4.1.4.1 Eskind KSP and VCC/VUMC staff will confirm that only the parent/guardian (proxy) account is selected as the recipient. The patient’s account will be deselected to avoid direct communication with the minor.

4.1.4.2 The MHAV message will be configured with the "do not allow replies" option. Parents or guardians interested in the study will be directed in the message to contact the study coordinator directly via phone or email, as specified in the message content.

4.1.5 Centrally-managed MHAV Recruitment Requests

The VICTR EHR Recruitment Support Team will send recruitment requests via My Health at Vanderbilt (MHAV) to eligible young adults (ages 18-21) who are marked as "OK to Contact" in eStar. MHAV, VUMC’s patient portal, enables patients or their proxies to manage healthcare activities and can be used to send recruitment messages to potentially eligible participants. The MHAV recruitment request message is included in this application.

For this study, the MHAV recruitment request message includes a direct link to the online interest form survey on REDCap. Patients will be

encouraged to click on this direct link and complete the IRB-approved online interest form directly, rather than clicking on 'I'm interested'.

If the patient clicks 'I'm Interested' instead of completing the online interest form, the designated KSP (with eStar access) will receive an In Basket message in eStar indicating the patient is interested. The In Basket messages in eStar will be monitored by VUMC KSP and/or the VU-VUMC Liaison team. In the event a patient clicks 'I'm Interested', they will receive a second message from VUMC KSP and/or the VU-VUMC Liaison team directing them to complete the online interest form. A copy of this message is included in this application.

From this point onward, VUMC KSP will manually update a patient's enrollment status accordingly. The study team will contact interested patients who sign the consent form by telephone or email to confirm their eligibility. Eligibility will be further confirmed through the screening process described below in section 4.2. If eligible, the study team will schedule an in-person or virtual baseline visit. If a patient does not meet eligibility criteria, they will be notified immediately upon completion of the screening process. This ineligibility notification will include contact information for the study coordinator should they have any questions or concerns.

4.1.6 Flyers in Designated Spaces

Flyers containing a QR code linked to the online interest form will be distributed by Eskind Clinic KSP and VUSN Research Staff. These flyers will be strategically placed in Eskind clinic practice manager-approved spaces, such as waiting rooms, and common areas. The QR code will direct individuals to an online form where they can express their interest in participating in the study. The flyers will include brief information about the study, its purpose, and instructions on how to use the QR code to access the interest form.

4.1.7 Flyers Distributed by Breakthrough T1D Staff

Breakthrough T1D is a leading organization dedicated to improving the lives of those affected by type 1 diabetes through advocacy, research, and community support. The local Middle-Tennessee chapter, based in Nashville, will distribute flyers containing a QR code linked to the online interest form in various community locations. These locations may include local diabetes support groups, local newsletters, and other local venues frequented by potential participants. The flyers will provide brief

information about the study, its purpose, and instructions on how to use the QR code to access the interest form.

4.1.8 Interest Cards in Eskind Clinics

Parents and young adults will be able to complete interest cards available to them in the Eskind Clinic, distributed to potential participants by study KSP. If completed, VUSN research staff will contact the parent or young adult followed by the adolescent (only if the parent consents). Consent will be obtained followed by screening questions for eligibility. The screening process is further described below in section 4.2.

4.1.9 Response to Completed Online Interest Forms

VUSN Research Staff will monitor and respond to completed online interest forms submitted by potential participants. Upon receiving a completed form, the research staff will reach out to the parent or young adult to provide further details about the study, address any questions, and guide them through the next steps. This may include completing the e-consent for screening data collection or scheduling a follow-up contact. The research staff will ensure timely and personalized communication to maintain participant engagement and facilitate the enrollment process.

4.2 Screening

After a parent/guardian or young adult has expressed interest in the study, via one of the methods described above, the next step will involve a screening process to confirm eligibility and collect key information. The study team will conduct the screening process using the screening script provided in this application or by accessing relevant information in the consented participant's medical record via the Vanderbilt Health Connect.

Vanderbilt Health Connect is a comprehensive platform designed to streamline and enhance patient care at VUMC. Vanderbilt Health Connect provides secure access to personal health records, including lab results, medical history, and treatment plans. By signing the consent, the parent/guardian or young adult participant will give permission to the study team to access relevant information from their medical record through Vanderbilt Health Connect for screening purposes. This information can only be obtained by VUSN study team personnel once the patient's research enrollment status has been updated accordingly in Epic by VUMC personnel with appropriate access to eStar.

4.2.1 Consent and Assent

Before initiating the screening process, consent will be obtained from the

parent/guardian or young adult (18-21 years old). The consent form will be sent electronically via REDCap, and the participant will be required to sign it before any screening questions are asked. For minor participants under the age of 18, only the parents may grant permission for their child's participation in research. After permission has been obtained from the parents via the signed consent form, assent is to be sought from the child. Assent may alternatively be collected during the baseline visit, if scheduled. No minor participant will be contacted prior to obtaining written/signed consent from the parent/guardian.

4.2.2 Screening Eligibility Confirmation

Using the screening script and/or screening relevant EHR data via the Vanderbilt Health Connect (described above), research staff will confirm the following eligibility criteria:

4.2.2.1 *Age*: Confirm that the potential participant is between 13 and 21 years old.

4.2.2.2 *Diagnosis*: Confirm that the participant has been diagnosed with type 1 diabetes for at least one year. Collect diagnosis date (if known).

4.2.2.3 *Smartphone Access*: Confirm that the participant has access to a smartphone.

4.2.2.4 *MHAV Patient Portal*: Confirm willingness to download and install the My Health at Vanderbilt (MHAV) patient portal app if not already in use.

4.2.2.5 *Language*: Confirm that the participant can read, speak, and understand English.

4.2.2.6 *Clinic Appointment*: Confirm that the participant has an appointment with a nurse practitioner at the Eskind Clinic within the next 7 months.

4.2.2.7 *HbA1c Score*: Confirm that the most recent HbA1c score is between 8.0% and 12.0%.

4.2.2.8 *Type 2 Diabetes* (exclusion criteria): Confirm that the participant does not have a diagnosis of type 2 diabetes or any other type of diabetes other than type 1.

4.2.2.9 *Other conditions* (exclusion criteria): Confirm that the participant does not have any physical, cognitive, sensory, or emotional conditions that would prevent them from participating in the intervention.

4.2.3 Additional Information Collection

In addition to confirming eligibility, the following key information will be collected during the screening process:

4.2.3.1 Name of the nurse practitioner the patient sees in routine care

4.2.3.2 Insurance status (provider; public/private/none)

4.2.4 Eligibility

Based on the screening results:

4.2.4.1 If eligible: The participant will be informed that they meet all the criteria for the study, and the next steps will be discussed.

4.2.4.2 If not eligible: The participant will be thanked for their time and interest, and informed that they do not meet the eligibility criteria for the study. Contact information will be provided for any further questions or information.

4.3 Randomization

This study will employ a 2:1 randomization ratio, assigning participants to either the intervention (Discovery Program, n=100) or control (usual care, n=50) group. The intervention group will receive the 3-month intervention followed by a 6-month follow-up. The usual care group participants will continue with standard diabetes care practices without the psychosocial intervention and will be administered the same research study measures as the intervention group on the same schedule. Randomization will occur during the baseline session after participants have been confirmed eligible for the study, consented/assented, and completed baseline assessments. Randomization will be managed through the REDCap randomization module, which will automatically assign participants to one of the two groups according to a pre-specified 2:1 ratio. To ensure comparability between groups, randomization will be stratified by the following key variables: 1) HbA1c Levels: Moderate (8-10%) and High (10.1-12%), and 2) Health Insurance Status: Private, public, or none. The REDCap module will manage this stratified randomization scheme, which helps maintain balanced group sizes within each stratum, thereby minimizing potential biases related to these characteristics. This approach will ensure allocation concealment and reduce the likelihood of unbalanced groups.

5.0 Study Procedures

5.1 Baseline Questionnaires

The measures described below in Section 5.2 and provided in the appendix will be administered after consent/assent and before random assignment. In addition to the baseline administration of measures, clinical and research data will be collected from both the intervention and usual care group participants at 3, and 6 months.

EHR and routine clinical data will also be obtained at 9 months. All self-report instruments used in this study have demonstrated adequate internal consistency (Cronbach's alpha ≥ 0.70). All measures are included in the appendix.

5.2 Study Measures

In addition to the baseline administration of measures described below, clinical and research data will be collected from both the intervention and usual care group participants at 3, and 6 months. EHR and routine clinical data described below in this section will also be obtained in collaboration with VCLIC and/or the VUMC DataCore.

Table 2. Study Measures and Schedule of Administration

Study Measure	Source	Baseline (REDCap)	Month 1		Month 3* (REDCap)	Month 6	
			Pre-NP Visit (MHAV)	Post-Visit (REDCap)		Pre-NP Visit (MHAV)	Post-Visit (REDCap)
Diabetes Distress (PAID-T)	Participant	X			X		X
Barriers to Diabetes Adherence (BDA)	Participant		X		X	X	
Problem-Solving Skills (SPSI-R: SF)	Participant	X			X		X
Self-Care Inventory (SCI-R)	Participant	X			X		X
Communication Assessment Tool (CAT)	Participant			X			X
Clinician Fidelity Check-In	Nurse Practitioner			X			
Economic and Logistic Burdens of Diabetes Care	Parent/Guardian and Young Adult Participants (18+)	X					
Collaborative Parent Involvement (CPI)	Participant	X			X		X
Exit Interview*	Participant (Intervention Group only)				X		

* Exit Interviews will be conducted with a subset of intervention group participants only during the month 3 visit with the study team described in the procedures below. All other measures will be administered via REDCap for both groups.

5.2.1 **Glycemic Outcomes**: including point-of-care HbA1c values, are obtained during routine clinic visits and recorded in the EHR. No additional testing will be requested or completed in relation to this research. Reports including data from diabetes devices such as CGM, insulin pumps, and blood glucose monitors, will also be obtained from the EHR for the year prior to the study, during the intervention period, and for 9 months after the intervention is complete.

5.2.2 **Demographic and Clinical Information:** will be obtained from the EHR and parent/young adult reports at baseline. Clinical data, including missed appointments, HbA1c history, and diabetes device reports will be obtained after consent/assent. All clinical data that will be obtained either through self-report or the EHR for this research is listed in the appendix.

5.2.3 **Economic and Logistic Burdens of Diabetes Care**: At baseline, parents and young adults will complete assessments related to the economic and logistical burdens of diabetes care, including socioeconomic status (household income, parent education, and insurance type/status), access to reliable transportation, distance from the clinic, and the difficulty of leaving work for diabetes care.

5.2.4 **Barriers to Diabetes Adherence**: The Barriers to Diabetes Adherence (BDA) questionnaire is administered in routine care before each NP visit through the My Health at Vanderbilt (MHAV) patient portal via patient devices at home or utilizing Clinic Epic Welcome tablets. All participants will complete the BDA for this study through this routine care administration. The Barriers to Diabetes Adherence (BDA) is a 21-item self-report measure assessing psychosocial barriers to diabetes self-management (DSM) in adolescents with T1D. The BDA includes five subscales: stress/burnout, stigma, social support, parental autonomy support, and time pressures. This measure has shown concurrent validity with HbA1c. All patients over 13 are administered the BDA in routine care within My Health at Vanderbilt patient portal before visits with their NP. Currently no patients see the results of the BDA. During the trial, intervention participants will be directed to their results feedback and to complete goal setting after completing the BDA. Usual care groups will continue as typical, with no results of their BDA. All data collected through MHAV patient portal will be pulled into the REDCap project nightly through a CDIS process built by the VICTR DataCore for this

research.

5.2.5 **Self-Management**: The Self-Care Inventory-Revised (SCI-R) is a 15-item questionnaire completed by participants assessing diabetes-related self-care behaviors for individuals with type 1 diabetes (Weinger et al 2005). Items cover the primary components of a diabetes treatment regimen such as monitoring and recording glucose levels, administering and adjusting insulin, regulating meals and exercise, and keeping medical appointments. Respondents indicate how often they do each behavior using a 5-point Likert scale (1 = "never do it"; 5 = "always do this as recommended, without fail", with a "not applicable" option only for certain questions). Scores on the SCI-R are converted to a 0- to 100-point scale (higher scores = more optimal T1D management behaviors)

5.2.6 **Diabetes Distress**: The Problem Areas in Diabetes – Teen version (PAID-T) is a 14-item self-report questionnaire that assesses diabetes-specific distress in adolescents. Unlike the BDA, which focuses on the frequency of barriers, the PAID-T examines the level of distress caused by those barriers. Respondents indicate how often they do each behavior using a 5-point Likert scale (1 = "not a problem"; 5 = "a large problem").

5.2.7 **Social Problem Solving**: The Social Problem-Solving Inventory – Revised, Short Form (SPSI-R: SF) is a 25-item self-report questionnaire that assesses an individual's social problem-solving skills in five key domains: positive problem solving, negative problem solving, rational problem solving, impulsivity, and avoidance. Each item is rated on a 5-point scale regarding how true that statement is for the participant.

5.2.8 **Parent Involvement**: The Collaborative Parent Involvement (CPI) questionnaire consists of 12 items assessing perceptions of parent involvement in DSM and problem-solving activities. This measure will be administered to adolescents at baseline and follow-up timepoints to assess the role of parental support in diabetes management.

5.2.9 **Communication**: The Communication Assessment Tool (CAT) is a 14-item self-report questionnaire that measures adolescent satisfaction with health-related communication and is completed by the adolescent. This measure will be administered at baseline and follow-up timepoints to assess changes in satisfaction with communication across the intervention period.

5.2.10 **Clinician Fidelity Check-In**: The Discovery Diabetes Clinician Check-In, administered via REDCap after the first routine clinic visit, evaluates clinician interactions with research participants. The form includes questions on positive engagement, reviewing results, discussing challenges and solutions, setting SMART goals, and providing feedback. It also captures guidance levels, goal changes, additional actions, encountered challenges, and insights for program improvement.

5.2.11 **Goal Setting**: The Goal Setting Questionnaire is administered ONLY to the intervention group participants through the MHAV patient portal. As described in this protocol, this questionnaire displays in MHAV after intervention participants complete their BDA. The questionnaire includes 13 questions focused on setting a goal in relation to their BDA results and other relevant factors, such as why a barrier may be occurring. The items on the BDA and this goal setting questionnaire are used to personalized communications using SMS.

5.2.12 **Intervention Experiences and Feedback Interview:** At month 3, intervention participants will meet with study staff. At the end of that meeting, a subgroup will participate in an 'experience and feedback' interview. The 20-minute semi-structured interview will initiate a discussion about experiences in participating in the program, any problems understanding or accessing the program, the role of the clinician in helping them, and any feedback to improve the program moving forward.

5.2.13 **Additional EHR Data to be Extracted for Participants**: Data to be extracted by the study team from the participant's EHR includes insurance status and diagnosis details, and most recent BDA score at time of recruitment, and BDA, PHQ-9, HbA1c tests, device data (pump, CGM, BG meter), and appointment records from 6 months prior to recruitment through 9 months of the study. A table of this data is included in the appendix.

5.3 Intervention

5.3.1 Intervention Orientation Session

Within 1 month prior to their NP clinic visit 1, consented participants randomly assigned to the intervention group will have an orientation session. This orientation will be conducted either in-person or virtual modality via Zoom depending on the availability of the participants. Up to 5 participants may take part in an orientation session.

Participants will receive an appropriate packet of information (intervention or usual care) about the program via mail, email or in person depending on the modality of the orientation session. Intervention participants will watch a 3-minute animated video about psychosocial problem-solving and view one of the digital stories from the program as an example of the intervention. The video, designed with input from adolescents, introduces strategies to address common diabetes management challenges, such as stigma around insulin bolus administration at school. They will also receive a walk-through of the intervention components (Journey Map in Appendix), including the problem-solving and text message components and a Discovery Users Guide handout. All onboarding materials are included in the appendix.

Parents, adolescents and young adults will be asked to log into their MHAV account during the orientation session. They will also be sent a test text message to establish the functionality of their mobile phone and interaction with the program via SMS. Intervention participants will be given a Discovery Program logo water bottle after orientation.

5.3.2 Pre-Visit MHAV Patient Portal

Once an intervention participant has completed their pre-visit BDA through the MHAV portal, they will be able to view their BDA results via a graph (see screenshot in Appendix) and will be taken to the goal setting questionnaire (appendix). The BDA and goal setting responses will be used to tailor the mobile content of the intervention. After viewing their results, they are guided through a series of goal-setting questions that help them identify specific, actionable self-management goals. This process will include problem identification, brainstorming solutions, and identifying potential barriers and facilitators to success.

5.3.3 Clinic Visit 1 with NP

During the clinic visit, the NP will review the intervention group participant's BDA results and guide them through a collaborative goal-setting session. The NP will either pull the participant's BDA results and share their screen with the participant or the participant will open their own MHAV app to share their results with the NP. The NP will discuss the specific barriers identified, review or develop a timeline for addressing them, and identify safe, realistic changes. Device data available in the medical record, such as continuous glucose monitoring, will be used to help inform the goal. The NP will help the participant locate the

appropriate handouts, called "Cheat Sheets" tailored to the psychosocial burden they identified during the goal-setting session. These 1-page documents, available in print and through MHAV, provide easy-to-understand information about the barrier, myths surrounding it, and actionable strategies for reducing its impact. The handouts are included in the appendix.

5.3.4 Mobile Support

All digital content is sent directly to participants via SMS and participants do not interact with each other in this program.

5.3.4.1 **SMS System Description:** The SMS system used in this study is designed to ensure secure and efficient communication with participants while maintaining compliance with HIPAA and institutional data security standards. All messages are encrypted using 256-bit HTTPS encryption to protect the privacy of transmitted data. The system integrates with Twilio, a cloud-based communication service, to facilitate reliable message delivery, two-way communication, and status tracking. Twilio processes all data in transit and does not store participant-identifying information.

The backend system is built using Ruby on Rails and is hosted on VUMC's secure IT infrastructure, managed by the Department of Biostatistics. Only the Subject ID and participant phone number are stored in the database, with all other data being transitory. Digital stories are hosted on Vimeo, and responses to story questions are reviewed by project staff before being shared anonymously with other participants. The system supports two-way messaging, allowing participants to interact with the study team, and offers an opt-out option for participants to discontinue SMS communications at any time.

5.3.4.2 **Digital Stories:** Once per week for 12 weeks intervention group participants will receive a link via SMS to digital stories created by AYAs with T1D. These stories, approximately 3-5 minutes, address common challenges in diabetes management, such as overcoming stigma or burnout. The stories provide relatable, real-life examples of problem-solving strategies as told by youth with T1D. After viewing each story, participants will complete a series of questions to facilitate learning from the story. These "food for

thought" questions prompt them to relate the story to their own experience, evaluate the outcome, and brainstorm ways to overcome similar challenges. Participants will also view peer responses to the questions to foster social learning. Examples of the digital stories are included in the appendix.

5.3.4.3 **SMS**: In addition to the digital stories, participants will receive four SMS messages per week (a total of 5 SMS messages per week). One message will contain a link to a digital story selected based on the participant diabetes barrier and self-management goal. The other messages reinforce the problem-solving behaviors viewed in the stories, guide the participant through problem solving steps for addressing their specific psychosocial burden, and link the intervention to intrinsic motivation through processes to encourage autonomy, relatedness, and competence.

5.3.5 Month 3 Session with Study Staff

Before this session with the study team, using REDCap participants will complete a BDA and complete self-reflection questions called “How did it Go?” regarding their perceptions of their problem solving. During the session, participants will review graphical feedback of their BDA results. Participants will receive a certificate summarizing their achievement at this time (see appendix). A subset of 20 adolescents from the intervention group will be invited to participate in exit interviews conducted by the study team at the 3-month time point. A non-probability sub-sample of participants that reflects the full range of age and male/female will be selected. These interviews, lasting 15-20 minutes, will document participants' experiences with the Discovery Program, focusing on: 1) Engagement with the mobile communications, 2) Perceived benefits or challenges of the intervention, and 3) Suggestions for improving the intervention and its clinical implementation. This visit will be conducted either in-person or virtual modality via Zoom depending on the availability of the participants.

5.3.6 Month 6 Clinic Visit 2 with NP

5.3.6.1 **Pre-Visit**: In routine care activities, all participants will proceed through completing the BDA before their routine care visit with their NP. The intervention group will proceed through BDA feedback, and follow-up goal setting questions.

5.3.6.2 **<u>During Visit</u>**: Their NP will discuss their BDA results and their experience in the program and provide additional guidance on sustaining the changes made. All participants will complete the 6-month study measures (same as baseline/3-month measures) in REDCap at this time point.

5.4 Usual Care Group

Participants in the Usual Care Group will continue receiving standard care as provided by the Eskind Pediatric Diabetes Clinic, without the intervention. The usual care group will complete the same study measures in REDCap at baseline, 3 months, and 6 months.

5.5 Parents/Guardians of Minor Participants

Parent/guardians of participants ages 13-17 will complete demographic and clinical measures at baseline and parent involvement questionnaire at baseline and 3 months as specified in the measures section.

5.6 Compensation

All adolescent and young adult participants (regardless of group allocation) will be paid $25 for each set of questionnaires completed for a possible total of $75 for questionnaires. In addition, adolescent and young adult intervention group participants who are invited and complete an interview after month 3 will be provided an additional $25. Compensation will be in the form of e-gift cards sent directly to participants.

6.0 Reporting of Adverse Events of Unanticipated Problems involving Risk to Participants or Others

All adverse events (AEs) or unanticipated problems (UPs) involving risk to participants or others will be reported promptly in accordance with institutional and regulatory requirements. If an AE or UP indicates that participants may be at increased risk of harm, affected participants will be notified as soon as possible. If necessary, modifications to the study procedures will be implemented to reduce the risk of future events, and participants will be informed of these changes. The principal investigator (PI) will be responsible for assessing, documenting, and reporting AEs and UPs. For any AE or UP, the PI will ensure appropriate follow-up actions are taken to protect participants' safety. All AEs and UPs will be documented in detail in the study records, including the nature of the event, the assessment of its relation to the study, and any actions taken to mitigate further risk. A summary of AEs and UPs will be included in progress reports submitted to the IRB as required.

6.1 Potential Risks to Participants and Mitigation Strategies

6.1.1 Consent and Assent

This research includes adolescents ages 13-17 and young adults ages 18-21. Parents of adolescents will always provide consent before the adolescent is introduced to the study and assent is obtained. After reviewing the study goals, protocol, and compensation, potential participants will be provided with detailed written information about the study through an electronic consent or assent form in REDCap. During the baseline study session participants, and their legal guardians if applicable, will have ample time to review the consent form, ask questions of study staff, and consider participation before providing consent or assent.

6.1.2 Emotional Distress

While the study involves minimal emotional or physical risks, participants may experience additional insights about problems when completing self-reflection activities or psychosocial assessments related to diabetes self-management. Should a participant express to the study staff that they are experiencing emotional discomfort or distress, they will be given the option to pause or discontinue participation at any time. If warranted, the PI (a clinical psychologist) may contact the parent/participant to discuss any possible distress and provide appropriate resources for further assistance. In cases of severe distress or concern for a participant's safety, the study team will notify the participant's parent or guardian and provide resources, such as referrals to mental health services.

6.1.3 Breach of Confidentiality

There is a potential risk of loss of confidentiality due to the collection of personal data and responses related to diabetes management and psychosocial burdens. All participants will be fully informed about how their data will be used and protected. Privacy will be maintained through the use of secure, HIPAA-compliant platforms (REDCap for data collection and Epic for medical records). All data, including study measures and clinical data, will be stored in a secure, password-protected digital environment. Participants will be informed that their identities will remain confidential throughout the study, and any shared data will be de-identified in reports or publications. If data are shared with other researchers, a data use agreement will be in place to ensure that confidentiality is maintained.

6.1.4 Time Commitment

Participants will be asked to engage in study activities over a 6-month

period, including baseline, 3-month, and 6-month assessments. These assessments will be completed online on their own device. While the time commitment involves routine diabetes management appointments, the commitment also includes study-specific measures and participants may experience inconvenience or time constraints. Feedback on the time burden will be collected through interviews, and participants will be encouraged to communicate any concerns to the study team throughout the study.

6.1.5 Technology Use

Participants will use technology platforms such as My Health at Vanderbilt (MHAV) to complete pre-visit activities and receive SMS notifications as part of the intervention group. The use of these platforms presents minimal risk, including potential technological difficulties or discomfort with mobile engagement. Participants will be provided with technical support if needed and will receive clear instructions on using these platforms to ensure smooth participation.

6.1.6 Physical Risks

This study does not involve any physical interventions or procedures beyond routine clinical diabetes care. There are no physical risks associated with completing study measures or viewing mobile content. As this study involves regular clinic appointments, the physical risks do not exceed those participants would encounter in standard diabetes care.

6.1.7 Summary of Risks

The risks associated with this study are minimal and primarily involve potential emotional discomfort during psychosocial assessments and potential confidentiality breach related to the unintended disclosure of personal health data. All measures will be taken to minimize these risks, and support will be provided to participants as needed to ensure their safety and well-being throughout the study.

7.0 Study Withdrawal/Discontinuation

Participants may voluntarily withdraw from the study at any time without any consequences or impact on their medical care. Participation in the study is entirely optional, and all efforts will be made to ensure that participants are aware of their right to discontinue at any point without penalty.

7.1 Reasons for Withdrawal by the Study Team

The research team may withdraw a participant from the study under the following

circumstances: 1) Failure to attend 2 consecutive scheduled study visits or complete 2 consecutive assessments within the specified timeframe, or 2) An adverse event or emergence of medical or psychological conditions that increase the participant's risk or make participation inadvisable, based on the discretion of the principal investigator (PI).

7.2 Procedures for Withdrawal

If a participant chooses to withdraw, or is withdrawn by the research team, the following steps will be taken:

7.2.1 Data Collection: Any data collected up to the point of withdrawal will be retained unless the participant specifically requests that their data be removed from the study. No further data will be collected after withdrawal. Participants are informed in consent/assent documents that participation or withdrawal will not impact their healthcare. The reason for withdrawal (if provided) and the date of withdrawal will be documented in the study records. If the participant is withdrawn by the research team, the rationale for this decision will also be documented.

7.3 Discontinuation of the Study

In the event that the entire study is discontinued due to unforeseen circumstances, all participants will be informed as soon as possible. The reasons for study discontinuation will be provided, and any necessary follow-up care or resources will be offered. Participants will be allowed to keep any incentives or compensation earned up to the point of discontinuation.

8.0 Statistical Considerations

This pilot randomized controlled trial will include 150 participants (100 intervention; 50 control) assigned using a 2:1 randomization ratio. Randomization will be stratified by baseline HbA1c category (moderate: 8–10%, high: 10.1–12%) and insurance status (private, public, none) using the REDCap randomization module to ensure balance across key prognostic factors.

The primary outcome is change in HbA1c over time (baseline, 3 months, 6 months, and 9 months) between the intervention and usual care groups. Secondary outcomes include changes in diabetes distress (PAID-T), self-management barriers (BDA), problem-solving (SPSI-R), and DSM efficacy (SCI-R).

As a pilot study, the primary objective is to assess feasibility and preliminary efficacy to inform a larger trial. Therefore, while the study is powered to detect a moderate effect size (Cohen's $d = 0.5$) in the primary outcome with 80% power and $\alpha = 0.05$, inferential statistics will be interpreted with caution, and emphasis will also be placed on estimating effect sizes

and confidence intervals.

Process and implementation outcomes (e.g., intervention fidelity, satisfaction, engagement with digital content) will be analyzed descriptively and thematically in the case of qualitative feedback (e.g., exit interviews).

9.0 Privacy/Confidentiality Issues

All data collection, storage, and sharing processes will adhere to institutional, legal, and regulatory standards, ensuring the confidentiality of participants' personal information throughout the study.

9.1 Data Collection and Storage

All study data, including demographic information, surveys, clinical data, and any psychosocial assessments, will be collected and stored in secure, HIPAA-compliant systems, including REDCap for surveys and Vanderbilt's Epic system for clinical data.

Personally Identifiable Information (PII) and Protected Health Information (PHI) will be collected only when necessary and will be de-identified wherever possible. Each participant will be assigned a unique study ID, which will be used to label all collected data and ensure confidentiality.

Access to identifiable data will be limited to authorized study personnel who have completed training in data security, HIPAA regulations, and the responsible conduct of research

9.2 Sharing of Study Data

Participants' clinical data and responses to psychosocial measures (e.g., BDA, PAID-T, SCI) will be collected for research purposes only and will be aggregated for dissemination. Interviews will be coded with a study ID and the matched participant data will be stored in a separate document within REDCap. De-identified data may be used for research publications or presentations.

9.3 Data Access and Use

Study data will be accessible only to the principal investigator (PI) and authorized study personnel. Data will not be shared with external parties unless consent is obtained from the participant.

Collected data will be used solely for the purposes outlined in the consent forms, including research analysis, publication, and presentations.

De-identified clinical and psychosocial data may be used for publications or

presentations, and no identifying information will be included in any external reporting.

9.4 Breach of Confidentiality

In the unlikely event of a data breach or unauthorized access to participant data, the research team will immediately inform the affected participant(s) and report the breach to Vanderbilt's Institutional Review Board (IRB) and the appropriate authorities, following institutional and regulatory guidelines. Affected participants will be notified of any risks posed by the breach, and corrective measures will be taken to prevent future breaches.

10.0 Follow-up and Record Retention

All de-identified research data will be retained indefinitely for research purposes, including future secondary analysis. Personal identifiers, including responses from surveys and other sensitive information, will be securely stored for up to six years following the completion of the study, after which they will be securely destroyed. Any data that are no longer needed or have reached the end of their retention period will be securely deleted or destroyed to ensure no unauthorized access.

10.1 **Record Retention**: All study records, including data collected during the intervention, post-intervention surveys, and any follow-up assessments, will be retained in compliance with institutional and regulatory requirements.

10.2 **Data Retention Period**: All research data, including consent forms, de-identified survey responses, clinical data, and interview transcripts, will be retained for at least six years after the completion of the study. This retention period ensures that the data are available for analysis, reporting, and potential publication.

10.3 **Confidentiality and Secure Storage**: All electronic records, including survey data, clinical information, and interview transcripts (if applicable) will be stored in HIPAA-compliant platforms such as REDCap and Vanderbilt's secure Box system. Access to the data will be restricted to authorized personnel and protected by password encryption. De-identified data used for analysis and reporting will be securely stored, and all identifying information will be kept separate from the research data.

10.4 **Disposal of Data**: At the end of the retention period, all data containing personal identifiers will be securely deleted or destroyed to protect participant confidentiality. This includes the deletion of survey responses, clinical records, and any personal information stored in electronic systems. De-identified data may be retained indefinitely for research purposes, including future secondary analysis.

10.5 **Participant Requests for Data Removal**: Participants have the right to request the removal of their data from the study at any point before or during the data retention period. If a participant withdraws from the study and requests their data be removed, the research team will ensure that all associated data are deleted, provided that it has not already been de-identified and included in published analyses. Participants will be informed of this option during the consent process.

10.6 **Compliance with Regulatory Requirements**: The research team will comply with all applicable regulatory requirements regarding the retention, security, and disposal of research data. Any changes to the record retention policy or additional retention requirements by the study sponsor or IRB will be promptly implemented and communicated to the relevant parties.