

1. Protocol

Protocol Title: Evaluating the feasibility of Type 1 Diabetes Education and Support (T1DES) intervention to improve diabetes distress among Black young adults

Principal Investigator: Teaniese “Tina” Davis, PhD, MPH

Version Date: 2/20/25

2. Objectives

The goal of this research is to test the feasibility and preliminary efficacy of a culturally adapted and tailored intervention to enhance diabetes management strategies among Black young adults with T1D, addressing the pervasive racial disparity in health outcomes for this population. OnTrack is a tested intervention that demonstrated improved outcomes (diabetes distress and HbA_{1c}) among adults (mean age 45.1 years, SD=15.0) with T1D and elevated HbA_{1c}. It involves highly structured, group-based sessions (facilitated by a counselor) and individual support. OnTrack had greater reductions in diabetes distress among patients with lower cognitive function or emotion regulation, higher distress, and higher diabetes knowledge at baseline. Though these baseline metrics among KPGA, Emory Healthcare and Grady Health System patients are unknown, formative work highlighting feelings of isolation, stress, and challenges with self-management render OnTrack an ideal starting place for patients with T1D. While OnTrack improved outcomes in T1D, its relevance to Black young adults has not been tested. More representative and culturally competent interventions are needed.

Primary Objective (or Aim)

Aim 1: Assess feasibility of the culturally tailored intervention T1DES by measuring intervention acceptability, demand (retention, completed > 80% of sessions), practicality, and implementation fidelity through participant surveys and key informant interviews with participants and the health care delivery team.

Secondary Objectives (or Aim)

Aim 2: Evaluate the effect of the T1DES intervention on diabetes outcomes in a pilot randomized clinical trial among N=80 Black young adults age 18-30 years with T1D and elevated HbA_{1c} (>7.5%) by comparing changes in HbA_{1c}, diabetes distress, and self-management from baseline to 6-months post-baseline among participants randomized to T1DES compared to the diabetes education-only control condition. We hypothesize T1DES participants will demonstrate improved HbA_{1c}, reduced diabetes distress, and increased self-management over time compared to controls. Results will be used to generate effect sizes and support an application for larger, fully powered, longer-term trial to evaluate the impact of T1DES on health outcomes and disparities. More research is critically needed on effective strategies that are both inclusive of Black young adults and tailored to their unique challenges.²⁴ Our goal is to provide diabetes education and emotion regulation support tailored for Black young adults’ experiences that will result in sustained glycemic control and can be incorporated into adult endocrinology practices.

3. Background Information and Rationale

Adolescents and young adults with T1D have poorer glycemic control and an increased risk for hypoglycemia and complications,² including diabetic ketoacidosis (DKA) and cardiovascular disease,³ compared to other age groups with T1D. Sustaining target A1c levels early after a T1D diagnosis is essential for preventing complications. In the T1D Exchange Clinic Registry, only 14% of patients aged 18-25 years reached their target HbA_{1c} (HbA_{1c} <7%), which was the lowest among all age groups (Figure 1).¹ Research suggests most adults in their 20s will not achieve target HbA_{1c}'s until age 30.¹ Longitudinal research indicates young adults have declining glycemic control over time¹ and higher rates of diabetes complications compared to older adults with diabetes.¹ Young adults with chronic conditions are at an increased risk being diagnosed with depression compared to peers without a chronic condition⁴⁻⁶. In a recent position statement, the American Diabetes Association (ADA) recommended that all people with diabetes should participate in education and support for diabetes self-management, which should include knowledge and skills-building. Continued education and support are also essential for implementing skills and behavior maintenance over time.⁷ This aligns with national standards for diabetes self-management. New interventions are needed to address ongoing education needs of young adults. Advances in diabetes management strategies have not been as successful among young adults. Our proposal would be the first to adapt and test a proven behavioral intervention among Black young adults with T1D.

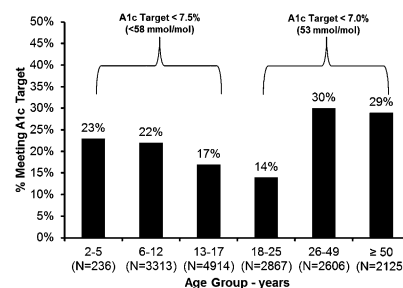


Figure 1. Percent of patients with T1D reaching ADA HbA_{1c} targets by age-group.¹

Racial disparities in T1D disease burden: Recent research has demonstrated the racial and ethnic-based disparities among young adults with T1D. After accounting for socio-economic status (SES), diabetes distress, diabetes self-management, and diabetes technology use were the largest contributors to the disparity in glycemic control between Black and White young adults (YA) with T1D, with Black YA having poor glycemic control.⁸ From 2002-2012 there were significant increases in T1D incidence among all youth aged 0-19 years⁹ and from 2011-2015 the annual percent change in increases in T1D incidence for Black Americans was 4%, as depicted in Figure 2.¹⁰ However, the statistically significant increase in disease incidence is climbing at a different rate for Black patients and indicates racial and ethnic differences in care, treatment, and outcomes^{9, 11-13} with disparities disproportionately burdening non-Hispanic Black patients compared to non-Hispanic White patients.^{1, 14} While T1D is more prevalent among White patients compared to other racial groups, research consistently indicates that Black patients with T1D have significantly poorer glycemic control, and more complications.^{1, 12, 15} Factors contributing to the racial health disparity in diabetes outcomes include depression, obesity, social and environmental stressors which contribute to poor treatment adherence, inflammation, and insulin resistance.¹² Even after controlling for age, time diagnosed with diabetes, and mean blood glucose, Black children with diabetes still had significantly higher HbA_{1c} levels.¹⁶ Psychosocial problems have been disproportionately higher among Black youth compared to

Figure 2. Model-adjusted incidence of type 1 diabetes among youths, overall and by race/ethnicity* — SEARCH for Diabetes in Youth Study (SEARCH), United States,† 2002–2015

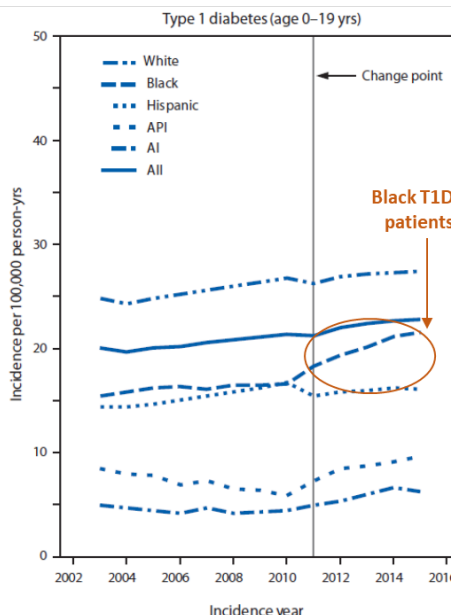


Figure modified from Divers et al. (2020)

non-Black youth, with increased reports of depressive symptoms, parenting stress, youth behavior problems, and family conflict.^{17, 18} The education and support provided to this population should be culturally competent,¹³ representative, and multimodal.¹⁹

The case for culturally tailored interventions. Providers have described diabetes education, the primary source for patient education and support, as too generic and lacking sensitivity to the needs of ethnically minority communities, namely Black African and Caribbean communities.²⁰ Culturally tailored interventions improve health outcomes for ethnic minorities with diabetes and other chronic conditions;²¹⁻²⁵ these interventions are emic in structure and emphasize unique practices common to a specific culture and especially necessary when existing interventions are Eurocentric in nature²⁶ or developed with Eurocentric groups. Using the tested ADAPT-ITT framework,²⁷⁻³⁰ our study would be the first to systematically adapt and evidence-based intervention to be culturally competent and tailored for Black young adults with T1D.

Diabetes Distress among people with type 1 Diabetes. Diabetes distress is the negative emotional effect of living with diabetes.³¹ Diabetes management requires consistent monitoring, complex navigation of social situations to remain adherent to self-management, and high engagement with health care providers, including the recommended blood draw to monitor HbA_{1c} levels every three months. Diabetes distress addresses the additional stressors and emotional impact a person with diabetes experiences that is specific to diabetes.³¹ Diabetes distress has been documented among people with both type 1 and type 2 diabetes and it presents differently in both groups. Among people with T1D, Fisher and colleagues identified seven (7) key sources of distress: powerlessness, management distress, hypoglycemia distress, negative social perceptions, physician distress, and family/friend distress.³² Diabetes distress is distinctly different from depression and is likely over diagnosed among people with diabetes.³³ In our formative work at KPGA with members with T1D, many of the themes that emerged in qualitative interviews were specific to their diabetes status and management – feelings of isolation, challenges communicating with family/friends, concerns about management, and feelings of helplessness. Diabetes distress has also been identified as one of the largest contributors to racial disparities between Black and White young adults ages 18-25 years with type 1 diabetes.⁸ Our study will address diabetes distress among Black young adults by tailoring an intervention relevant to their experiences managing T1D.

Representation of Black patients with T1D in diabetes distress intervention research. While a few tested behavioral interventions have been proven effective in improving glycemic control and diabetes stressors among adults, these interventions were tested primarily among white patients³⁴⁻³⁷ or did not report race.³⁸⁻⁴⁰ In studies examining diabetes distress self-regulation that reported race, the largest representation of Black patients was 5.8% among adults.³⁷ Interventions that are developed and tested with majority White samples may miss critically important opportunities to include culturally relevant examples, scenarios, and solutions. Black patients are heterogeneous and study samples with a lower percent of Black participants may miss their heterogeneity.⁴¹ Further exacerbating the lack of representation is a well-documented hesitancy among Black people to participate in medical research.⁴²⁻⁴⁵ Recent research examining racial disparities in young adults with T1D suggested that Black young adults with T1D may benefit from re-education and behavioral interventions addressing diabetes distress and self-management.⁸ To our knowledge, no previous behavioral interventions to reduce diabetes distress have been tailored and tested for high-risk Black young adults with T1D. The goal of this research is to address the empirical gap and add greater representation of Black young adults with T1D by ensuring their experiences and narratives are included in the intervention development phase and then tested to determine if the intervention is feasible and efficacious. Based on focus group data, we recommend refining scenarios and diabetes management recommendations to be inclusive of Black adolescents' lives.⁴⁶

- a. **Intervention modality.** In a meta-analysis of interventions that have reduced diabetes distress among people with diabetes, effective interventions used psycho-education with both diabetes and mood/motivation content, were 3-6 months in length, delivered intensely and were implemented by a generalist (GP or practice nurse); most effect sizes were <0.2. Motivational interviewing was included in many of the psycho-educational interventions; seven (7) studies demonstrated that motivational interviewing improved self-management and reduced elevated HbA_{1c} levels.³⁴ Diabetes distress interventions that often use motivational interviewing have demonstrated significant reductions diabetes distress, and improvements in diabetes self-management and glycemic control.^{31, 34, 35, 47, 48} Recent research suggests intervening before diabetes distress starts can prevent development of diabetes distress among adolescents.⁴⁹ Support groups⁵⁰ and other care pathways⁵¹ have improved HbA_{1c} levels and reduce depressive symptomatology among patients with T1D.⁵² Research indicates young adults may benefit from diabetes care activities that engage others in their diabetes management.⁵³
- b. **Use of technology to extend program reach.** Technology-based health education is a viable tool to provide support and information to emerging adults. In a study conducted by Pew⁵⁴, 72% of adults with chronic conditions use the internet and were significantly more likely than adults without chronic conditions to use the internet to gather information about their health, treatment, or view stories or videos about another person's health experience.⁵⁴ There is increasing evidence of the potential for self-management using mobile health (mHealth) applications and technology-based resources to improve outcomes among adolescents with chronic conditions; mHealth can be a key component in enhancing effectiveness and efficiency of achieving and sustaining health goals.⁵⁵ Pew data indicate 95% of Americans own a cellphone, 100% of people aged 18-29 own a cellphone, of whom 94% own a smartphone.⁵⁶ Use of text messages in disease management may be under-utilized. In 2012, 80% of cell phone users reported sending/receiving text messages, while only 9% reported receiving health information via text.¹⁹ Interventions for T1D have successfully used a combination of mHealth and clinical support⁵⁷ including counseling sessions with a nurse,⁵⁸ feedback from a Diabetes Educator,^{59, 60} and telephone reinforcement.⁶¹ Interventions report improved diabetes symptom control,⁶² insulin management,^{63, 64} patient-provider interaction,⁶⁴ management efficacy,⁶⁴ and blood glucose (BG) readings,⁶⁵ and decreased HbA_{1c}s.⁶⁶ Our proposed study will use SMS to extend the reach of the T1DES intervention using tailored messages, a strategy with high utilization among young adults.
- c. **Engaging both insured and uninsured populations:** With diabetes disproportionately affecting low-income populations, Medicaid plays a key role in financing diabetes care since it is the U.S.' primary health insurance program for low-income populations. Compared to uninsured adults with diabetes, their insured counterparts have better diabetes management and fewer preventable complications. Given lack of Medicaid expansion in Georgia and less favorable health care engagement and outcomes for uninsured adults with diabetes, it is important to develop strategies to improve diabetes management and prevent diabetes complication for young adults receiving diabetes care at a public hospital in Georgia.
- d. **Summary.** Given the pervasive racial disparity in T1D outcomes disproportionately burdening Black patients, it is imperative to have evidence-based interventions tailored to Black patients. Representation of patients' lived experience is vital to engaging disenfranchised groups in behavioral interventions. In addition, Black young adults have dual memberships in groups with low glycemic control, highlighting a critical need currently not addressed by existing evidence-based interventions to decrease diabetes distress and improve glycemic control among adults with T1D. Our feasibility study will address a critical gap for Black young adults by tailoring and testing an evidence-based intervention to improve diabetes distress and glycemic control.

4. Study Design

This is a pilot randomized trial to assess feasibility of the T1DES intervention for young adults aged 18-30 years with T1D at Kaiser Permanente Georgia (KPGA), Emory Healthcare and Grady Health System, including Children's Healthcare of Atlanta at Hughes Spalding. The study will tailor OnTrack for Black young adults with T1D then aim to evaluate feasibility (Aim1) and evaluate effect of T1DES on diabetes distress and glycemic control (Aim 2). This study will enroll 80 total members to participate in a randomized clinical trial (RCT) with two study arms: 1) T1DES intervention condition and 2) a diabetes education-only comparison condition. The intervention will be 3-months in duration and will include 5 sessions and SMS-based intervention messages delivered. Study activities may be recorded and transcribed for study purposes.

5. Study Population

a. Number of Participants

We will run multiple cohorts until we reach a total sample size of N=80 over a 24-month recruitment period.

b. Inclusion and Exclusion Criteria

KPGA Inclusion and Exclusion Criteria

Inclusion Criteria

- Kaiser Permanente Georgia Member at time of enrollment
- Aged 18 – 30 years
- Confirmed diagnosis of Type 1 diabetes
- Recent A1c > 7.5
- a cell phone able to send/receive text messages
- Self-reported race of Black or African American
- Ability to read in English and provide informed consent

Exclusion Criteria

Exclusion Criteria: Members with the following characteristics will be excluded from study:

- Developmental delay or other cognitive impairment that would render the participant unable to provide informed consent
- Subjects with visual impairment or have severe hearing or other physical disabilities that would be a barrier for participating in-group or web sessions
- Diabetes complications that would preclude participation in the study

Emory Healthcare Inclusion and Exclusion Criteria

Inclusion Criteria

- Emory Healthcare Patient
- Aged 18 – 30 years
- Confirmed diagnosis of Type 1 diabetes
- Recent A1c > 7.5
- a cell phone able to send/receive text messages
- Self-reported race of Black or African American
- Ability to read in English and provide informed consent

Exclusion Criteria

Exclusion Criteria: Members with the following characteristics will be excluded from study:

- Developmental delay or other cognitive impairment that would render the participant unable to provide informed consent
- Subjects with visual impairment or have severe hearing or other physical disabilities that would be a barrier for participating in-group or web sessions
- Diabetes complications that would preclude participation in the study

Grady Inclusion and Exclusion Criteria

Inclusion Criteria

- Grady Hospital Patient or Children's Healthcare of Atlanta at Hughes Spalding Patient
- Aged 18 – 30 years
- Confirmed diagnosis of Type 1 diabetes
- Recent A1c > 7.5
- a cell phone able to send/receive text messages
- Self-reported race of Black or African American
- Ability to read in English and provide informed consent

Exclusion Criteria

Exclusion Criteria: Members with the following characteristics will be excluded from study:

- Developmental delay or other cognitive impairment that would render the participant unable to provide informed consent
- Subjects with visual impairment or have severe hearing or other physical disabilities that would be a barrier for participating in-group or web sessions
- Diabetes complications that would preclude participation in the study

Study Enrollment Session: Enrollment sessions will take place in a dedicated study space (e.g. conference room or education classroom) that will be staffed by a project manager and research staff(s). Upon agreeing to participate in the study, participants will be given the option to complete the consent and survey electronically. This does not apply for those who need an A1C to determine eligibility. There will be stations with rotation among stations 1) Check-in, 2) consent, review of study procedures 3) electronic survey administration via an iPad or other device (if not completed prior to enrollment), and 4) POC (point-of-care A1c station). A paper back-up of the survey will be available if there are technology or connectivity challenges.

Disenrollment Session: Study participants will be asked to complete a disenrollment session at 6-months following their enrollment session. Approximately 2-weeks in advance of that date, participants will receive a text message and/or e-mail reminder followed by a phone follow-up call by a research staff to confirm participation. The disenrollment session will be held in conference room or education classroom. At the disenrollment session, participants will complete a survey (via an iPad) and POC A1c test. Participants will receive a \$50 gift card for their time spent at the disenrollment session.

c. Vulnerable Populations

Vulnerable Populations (VPs)	Include/Exclude	Rationale
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Pregnant women	Include	Pregnant women could potentially participate in the study if they meet the criteria for participation. Pregnancy does not preclude participation.
Children	Exclude	Outside of the scope.
Neonates of uncertain viability or nonviable neonates	Exclude	Outside of the scope.
Prisoners*	Exclude	Outside of the scope.

Other VP	Rationale for Inclusion
Limited English proficiency	Not applicable
Decisionally impaired adults	Not applicable

Inclusion of women

This study makes no exclusion on the basis of gender; and, preliminary data indicate approximately 54% of intervention participants will be women. Based on this estimate, we expect that 20 participants recruited into this study will be women. Inclusion of both men and women should allow for meaningful comparison of study measures by gender. Efforts will be made to include equal number of men and women in this study. T1D management during pregnancy requires additional monitoring and physician oversight.

Inclusion of minorities

This study is explicitly designed to evaluate an intervention in a minority population. All subjects included in the study have a self-reported race of Black or African American. Therefore, the racial distribution of our enrolled cohort is expected to be 100% Black. Other racial and ethnic minority groups will not be included in this study. Because this is a pilot study in which our intervention is culturally tailored to the unique experiences and challenges of Black young adults with Type 1 diabetes (T1D), a high-risk population, other minority groups will not be included at this time.

We will recruit KP participants by: (1) using our KP data warehouse to identify Black members aged 18-30 with a T1D diagnosis and (2) by posting study recruitment materials at our KP Georgia clinics with a high minority population. Additional recruitment strategies include: 1) an e-mailed letter 2) recruitment flyers provided to eligible participants during Endocrinology or Behavioral Health office visits, 3) recruitment flyers placed in KPGA, Emory, and Grady locations, 4) phone/text follow-up by a research staff, 5) in person recruitment at site locations 6) mailed letters and postcards, 7) provider referrals, and 8) recruitment videos.

We will recruit Emory participants by: (1) using our EMR data to identify Black members aged 18-30 with a T1D diagnosis and (2) by posting study recruitment materials at Emory clinics and facilities. Additional recruitment strategies include: 1) an e-mailed/electronic/mailed letters 2) recruitment flyers provided to eligible participants during office visits, 3) recruitment flyers placed in Emory locations 4) phone/text follow-up by a research staff, 5) in person recruitment at site locations 6) mailed letters and postcards, 7) provider referrals, and 8) recruitment videos.

We will recruit Grady participants using various methods: 1) an e-mailed invitation letter from the Endocrinology Department sent to patients with an email address on file, 2) recruitment flyers provided to eligible participants during Endocrinology visits, 3) recruitment flyers placed in Grady hospital waiting rooms, 4) phone follow-up by a study research assistant, and 5) in-person at Grady Hospital or Children's Healthcare of Atlanta at Hughes Spalding. We will recruit approximately ten (10) participants per cohort. Participants will be recruited in cohorts until we reach a total sample size of N=40.

Recruitment materials have been updated to allow for recruitment at CHOA and Emory Healthcare. These documents are included in this submission.

Inclusion of Children

This proposed intervention will not be examined in children. The inclusion criteria states that participants must be 18 years or older at the time of consent.

d. Setting

For KPGA

This study will take place in Atlanta, Georgia, primarily at KPGA offices, medical office buildings, or a non-KP community location. KPGA will be the primary IRB.

Study Sites and Sample: KPGA serves over 300,000 members at 26 sites in Georgia; 25 sites in Metro Atlanta and one (1) in Athens, Georgia. T1DES will be offered in KPGA medical office buildings (MOBs) with endocrinology practices in metro Atlanta. The selected sites serve 40% of our target population. Eligibility criteria is members aged 18-30 years with a confirmed T1D diagnosis >6 months prior (based on ICD 9 and 10 codes in the EMR), HbA1c > 7.5 (an HbA1c over the ADA target of 7%), a cell phone able to send/receive text messages and enrolled at KPGA at the time of enrollment.

Grady Health System recruitment

This study will take place in Atlanta, Georgia, primarily at Emory or Grady offices, medical office buildings, or a community location. KPGA will be the primary IRB of record; the Emory IRB will cede.

Study Sites and Sample: Grady Health System, including Children's Healthcare of Atlanta at Hughes Spalding. The Grady Diabetes Clinic is staffed by 7 faculty physicians (PI included), 8 mid-level providers, one registered dietitian, a podiatry service, one certified ophthalmic technician, and 12 laboratory and support personnel. There is more than 1200 sq of clinical space comprising of exam rooms for individual patient visits as well as group visits. The Diabetes Clinic serves more than 6,000 patients, with ~900 new patient visits and ~19,000 follow-up visits annually. The General Medical Clinics, located in the outpatient wing, serve an additional ~20,000 patients with diabetes with ~57,000 clinic visits a year. The Diabetes Clinic has a specialized clinic that is held twice a month to integrate diabetes technology into care for patients with T1D, providing adequate numbers of patients for the supplement. Eligibility criteria is members aged 18-30 years with a confirmed T1D diagnosis >6 months prior, HbA1c > 7.5, a cell phone able to send/receive text messages, and Grady patient at the time of enrollment.

This study will take place in Atlanta, Georgia, primarily at Emory or Grady offices, medical office buildings, or a community location. KPGA will be the primary IRB of record; the Emory IRB will cede.

Study Site and Sample:

Emory Healthcare (EHC) is an integrated academic health care system. As of 2022, it is the most comprehensive health system in Georgia. EHC offers patients and families the choice of more than 3,200 physicians and 250 locations, including 11 hospital campuses as well as primary care, urgent care, and MinuteClinics. Recruitment at Emory will be used to supplement recruitment at KP and Grady, in order to achieve our goal of receiving 80 participants across all 3 sites.

e. Recruitment Methods

Recruitment and Retention: Due to the complex nature of recruitment and the need for concurrent collection of survey data, biospecimens and review of study procedures, the study team will conduct enrollment and disenrollment sessions. Three to four weeks prior to the enrollment session, programmer will identify eligible participants. Eligible participants will be recruited using various methods: 1) an e-mailed letter 2) recruitment flyers provided to eligible participants during Endocrinology or Behavioral Health office visits, 3) recruitment flyers placed in KPGA, Emory, and Grady locations, 4) phone/text follow-up by a research staff, 5) in person recruitment at site locations 6) mailed letters and postcards, 7) provider referrals and 8) recruitment videos. We will recruit approximately eight (8) participants per cohort. We will leave voicemails as part of phone outreach. An interest form will also be used to assist with recruitment. Participant incentives for completing assessment will be offered at baseline, 3 and 6 months in the amount of \$50 per assessment. For each session, participants will receive \$50 for session 1 and \$25 for sessions 2-5 (\$25/session 2-5).

Patients will receive up to \$20 for transportation for the 3 in-person visits.

Group Based Recruitment: Co-I Dr. McCracken was the lead statistician on recently completed a pilot randomized trial of a 12-week, group-based, intervention study (NCT02712281). Participants were recruited in cohorts of size 8-10 based on common weekly availability. Half of participants were randomized to the experimental condition and half were randomized to the control condition. For this study we will take a similar approach by identifying and recruiting a cohort of subjects with common availability. We will get a list of all eligible study participants at the start of enrollment and contact them about study participation. Cohorts of at least 10 participants will be enrolled at a time based on common availability. Following informed consent, subjects will complete baseline assessments and then will be randomized (prior to session 1) to receive T1DES (the behavioral intervention) or Streamline (diabetes education).

Retention: Study retention includes sending reminder text messages prior to every study session and assessment. We may also call. If there are changes to participants' cell phone numbers, resulting in a loss of phone contact, we will send reminders via email and U.S. mail and call the alternate contact number. We will leave voicemails as part of phone outreach.

AASAP to Strengthen Recruitment and Retention. AASAP81 is a strategy that overtly labels the emotions and expectations that are the foundation of individuals' reasons for study participation and retention that are linked to the participant's ambivalence, one of the core tenants of motivational interviewing. With AASAP, if a participant joins but begins to miss appointments, instead of calling to remind them about the appointment, the study staff person will verbally reflect what they hear the participant saying. For example, if the study participant says, "I did not attend my appointment to get my blood drawn for the study because they had family obligations or an exam to study for," then the study staff person may say, "I know you really want to participate in the study because you are such an active member of the group, but you may also be worried that the sessions might not be as helpful for you." The goal of this comment is to 1) begin a dialog about the realistic assessment of the pros and cons of participating and 2) normalize the ambivalence participants experience. The subject can expand upon this statement and discuss what may be complex attitudes or concerns about participation. The AASAP strategy was employed in the three-arm RCT including OnTrack and research staff implementing recruitment and retention procedures will be trained on the strategy; KPGA has highly skilled research staff and can add AASAP to their skillset. The five (5) steps of AASAP include anticipate, acknowledge, standardize, accept, and plan.

*Recruitment and retention materials will be developed and submitted to IRB for review and approval before recruitment begins at Emory. KPGA and Grady currently have IRB approved documents for recruitment and retention.

f. Consent

A copy of the consent will be sent [if possible] to study participants at the time they are scheduled for their first session. This will give them the opportunity to review ahead of their initial visit. All participants will be given the opportunity to complete the consent electronically ahead of the in-person baseline session. The electronic consent will be hosted in redcap, and participant will be given a unique link/QR codes to access it. We will send a link/QR code to the consent form through their preferred contact methods (text and/or email), which the member will indicate at the time of outreach. We will give the participant the option for the staff person to walk them through the consent form or complete it on their own time. If participants have questions about reviewing the consent form, the study team will be available to answer all questions. Physical copies of the consent form will always be available, in cases where written consent is preferred.

Consent may be conducted individually or as a group consent. If group consent is done, we will give the participants time to review the form independently and also offer to answer questions or concerns one-on-one.

Consent for Point of Care (POC) A1c Pre-Screening Activities

For members who are eligible on all factors with the exception of the A1c, we will invite them to complete a point of care (POC) A1c. This will impact members who do not have an A1c on file within the given time frame. As of 12/2022, there are ~20 members who might fit within these criteria. Once, IRB approved we will determine the number of Grady and Emory patients that need an A1C to determine eligibility. They will receive \$10 for completing the A1c. If they are eligible based on the POC A1c, then they will be invited to stay, consent, and participate in the T1DES trial. If they are ineligible, we will thank them for their time. During the recruitment calls (see call recruitment call script) they will be informed of the process for completing the POC A1c prescreening. There is a separate consent for the A1c Pre-Screening.

T1DES Trial Informed Consent Process

Upon agreeing to participate in the study, participants will be given the option to complete the consent and survey electronically. This does not apply for those who need an A1C to determine eligibility.

Study Enrollment Session: Enrollment sessions will take place in a dedicated KPGA, Emory, or KPGA facility space (e.g. conference room or education classroom) that will be staffed by a project manager and research staff(s). Staff will handle study consent and review of study procedures.

Procedures for recruitment and informed consent

The legal contract between the enrollees and KPGA allows research staff to access their health records for the purposes of recruitment and monitoring performance in research studies, as long as the study protocol has been reviewed and approved by the KPGA Institutional Review Board (IRB). In addition, approval of a waiver of authorization for recruitment purposes will be requested from the KPGA IRB for recruitment across sites.

Potentially eligible participants during the recruitment period will be recruited using various methods: 1) e-mailed letters 2) recruitment flyers provided to potentially eligible participants during Endocrinology or Behavioral Health office visits, 3) recruitment flyers placed in site locations, 4) phone and text follow-up by a study research staff, and 5) in person recruitment at site locations, 6) mailed Letters and postcards, 7) provider referrals, and 8) recruitment videos.

Recruitment e-mails, flyers and phone calls will explain the study objectives, design and next steps (including basic information about data collection and incentive benefits) to participate. Recruitment materials will also include information that will make it clear that participation in this study is voluntary and that members may refuse to participate or withdraw at any time.

Potential participants will be screened by the research staff to ensure they meet study criteria. Prior to first session, eligible participants will be required to read and sign an informed consent and to read and sign a Health Information Portability and Accountability Act (HIPAA) authorization to participate in the study. The consent process and forms will be reviewed and approved by the KPGA IRB prior to use. Consent will be administered by a research staff who has completed the required human subjects training.

Non-English-Speaking Subjects This pilot study intervention will only be offered in English.

Assent of Children and Parent Permission

This is not applicable. The study will only be offered to members age >17 years.

Adults Unable to Consent/Decisionally Impaired

Adults who are decisionally impaired and unable to consent will not be recruited for this study.

- g. HIPAA Privacy Rule Authorization – if study will use or disclose Protected Health Information (PHI)

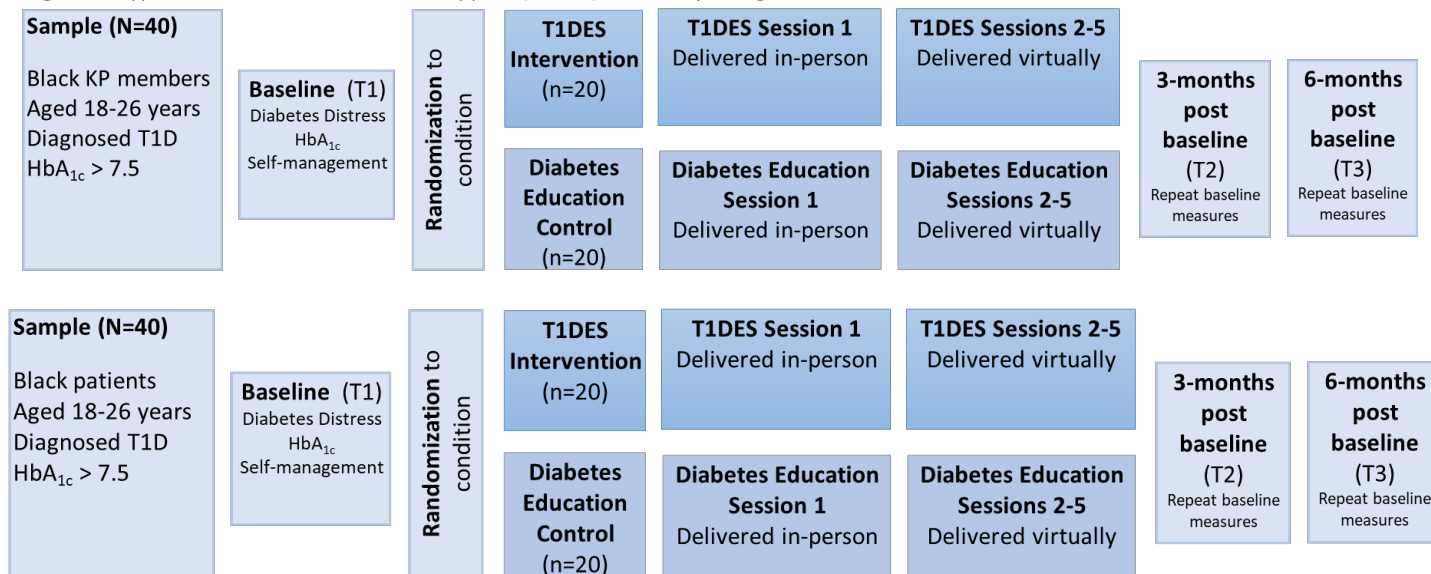
At the baseline enrollment session, eligible participants will be required to read and sign an informed consent and to read and sign a Health Information Portability and Accountability

Act (HIPAA) authorization in order to participate in the study. The consent process and forms will be reviewed and approved by the KPGA IRB prior to use. Consent will be administered by a research staff who has completed the required human subjects training.

6. Study Procedures

A.1. Study Design Overview. This study is a two-arm pilot randomized clinical trial (RCT) using mixed methods to evaluate the T1DES' feasibility (Aim 1) and effect of T1DES on diabetes outcomes (Aim 2). The study duration is 6 months; 3 months of intervention with an additional 3 months of follow-up. Upon providing consent, participants will be enrolled in the study. At baseline (T₁) participants will complete a quantitative survey, POC A1c test if they do not have a recent HbA_{1c} in the EMR, and complete session 1. Intervention sessions 2-5 will occur over the first 3 months. At the completion of intervention and control group sessions, which is also 3-months post baseline (T₂), At baseline (T₁) participants will complete a quantitative survey, POC A1c test, and complete session 1. At 6-months post baseline (T₃) participants will complete the quantitative survey and POC A1c test followed by exit focus groups. Monitoring HbA_{1c} every 3 months aligns with KPGA's recommended HbA_{1c} standing orders in endocrinology. Participants will be compensated for 3 study assessments (\$50 per assessment) and the exit focus group (\$50), a total of up to \$200 in gift cards. Figure 6 details the T1DES RCT study design for all locations. The study designs for each location are the same.

Figure 6. Type 1 Diabetes Education and Support (T1DES) RCT Study Design



Assignment to Condition. We will randomize N=80 participants total across all sites (KP, Emory and Grady) to either T1DES intervention (n=40) or Streamline diabetes education (n=40). A new cohort for the T1DES study will begin approximately bimonthly. Eligible participants will be invited to attend one of the predefined start dates (baseline) for each cohort. Upon completing consenting procedures and the baseline (T₁) assessment, participants will be randomly assigned to the intervention or control condition using random-permuted blocks of size 2 and 4. Randomization will be further stratified if needed by sex to ensure a balance of males and females in each intervention condition. Randomization assignments will be performed by the study statistician.

T1DES Intervention: Participants will participate in a 3-month intervention including 5 group sessions, individual check-ins before each group session, and SMS-delivered T1DES intervention content. Before each group session, staff will contact participants individually to virtually check-in with participants about the upcoming session and remind participants to complete the session homework.

Techniques in OnTrack stem from motivational interviewing empowerment-based communication, and AASAP (described in further detail in section C.9.4). It incorporates scenarios and activities to help participants cope with the emotional components of having type 1 diabetes and is based on emotion regulation. OnTrack helps patients develop personalized emotion management techniques and upon strengthening these techniques, participants can then make behavioral changes important for diabetes self-management. During session 1, participants in T1DES will develop a personalized action plan and outline the positive and negative feelings associated with each behavior change. At the follow-up sessions (2-5), facilitators follow-up with participants on their personalized action plan, discuss daily navigation of T1D, coping with disappointing blood glucose numbers, and interacting with family/friends.

Facilitators. T1DES sessions will be facilitated by a counselor or psychologist with experience using motivational interviewing (MI) among people with chronic conditions. We will hire facilitators through KPGA's Health Education Department that has held similar group-based sessions with the Coronary Health Improvement Program (CHIP) targeting heart disease prevention. External hires may also be considered if they have the appropriate qualifications. We will engage our clinical champion from the KPGA Behavioral Health Department, Dr. Abby Myers, to give input on hiring, training, and providing support during intervention implementation. Dr. Myers has experience facilitating the CHIP program at KPGA.

SMS. In our formative research, advisory board members expressed their desire to receive SMS-based reminders of content discussed during the intervention sessions. SMS will include a combination of one-way and two-way text messages, an extension of information, tools, and resources introduced during the group sessions. SMS will be delivered periodically, starting after T1DES Session 1. SMS will be a mix of cues to action and interactive polling activities. SMS content will be based on key messages delivered during the sessions and existing information from other resources tailored to our target population, including messages for young adults with T1D developed by the The Diabetes Link tailored for Black young adults with T1D. The Diabetes Link will partner with our study team to develop and adapt existing materials based on our formative research. Past advisory board members discussed being more inclined to reply to messages that are tailored and require a response. Members suggested one-way messages would be ignored. Dr. Graetz (Co-I) will lead the team in using mHealth to extend the reach of T1DES intervention content and deliver resources to participants.

Diabetes Education-Only Standard of Care Condition: The control condition will be 5, time-matched, diabetes education-only sessions facilitated by a qualified Diabetes Educator (CDE). The control condition will follow the standard of care model which offers diabetes education sessions for members with diabetes. In addition, the endocrinology department offers links to resources both internal and external to KPGA. These include connecting members with various departments and resources on the intranet to help navigate healthcare at KPGA, pamphlets produced by external sources such as the American Diabetes Association and The Diabetes Link, and links to online sources of information and support. The resources provided vary by provider. Therefore, for this study, we will standardize the resources traditionally provided at KPGA for the diabetes education-only control condition. We will hire multiple CDEs to rotate group facilitation. Session 1 will be in-person and sessions 2-5 will be group sessions facilitated virtually. Content will include resource booklets from The Diabetes Link, diabetes education

workbooks from KPGA's Health Education Department. and links to KPGA resources available on the KPGA intranet. Content from The Diabetes Link is already developed and is ready to utilize. The Diabetes Education series focuses on defining A1c, health and nutrition recommendations, diabetes management tools, navigating hypo- and hyper-glycemia, and diabetes complications.

Measures. Table 2 details the measures for evaluating feasibility⁶⁸ (Aim 1) and effectiveness (Aim 2) of T1DES; the constructs outlined align with the RE-AIM framework^{69, 70} RE-AIM is model widely used to measure disease management intervention feasibility and effectiveness.^{68, 71}

Feasibility (Aim 1): To assess the **feasibility of T1DES** by measuring intervention acceptability (satisfaction, perceived appropriateness), demand (uptake, retention), practicality (factors affecting implementation), and implementation (degree of execution; intervention fidelity) through quantitative surveys and key informant interviews with participants and the health care delivery team.

1a. Measure percentage of participants who complete the study or lost to follow-up compared to enrolled.

1b. Measure intervention acceptability based on number of sessions completed (at least 80% completed).

Facilitator and Participant Feedback. At T1DES sessions, facilitators will be asked to complete a session feedback form (Appendix A) to understand 1) unexpected topics/events that came up at the session and 2) facilitator perspectives on session delivery and participant interaction. After T1DES sessions, participants will be asked to complete a feedback form rating facilitators' level of listening, displaying support, and answering questions. (Appendix B). The form asks open-ended questions on what concepts resonated with participants (liked best/least), new items learned, and unanswered questions. This form will provide process-level feedback about sessions; study staff will review and compile feedback for facilitators to help improve future sessions, especially for unanswered questions or concerns.

Observer Checklist. An observer complete the T1DES Observer Rating Form to monitor implementation fidelity (intervention adherence and quality of delivery)⁷² for each session (Appendix C).

Exit Focus Groups (Participants) and Interviews (Providers): The exit focus groups will occur after the 6-month study assessment (T₃) and elicits participants' feedback on T1DES study components, including overall satisfaction, in-person sessions, SMS content and timing, assessments, and diabetes management (Appendix D). Providers in endocrinology, behavioral health, and health education will complete an interview exploring helpfulness and interest continuing T1DES (Appendix E).

SMS Acceptability and Feasibility Assessment: We will send a questionnaire via SMS to assess functional acceptability (ease of viewing, receiving, understanding, appropriateness); educational acceptability (how educational, applicable, or entertaining SMS was); and comparative acceptability (how information would compare if in another medium). These are adapted from previous research.^{73, 74} These will be sent intermittently during the 24 weeks of SMS (Appendix F).

Effectiveness (Aim 2): Evaluate **effect of T1DES diabetes outcomes** in a pilot randomized clinical trial among **N=80** (n=40 at each site) Black young adults age 18-30 years with T1D and elevated HbA_{1c} (>7.5%) by comparing the changes in HbA_{1c}, diabetes distress, and self-management

behaviors from baseline to 6-months post-baseline among participants randomized to the T1DES intervention compared to the diabetes education-only condition.

Biomarker data - HbA_{1c}: POC Hemoglobin A1c - Hgb A1c results **monitor glucose control over the preceding 90 to 120 days**. The POC A_{1c} measures average blood sugar level over the past 3-months; we will measure POCA_{1c} at all timepoints (T₁-T₃). The HbA_{1c} blood test will occur at a site hosting a T1DES group. The test will be conducted by trained study staff.

Survey data: Surveys will be administered via an online portal using iPads or other enabled device. Survey measures are in Appendix G. Survey data at baseline, 3-, and 6-months post-baseline will collect outcome measures: diabetes distress and diabetes self-management. We will collect measures on covariates such as insulin delivery mode, self-monitoring of blood glucose (SMBG), self-reported age at diagnosis, and descriptive data such as relationship status, work status, educational level, living status, level of support, race, and gender. Table 3. provides the Cronbach's alpha for survey subscales.

Type 1 Diabetes Distress (T1-DDS)^{75, 76} is a 28-item scale with seven (7) subscales: powerlessness, management distress, hypoglycemia distress, negative social perceptions, eating distress, physician distress, and family/friend distress. Response options range from 1 (not a problem) and 6 (a very serious problem). Higher scores indicate higher levels of diabetes distress.

*Diabetes Self-Management Questionnaire (DSMQ)*⁷⁷ is a 16-item instrument measuring self-care behaviors in five (5) areas in the past eight (8) weeks: dietary control, medication adherence, blood glucose monitoring, physical activity, and physician contact/appointment adherence. Response options range from *does not apply to me* (0) to *applies to me very much* (3). Higher scores indicate more desirable self-care behaviors.

Electronic Medical Record (EMR) data. We will measure healthcare utilization (number of encounters, encounter type) and medication usage (prescriptions and fills) using EMR data.

Table 3. Survey items for outcome measures

Scales (and subscales)	Items	(α)
T1-DDS (Diabetes Distress)	28	0.91
Powerlessness	5	0.87
Management distress	4	0.76
Hypoglycemia distress	4	0.79
Negative social perceptions	4	0.84
Eating distress	3	0.78
Physician distress	4	0.82
Family/friend distress	4	0.80
DSMQ (Self-Management)	16	0.94
Dietary control	4	0.79
Medication adherence	2	0.75
Blood glucose monitoring	3	0.83
Physical activity	3	0.74
Appointment adherence	3	0.72

Table 2. Feasibility and effectiveness study measures for evaluating T1DES Intervention linked to RE-AIM Framework.

	Measure	Description	Timing	Data Collection Method	RE-AIM link
Feasibility (Aim 2)	Acceptability	Patient satisfaction with T1DES	After each session	Survey administered via iPads at in-person baseline and follow-up appointments	I
		Perceived appropriateness: assess functional, educational, and comparative acceptability of SMS	Intermittently after SMS messages	Survey delivered via link texted to participant phone	I
		Fit within organizational culture: facilitator time, provider burden, and level of integration	Between 3m and 6m	Qualitative Exit Interviews with Providers (endocrinology, health education, and behavioral health)	A, M
	Demand	Recruitment and retention rates	Baseline	Recruitment & Retention Database	R
		SMS engagement rate: # of SMS responded to (for 2-way messages); track # of bounce back messages	3m (after SMS completion)	SMS Platform	R, I
		Treatment-specific retention and fidelity rates: #attended each session / # consented	Sessions 1-5	Session attendance forms	R, I
	Practicality	Factors affecting implementation: 1) Ask reasons for non-attendance (1 question) 2) Participant feedback on barriers to participation 3) facilitator report on session challenges and topics covered/missed	Sessions 1-5	1) Participant post-session survey via SMS; 2) Participant exit interviews 3) Facilitator session feedback forms	I
	Implementation Fidelity	Quality of delivery: ratings of session facilitators Program differentiation; participant responsiveness and level of participant engagement during the sessions	Session 1-5	Facilitator self-evaluation and participant session feedback forms completed after each session; participant exit interviews; observer rating form of sessions and homework completion	I
		Adherence: Checklist of session activities; intervention deviation or drift (% of activities completed as planned) Program exposure (dose): session frequency and duration	Session 1-5	Observer rating form with checklist of activities to measure adherence and exposure; session length	
		Resources needed to implement: cost of SMS platform; cost of facilitator and staff time	6m	Administrative paperwork	I
Effectiveness (Aim 3)	Diabetes Distress	A1c to measure average blood sugar level over the past 3-months	Baseline, 3m, 6m	Type 1 Diabetes Distress Scale (T1-DDS) administered via iPads	E, M
	Glycemic control	A1c to measure average blood sugar level over the past 3-months	Baseline, 3m, 6m	Blood draw at KPGA lab	E, M
	Diabetes self-management	SMOD-A: Collaboration with parents, goals, diabetes care activities, problem solving, communication	Baseline, 3m, 6m	Survey administered via iPads	E, M

IPT = Immediately Post Treatment; 3m = 3-month; 6m = 6month

RE-AIM links: R = Reach, E = Effectiveness, A = Adoption, I = Implementation, M = Maintenance

a. Data Analysis

Statistical Methods

Data from both sites will be combined for a total proposed sample size of N=80 participants. Feasibility metrics including participation rates, attrition rates, satisfaction/acceptability with T1DES, measures of intervention fidelity, etc. will be tabulated using counts and percentages or means and standard deviations, as appropriate. Descriptive statistics will be calculated for all measures across all time points stratified by intervention condition (T1DES vs. Diabetes Education). Efficacy outcomes including A1c, diabetes self-management, and diabetes distress, and descriptive data (such as relationship status, work status, educational level, living status, level of support), and demographics (such as age and gender) will be summarized at each time point (baseline, 3 months, 6 months) overall and stratified by intervention condition. We will use generalized linear mixed models to examine changes in outcome measures over time. Models will include the fixed effects time (baseline, 3 months, 6 months), the intervention condition, and the intervention X time interaction term. The interaction term will be included in all models and will serve as the primary test of efficacy. Intervention differences will be estimated at 3 months and 6 months, conditional on baseline response levels.¹ Results will be presented as model-based least square means, conditional on baseline, (or difference in means) with associated 95% confidence intervals. Effect sizes will be calculated for all efficacy measures and be used inform future power calculations for a large-scale RCT. Adverse events will be summarized by type of event, severity of event and relatedness, both overall and by

intervention group. Analysis will be conducted using the intention to treat dataset and all statistical tests will be two-sided. Significance will be assessed at the 0.05 level and analysis will be conducted using SAS v. 9.4 (Cary, NC).

Power Analysis

While the primary goal of the study is to determine the feasibility of a subsequent multisite RCT, our key secondary goal is to evaluate the effect of T1DES on diabetic outcomes in Black young adults by comparing changes from baseline and to participants randomized to Diabetes Education (control). We recognize that this pilot study is underpowered to detect small to moderate differences in outcomes between our intervention groups, nevertheless **data generated from this small R01 pilot study are essential for generating effect size estimates** to use when planning our larger multi-site RCT. Combining data from KPGA, Emory and Grady will increase our sample size in our parent grant (KPGA) from N = 40 to N = 80 (KPGA + Grady + Emory). This increased sample provides at least 80% power to detect a 1.5-point difference in the *change* in HbA_{1c} (from baseline to 3 or 6 months) between the intervention group and control conditions using a two-sided two-sample t-test with alpha = 0.05. This results in an effect size of $d = 0.75$ (0.91 in parent grant). If we experience 10-20% attrition, we will have 80% power to detect effect sizes between 0.78 – 0.83. We recognize that these large effect sizes may not be observable in our trials, however, these data will provide an estimate of the anticipated change in our outcome measures that can be used to adequately power a future large scale RCT. Power estimates were calculated using PASS v. 14.0.8 (Kaysville, UT).

Reference: Carpenter J, Kenward M. Missing data in randomized controlled trials- a practical guide. London School of Hygiene and Tropical Medicine; 2007.

b. Sharing of Results with Subjects

Dissemination Plan for T1DES

We ensure that the T1DES clinical trial will register the trial and summary results on the ClinicalTrials.gov website in a timely manner. This has already been done for the protocol affiliated with KPGA site and Grady. The clinical trials website will be edited to include Emory. Informed consent documents for the clinical trial will include a specific statement highlighting the posting of clinical trial information at ClinicalTrials.gov.

Once study results are available (in the last quarter of the study timeline) the Lead Project Manager will make sure a results summary is submitted and posted on ClinicalTrials.gov as outlined in the NIH policy on the dissemination of NIH-funded clinical trial information. In addition, KPGA has an internal policy ensuring clinical trials registration and results information take place in compliance with the NIH policy. Throughout the study, if there are any protocol changes or developments, we will make sure to publish the protocol changes on the ClinicalTrials.gov website.

Upon completion of the study, we will submit at least 1 manuscript that reports our study findings on our primary and secondary outcomes. We will present our findings internally within our Adult Primary Care and Endocrinology departments. We also plan to present the study results at a regional or national meeting.

c. Data and/or Specimen Banking

Specimen will not be banked and stored for this study.

7. Privacy, Confidentiality and Data Security

Although this is not a pharmacological trial, the study will be conducted in accordance with “good clinical practice” as outlined in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (Dixon & Hallinan, 1999).

The Advisory Committee will be comprised of an endocrinologist, a behavioral health practitioner, and a data analyst/programmer from KP. The people in these roles will not occupy other roles on the study. Drs. Davis and Barzilay will meet weekly to discuss the conduct of the trial including recruitment, attrition, attendance, and rate of successful data collection. They will also discuss protocol adherence and any study-related challenges. Dr. McCracken will join the meeting every other week. The project manager will keep minutes. Decisions will be made by consensus. The Advisory Committee will provide oversight and ensure that the study is conducted in accordance with the protocol and will convene monthly or more frequently, as needed.

The Principal Investigator (PI) and Clinical Co-Investigator will be responsible for ensuring participants’ safety daily. Data safety and monitoring will occur at several levels. First, as described above, we will systematically elicit and document unanticipated adverse events and serious adverse events at enrollment and during the in-person sessions. Additional information regarding adverse events will be solicited from the participant during follow-up visits with the study team during the study period.

We will follow best practices for data safety. Research personnel and collaborators will all complete the CITI training and will follow best practices for data collection and storage. The primary location of the data from KPGA will be at Kaiser Permanente Georgia – Center for Research and Evaluation. The primary location of data and files from Grady and Emory will be at the Glenn Memorial Building on the Grady campus. The offices are equipped with password-protected personal computers and locked cabinets for file storage. We will follow all procedures consistent with NIH, Kaiser Foundation Research Institute, Grady Memorial Hospital, and Emory University data safety policies. Study staff will secure all data collected. Data, both quantitative and qualitative, will be de-identified before data analysis.

The T1DES study team will monitor site performance related to participant recruitment and retention. Once recruitment begins, we will track demographic information for all eligible participants, including, age, gender, race, and ethnicity. We will also track reasons eligible members declined to participate. We will also track retention to assure there is not differential attrition based on age, gender, or race. Once recruitment begins, one of the research staff will provide a weekly recruitment report to share each week. Our biostatistician Dr. Courtney McCracken has effort to dedicate time monitoring participant data as it is collected.

Describe the plan for storage of data and/or specimens.

Data will be password protected for secured in a locked filing cabinet.

Collection of data from participants

Data will be collected via REDCap, a HIPPA compliant program, and paper form. All participant data collected on paper will be stored in a locked file cabinet in the Glenn Memorial Building or Kaiser Permanente Georgia Building. Data collected on paper will be transferred to REDCap.

Does this study involve the disclosure of PHI to a collaborator?

Data for this study will not be disclosed to off-site collaborators. All analyses will take place with KPGA staff and on KPGA computers under the supervision of Dr. Courtney McCracken (Co-I).

Data Commitments (data and specimen sharing)

Recipient and Description of Materials	Identifiers* (note w/an X)	Health Information** (note w/an X)	HIPAA Documentation (see policy NWRC.PRIV.04)
Big Sky Transcription Interview Transcripts	<input type="checkbox"/> Fully Identifiable <input checked="" type="checkbox"/> Limited Data Set <input type="checkbox"/> De-Identified <input type="checkbox"/> Aggregate	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Signed Authorization <input type="checkbox"/> Waiver of Authorization <input type="checkbox"/> Limited Data Set only <input type="checkbox"/> De-Identified or Aggregate Data <input type="checkbox"/> N/A, No Health Information

Sender and Description of Materials	Identifiers* (note answer w/X)	Health Information** (note answer w/X)
Kaiser Permanente Georgia, Grady, or Emory Interview Transcripts	<input type="checkbox"/> Fully Identifiable <input checked="" type="checkbox"/> Limited Data Set <input type="checkbox"/> De-Identified <input type="checkbox"/> Aggregate	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

8. Provisions to Monitor Data to Ensure the Safety of Subjects

PARTICIPANTS SAFETY

A.1 Potential Risks and Benefits for Participants

This section outlines the potential risks and benefits of participants.

Potential Risks: This is a minimal risk study. Potential risks associated with T1DES study participation fall into 4 categories:

- Risks associated with survey and blood sample collection (POC A1C test)
- Risks associated with the potential loss of confidentiality
- Risks associated with group intervention sessions and focus group participation
- Risk associated with changes in management of type 1 diabetes

Risks associated with survey and blood sample collection (POC A1C test). Survey data collection procedures are generally innocuous in nature, although some individuals may feel uncomfortable answering specific questions. There may be minor risk associated with this test in that you may experience slight pain when we pierce the skin on your finger. Drawing blood from a finger stick may, in rare cases- cause discomfort, bruising, prolonged bleeding and

infection at the site of puncture. To minimize risk, we will swab the site of puncture with alcohol to disinfect the area, use disposable lancet and capillary tubes to collect blood and apply pressure to the puncture site following the blood draw to minimize bruising. We will cover the puncture with an appropriate dressing and provide you with information on how to monitor for signs of infection.

Risks associated with potential loss of confidentiality. The confidentiality of participants could be compromised in the intervention phase by an accidental release of name, email, telephone, or address information through an exposure of data files. It is possible that technical or human error could lead to the release of patient data research records that might be accessed/obtained by a person not authorized to do so, or a “hacker” could gain access to the research database. The risk is extremely small, given the extreme caution and multiples layers of protections that we will use in setting up our data systems, but the risk can never be zero.

Risks associated with group sessions and focus groups. Within a group session or focus group, some individuals may feel uncomfortable asking questions, answering questions, or expressing their honest opinions with others present. “Gossip” about group session or focus group discussion may subsequently occur and cause embarrassment to a participant.

Risk associated with changes in management of Type 1 Diabetes

While this study is not directly changing the medical management of Type 1 diabetes, participants receiving the intervention will be likely have better glycemic control through decreasing diabetes distress and better disease management. With better HgA1c values and stricter glycemic control, it is possible for participants to be at increased risk for hypoglycemia.

Potential Benefits: The potential benefits to this study include:

- Participation in group sessions facilitated by a professional counselor trained to use motivational interviewing
- Increased engagement and monitoring related to diabetes care
- Increased knowledge about diabetes management and care
- Better type 1 diabetes disease control

A.2 Adverse Event and Serious Adverse Event Collection and Reporting

This is a minimal risk study that will not use any investigational drugs or medical therapy in our study population. Subjects randomized to T1DES will receive is a 3-month intervention including 5 group sessions facilitated by a counselor with experience using motivational interviewing (MI) among people with chronic conditions. Subjects randomized to control condition will receive usual diabetes education care. Given the minimal risks involved in this study, we do not anticipate adverse events related to this study. Nevertheless, unanticipated adverse events related or potentially related to the study will be collected and reviewed at the time of safety review. The safety review will occur in conjunction with review of the DSMP and will occur after the first subject is enrolled and every 6 months there-after. The Principal Investigator (T. Davis) and Co-Investigator (J. Barzilay) will evaluate any unanticipated adverse event and determine whether the adverse event affects the Risk/Benefit ratio of the study and whether modifications to the protocol or consent form are required. A summary of any adverse events will be reported to the IRB, at minimum, when annual re-approval of the protocol is sought. All serious adverse events will be collected and reported to the IRB per the KPGA IRB’s guidelines. For each adverse event, the clinical Co-I (Barzilay) will be responsible for determining both the attribution and classification of the event.

Attribution is classified as:

- Definite: AE is clearly related to study treatment
- Probable: AE is likely to be related to the study treatment
- Possible: AE may be related to study treatment
- Unlikely: AE is doubtfully related to the study treatment
- Unrelated: AE is clearly not related to the study treatment

Classification of Event:

Mild: AE poses no interference and no intervention is required

Moderate: AE poses some interference OR requires some intervention that is considered routine

Severe: AE poses some interference AND requires intervention.

Serious AEs are defined as follows:

- Results in Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Results in Persistent or Significant Disability or Permanent Damage
- Congenital Anomaly/Birth Defect
- Other Serious (Important Medical Events)- These events may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes.

Reporting of Serious Adverse Events (AE). Serious AEs will be summarized in narrative form and sent to the KPGA IRB within 48 hours.

A.3 Protection against Study Risks and Confidentiality

This study poses minimal risks to participants. The study protocol includes many features to minimize any potential risks. Protection procedures are detailed below.

B. Procedures for recruitment and informed consent. The legal contract between the enrollees and KPGA allows research staff to access their health records for the purposes of recruitment and monitoring performance in research studies, as long as the study protocol has been reviewed and approved by the KPGA Institutional Review Board (IRB). In addition, approval of a waiver of authorization for recruitment purposes will be requested from the KPGA IRB.

Potentially eligible participants during the recruitment period will be recruited using various methods: 1) an e-mailed letter from KPGA's Chief of Endocrinology sent through kp.org (KP's secure email system), 2) recruitment flyers provided to eligible participants during Endocrinology or Behavioral Health office visits, 3) recruitment flyers placed in pharmacies and clinics and 4) phone follow-up by research staff and 5) in person recruitment at KP, Grady, and Emory locations, 6) mailed letters and postcards, 7) provider referrals and 8) recruitment videos.

Recruitment e-mails, flyers and phone calls will explain the study objectives, design and next steps (including basic information about data collection and incentive benefits) to participate. Recruitment materials will also include information that will make it clear that participation in this study is voluntary and that members may refuse to participate or withdraw at any time.

At the baseline enrollment session, eligible participants will be required to read and sign an informed consent and to read and sign a Health Information Portability and Accountability Act (HIPAA) authorization in order to participate in the study. The consent process and forms will be

reviewed and approved by the KPGA IRB prior to use. Consent will be administered by a KPGA research staff who has completed the required human subjects training.

C. Procedures for surveys and blood samples. Surveys will be completed electronically or on an iPad in a reserved conference room or classroom in a KPGA medical office building or community location. The consent form and the first page of the survey will let the participant know that s/he may refuse to answer any or all questions asked of them. The survey will include mostly items and scales that have been used in several surveys administered to KPGA adults in previous KPGA IRB approved research protocols.

The blood sample for the POC A1C test provided by study participants will be obtained by train research staff where the study sessions will be offered. The consent form will inform the participants know the potential risks associated with a POC a1c test.

D. Procedures to minimize loss of confidentiality. Data for all participants will be kept strictly confidential, except as mandated by law (e.g. evidence of imminent danger to self or others). Statistical analyses will be performed a limited dataset where participants name and date of birth have been removed from the dataset. Only dates of enrollment and study encounters will be used. All other data are non-identifiable.

All KPGA electronic research files are kept on a secure server that uses multiple layers of data protection, and all research personnel sign a confidentiality agreement and receive NIH and CITI human subjects training. Data are accessible only to research staff, using confidential usernames and passwords. All KPGA paper research files are kept in locked file cabinets in the KPGA Research Department, which has secured locked doors allowing only access to authorized KPGA research staff. Survey data will be collected using REDCap's HIPPA compliant features which will help safeguard against data breaches and maintain security of participant data.

E. Procedures for group sessions and focus groups. The participants' consent form will describe the nature of the group sessions and focus groups, and let the participant know that s/he may refuse to participate in any or all aspects of the discussion. The consent form will also warn against gossip ("what is said in the group session stays in the group session"). These guidelines for fair and open discussion will be repeated at the beginning of each group session and at the beginning of the participant focus group.

F. Procedures for management of Type 1 Diabetes. During the informed consent process participants will be told that this study is evaluating a behavioral intervention to improve management of diabetes and decrease distress associated with diabetes. The study will not dictate how their diabetes should be medically managed and that they should continue to manage their diabetes as directed by their primary medical provider from whom they receive their diabetic care. They will be encouraged to reach out to their primary physician if they have additional questions or concerns about the medical management of their diabetes. During the first session in both the T1DES and Diabetes Education conditions, participants will be given standard educational material from Endocrinology, including signs and symptoms of hyper/hypo glycemia, when to contact their doctor, as well as the contact information of the study PI and Co-I (Barzillay), should they have any issues to report. Participants will also be directed to the KPGA intranet which includes similar resources and information. Participants will be strongly encouraged to contact their provider if they are experiencing more frequent episodes of hypo or hyperglycemia.

Protection of Confidentiality. All study protocols will be reviewed and approved by the Institutional Review Board (IRB) and will therefore follow all compliance rules for protecting research participant confidentiality. Data for all participants will be kept strictly confidential,

except as mandated by law (e.g. evidence of imminent danger to self or others). Statistical analyses will be performed on de-identified data; participants will never be individually named. All KPGA electronic research files are kept on a secure server that uses multiple layers of data protection, and all research personnel sign a confidentiality agreement and receive NIH and CITI human subjects training. Data are accessible only to research staff, using confidential usernames and passwords. All KPGA paper research files are kept in locked file cabinets in the KPGA Research Department, which has secured locked doors allowing only access to authorized KPGA research staff. Survey data will be collected using REDCap's HIPPA compliant features which will help safeguard against data breaches and maintain security of participant data. The study investigators will also obtain a Certificate of Confidentiality to provide special protection for subjects involved in clinical research. We will apply for the certificate in the first quarter of the study.

INTERIM ANALYSIS

This is a pilot study with minimal risk, there is no plan for interim analysis for this study. Given sample size of 40 (20 per group) in this pilot study, we have not declared any stopping rules for benefit or futility. Based on a review of the safety and efficacy data during the safety review, the PI may decide to perform an unplanned interim analysis due to concerns about safety, futility and/or participant benefit. The PI will seek advice of the Advisory Board and other physicians not involved in the conduct of this study prior to conducting any unplanned interim analysis.

DATA AND SAFETY MONITORING

Overview

Although this is not a pharmacological trial, the study will be conducted in accordance with "good clinical practice" as outlined in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (Dixon & Hallinan, 1999).

The Advisory Committee will be comprised of an endocrinologist, a behavioral health practitioner, and a data analyst/programmer from KP. The people in these roles will not occupy other roles on the study. Drs. Davis and Barzilay will meet weekly to discuss the conduct of the trial including recruitment, attrition, attendance and rate of successful data collection. They will also discuss protocol adherence and any study-related challenges. Dr. McCracken will join the meeting every other week. The project manager will keep minutes. Decisions will be made by consensus. The Advisory Committee will provide oversight and ensure that the study is conducted in accordance with the protocol and will convene monthly or more frequently, as needed.

The Principal Investigator (PI) and Clinical Co-Investigator will be responsible for ensuring participants' safety on a daily basis. Data safety and monitoring will occur at several levels. First, as described above, we will systematically elicit and document unanticipated adverse events and serious adverse events at enrollment and during the in-person sessions. Additional information regarding adverse events will be solicited from the participant during follow-up visits with the study team during the study period.

We will follow best practices for data safety. Research personnel and collaborators will all complete the CITI training and will follow best practices for data collection and storage. The primary location of the data will be at Kaiser Permanente Georgia – Center for Research and

Evaluation. We will follow all procedures consistent with NIH and Kaiser Foundation Research Institute data safety policies. Kaiser Permanente Georgia – Center for Research and Evaluation will secure all data collected. Data, both quantitative and qualitative, will be de-identified before data analysis.

The T1DES study team will monitor site performance related to participant recruitment and retention. Once recruitment begins in Project Year 1, Quarter 3, we will track demographic information for all eligible participants, including, age, gender, race, and ethnicity. We will also track reasons eligible KP members declined to participate. We will also track retention to assure there is not differential attrition based on age, gender, or race. Once recruitment begins, the research staff will provide a weekly recruitment report to share each week. Our biostatistician Dr. Courtney McCracken has effort in both project years to dedicate time monitoring participant data as it is collected.

Frequency of DSMP Reporting

The PI, Co-I, and unblinded biostatistician will review the DSMP every 6 months after the first subject is randomized. While the statistician will be unblinded, the DSMP report will be blinded by using generic treatment assignments (e.g., “A” and “B”) in the reporting of outcomes. Given that this is a minimal risk study where the study investigators are not blinded, a DSMB will not be utilized for this study. Instead the PI and Co-I (Barzilay) will be responsible for carrying out the DSMP. In addition, we will assign an independent safety monitor who will independently review the DSMP. We will select an Endocrinologist not involved with the care of subjects in this study.

Content of DSMP

The DSMP will be prepared by the unblinded biostatistician and programmer and will include:

- Review of adverse events
- Eligibility and enrollment numbers
- Demographics of all consented participants
- Protocol deviations
- Retention and missing data

9. Risks and Benefits

a. Risks to Subjects

Potential risks fall into 4 categories: Risks associated with survey and blood sample collection (POC A1C test) risks associated with the potential loss of confidentiality, risks associated with group intervention sessions and focus group participation, risk associated with changes in management associated with diabetes.

Risks associated with survey and blood sample collection (POC A1C test)

Survey data collection procedures are generally innocuous in nature, although some individuals may feel uncomfortable answering specific questions. There may be minor risk associated with this test in that participant may experience slight pain when we pierce the skin on your finger. Drawing blood from a finger stick may, in rare cases- cause discomfort, bruising, prolonged bleeding and infection at the site of puncture. To minimize risk, we will swab the site of puncture with alcohol to disinfect the area, use disposable lancet and capillary tubes to collect blood and apply pressure to the puncture site following the blood draw to minimize bruising. We will cover the puncture with an appropriate dressing and provide the participants with information on how to monitor for signs of infection.

Risks associated with potential loss of confidentiality

The confidentiality of participants could be compromised in the intervention phase by an accidental release of name, email, telephone or address information through an exposure of data files. It is possible that technical or human error could lead to the release of patient data research records that might be accessed/obtained by a person not authorized to do so, or a “hacker” could gain access to the research database. The risk is extremely small, given the extreme caution and multiple layers of protections that we will use in setting up our data systems, but the risk can never be zero.

Risks associated with group sessions and focus groups

Within a group session or focus group, some individuals may feel uncomfortable asking questions, answering questions or expressing their honest opinions with others present. “Gossip” about group session or focus group discussion may subsequently occur and cause embarrassment to a participant.

Risk associated with changes in management of Type 1 Diabetes

While this study is not directly changing the medical management of Type 1 diabetes, participants receiving the intervention will be likely have better glycemic control through decreasing diabetes distress and better disease management. With better HgA1c values and stricter glycemic control, it is possible for participants to be at increased risk for hypoglycemia.

d. Adequacy of Protection Against Risks

This study poses minimal risks to participants. The study protocol includes many features to minimize any potential risks. Protection procedures are detailed below.

Procedures for recruitment and informed consent

The legal contract between the enrollees and KPGA allows research staff to access their health records for the purposes of recruitment and monitoring performance in research studies, as long as the study protocol has been reviewed and approved by the KPGA Institutional Review Board (IRB). In addition, approval of a waiver of authorization for recruitment purposes will be requested from the KPGA IRB.

Potentially eligible participants during the recruitment period will be recruited using various methods: 1) an e-mailed letter 2) recruitment flyers provided to eligible participants during Endocrinology or Behavioral Health office visits, 3) recruitment flyers placed in study site locations 4) phone follow-up by research staff, 5) in person recruitment at study site locations, and 6) mailed communications 7) provider referrals, and 8) recruitment videos.

Recruitment e-mails, flyers and phone calls will explain the study objectives, design and next steps (including basic information about data collection and incentive benefits) to participate. Recruitment materials will also include information that will make it clear that participation in this study is voluntary and that members may refuse to participate or withdraw at any time.

Prior to first session, eligible participants will be required to read and sign an informed consent and to read and sign a Health Information Portability and Accountability Act (HIPAA) authorization in order to participate in the study. The consent process and forms will be reviewed and approved by the KPGA IRB prior to use. Consent will be administered by a KPGA research staff who has completed the required human subjects training.

Procedures for surveys and blood samples

Surveys will be completed electronically or on an iPad in a reserved conference room or classroom in a KPGA medical office building or other community location. The consent form and the first page of the survey will let the participant know that s/he may refuse to answer any or all questions asked of them. The survey will include mostly items and scales that have been used in several surveys administered to KPGA adults in previous KPGA IRB approved research protocols. Survey data will be collected using REDCap's HIPPA compliant features which will help safeguard against data breaches and maintain security of participant data.

The POC A1c test will be done by trained research staff using commercially available systems that have been approved by the FDA.

Procedures to minimize loss of confidentiality

Data for all participants will be kept strictly confidential, except as mandated by law (e.g. evidence of imminent danger to self or others). Statistical analyses will be performed on aggregate-level data; participants will never be individually named.

All KPGA electronic research files are kept on a secure server that uses multiple layers of data protection, and all research personnel sign a confidentiality agreement and receive NIH and CITI human subjects training. Data are accessible only to research staff, using confidential usernames and passwords. All KPGA paper research files are kept in locked file cabinets in the KPGA Research Department, which has secured locked doors allowing only access to authorized KPGA research staff. Survey data will be collected using REDCap's HIPPA compliant features which will help safeguard against data breaches and maintain security of participant data.

Procedures for group sessions and focus groups

The participants' consent form will describe the nature of the group sessions and focus groups, and let the participant know that s/he may refuse to participate in any or all aspects of the discussion. The consent form will also warn against gossip ("what is said in the group session stays in the group session"). These guidelines for fair and open discussion will be repeated at the beginning of each group session and at the beginning of the participant focus group.

Procedures for management of Type 1 Diabetes

During the informed consent process participants will be told that this study is evaluating a behavioral intervention to improve management of diabetes and decrease distress associated with diabetes. The study will not dictate how their diabetes should be medically managed and that they should continue to manage their diabetes as directed by their primary medical provider from whom they receive their diabetic care. They will be encouraged to reach out to their primary physician if they have additional questions or concerns about the medical management of their diabetes. During the first session in both the T1DES and Diabetes Education conditions, participants will be given standard educational material from Endocrinology, including signs and symptoms of hyper/hypo glycemia, when to contact their doctor, as well as the contact information of the study PI and Co-I (Barzilay), should they have any issues to report. Participants will also be directed to the KPGA intranet which includes similar resources and information. Participants will be strongly encouraged to contact their provider if they are experiencing more frequent episodes of hypo or hyperglycemia.

b. Potential Benefits to Subjects

Potential benefits for intervention participants include learning additional ways to manage their diabetes care and lower their A1c level. Participating in this study also helps researchers and

administrators at KP understand if this is an intervention we should offer as part of KPGA's Healthy Lifestyle courses. An additional benefit for some participants may be personal satisfaction in being part of a study which may further scientific knowledge concerning type 1 diabetes management among young adults. No benefit from this intervention can be guaranteed.

10. Economic Burden to Subjects

Participants may experience transportation burden or any expense they incur coming to the in-person session. We will provide up to \$20 for each in-person visit attended to mitigate this.

11. Compensation to Participants

The study duration is 6 months; 3 months of intervention with an additional 3 months of follow-up. Upon providing consent, participants will be enrolled in the study. At baseline (T1) participants will complete a quantitative survey, POC HbA1c level and complete session 1. Intervention sessions 2-5 will occur over the first 3 months. At the completion of intervention and control group sessions, which is also 3-months post baseline (T2), participants will complete the quantitative survey and POC HbA1c. At 6-months post baseline (T3) participants will complete the quantitative survey and PCO A1C followed by exit focus groups. Monitoring HbA1c every 3 months aligns with KPGA's recommended HbA1c standing orders in endocrinology. Participants will be compensated for 3 study assessments (\$50 per assessment) and the exit focus group (\$50), 50 for session 1 attendance, and 25 for session 2-5 attendance, a total of up to \$350 in gift cards. A \$20 transportation voucher will be provided for the 3 in person visits. Figure 6 details the T1DES RCT study design.

12. Resources Available

All study team members will be required to complete research ethics training before engaging in study activities. Additional training needed for session facilitation will be provided prior to intervention implementation.

13. Additional Approvals

No additional approvals are required at this time.

14. Drugs or Devices

This study does not include testing drugs or devices.

15. Multi-Site Research

This study is a multi-site study and will have sites at Kaiser Permanente Georgia and Grady Memorial Hospital.

16. Community-Based Participatory Research

Stakeholder advisory board which KP, Grady, and Emory patients and we will also include non-KP stakeholders in the community advisory board to provide expertise in type 1 diabetes and care (providers, patients, head of The Diabetes Link)

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